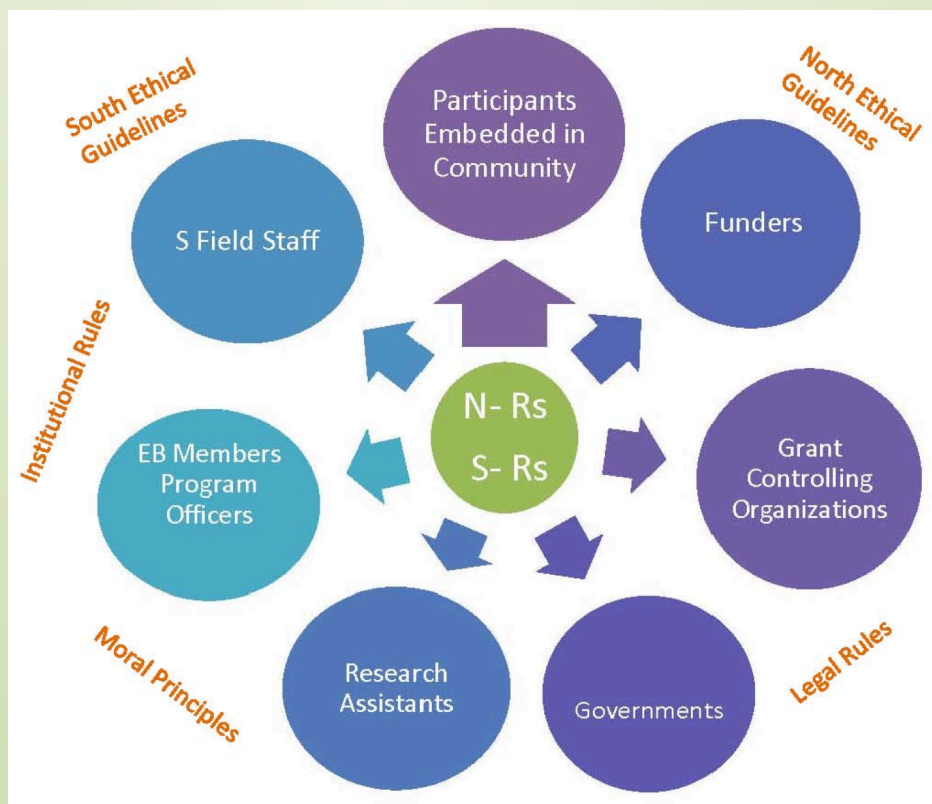


SAMKET + H + L

Ethical Issues Facing North-South Research Teams

Global Population Health Research



Final Report

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Acronyms and Abbreviations

CAS	Complex Adaptive Systems
CEHP	Caribbean Eco-Health Program
RFA	Request for Application
GPHR	Global Population Health Research
GHRI	Global Health Research Initiative
IDRC	International Development Research Centre
IRB	Institutional Review Board
LMC	Lower and middle income country
LOI	Letter of Intent
MOH	Ministry of Health
N	North
NER	Network of Ethical Relationships
N-S	North-South
NGO	Non-governmental Organization
PAHO	Pan American Health Organization
REB	Research Ethics Board
RFA	Request for Application
SAMKET	Sandra Angela Martin Karen Ethics Team
SAMKET+H+L	Sandra Angela Martin Karen Ethics Team + Heather + Laura
S	South
SGU	St. George's University
TC	Teasdale-Corti
TCPS	Tri-Council Policy Statement
UWI	The University of the West Indies
WINDREF	Windward Islands Research & Education Foundation

1.0 Introduction

Although a substantial body of literature exists that details how to address ethical issues and provide ethical oversight for classical research study designs, there currently is very little guidance available to researchers on how to deal with the unique and novel challenges that arise when conducting research that goes outside of these well-defined boundaries. Global population health research (GPHR) conducted by researchers from North (developed) and South (developing) countries is one such example.

North-South global population health research projects are typically characterized by North-South (N-S) research teams, multi-agency involvement, and participants that are often drawn from vulnerable populations. Added to this complexity is the possibility of different moral principles and values or possible different interpretations of the same principles and values on the part of researchers working on N-S teams. These possible different interpretations may also extend to the Southern participants or collaborators.

In 2005, the Canadian Global Health Research Initiative (GHRI) launched the Teasdale-Corti (TC) research partnership grant program. The overall mission of the TC program was to support *global health research teams* working with research users in low- and middle-income countries, to develop, test and implement innovative approaches to “making research matter” for health and development. The total of 14 such global health research TC teams were eventually granted an average of CAD\$1.6 million each to accomplish the above stated goals in various low- and middle-income countries scattered throughout the world.

Coming out of the experiences of these 14 Teasdale-Corti teams, all of which were engaged in some form of global population health research (GPHR), it soon became apparent that North-South global population health research falls outside the narrow boundaries of the dominant bioethics-anchored research paradigm. Given that the essential characteristics of GPHR is not adequately served by the ethical thinking that created the current set of research ethics guidelines and protocols, we hypothesized that these guidelines and protocols may actually contribute to the challenges faced by researchers involved in GPHR partnerships. If this indeed is the case, new (more appropriate) ethical guidelines and protocols will need to be created so that GPHR researchers and those in their network of relationships will have the information and tools that will enable them to prevent and/or address ethical challenges.

The fundamental goal of this research project was to determine the nature and sources of the ethical issues and challenges that arise in North-South GPHR initiatives. The focus has been on three key areas where ethical issues as experienced by N-S GPHR researchers in their network of relationships have arisen: (i) GPHR researchers relationships with one another, (ii) GPHR researchers relationships with funding agencies, and (iii) GPHR researchers

relationships with multiple research ethics review boards, both from the North and the South.

With regard to the potential for ethical issues in the GPHR researcher's relationship with participants (typically drawn from the South) recognizing the moral significance of these issues and given the very limited financial resources allocated to this research project, this research study was not able to collect empirical data pertaining to them. It is clearly acknowledged, however, that the researcher-participant relationship is as central to North-South global population health research as it is to all research involving human subjects. For the purposes of this research study, since every person who is involved in such research presumes that the GPHR researcher's ethical treatment of participants is *the* primary ethical concern, as is commonly done in the literature, this important ethical relationship is tangentially examined on the basis of second hand reports of GPHR researchers and members of research Ethics Boards (EBs). Also, in the case study of the Caribbean Ecohealth Programme (CEHP) Teasdale-Corti (TC) team, a few CEHP participants were identified and interviewed.

It is anticipated that sharing the findings of this research on the nature and sources of ethical issues experienced by GPHR researchers with those who fund and provide ethics oversight of their research will contribute to reducing the instances of discordance between GPHR researchers and agencies that support and oversee such research. Additionally, by sharing the knowledge gleaned from this research project with GPHR researchers, funders and members of ethics review boards, it is hoped that it will facilitate a collaborative process that will eliminate and/or reduce some of the ethical challenges frustrating GPHR researchers as they attempt to efficiently design and implement their research activities. The presumption is made that a reduction of ethical issues and dissonance would be indicative of research that is more ethical.

1.1 Research Study Objectives

At the outset of this project, the initial objectives were as follows:

- (i) Identify and characterize the issues and challenges faced by global population health researchers (GPHR); and
- (ii) Generate a set of appropriate guidelines and recommendations for both GPHR researchers and members of research ethics boards (REBs) that would facilitate the prevention and resolution of these issues.

As this research project evolved, it became clear that the ethical issues being studied were often entangled in procedural and legal processes and rules. In some instances, moral issues arose because of non-moral guidelines and procedures that were put in place as a purported means to ethical research practice. Also, in some instances, conflicting cultural norms and expectations provided the context for ethical issues. These additional insights highlighted the need for the development of a normative conceptual framework for

distinguishing ethical issues and conflicts based directly on differing moral principles and values from ethical issues and conflicts only indirectly based on moral principles and values. As a result, developing this normative conceptual framework emerged as an explicit component of research activity related to the first objective stated above. Further, over time, it also became clear that some of the most morally significant ethical issues faced by North-South GPHR researchers arose in their relationship with funding agencies. As a result, generating appropriate guidelines and recommendations that would prevent and resolve these issues emerged as an explicit component of research activity related to the second objective stated above.

1.2 North-South Terminology Explained

The North-South definition and key independent research parameter used in this exploratory research study originated from the RFA put forward by the funders, is used by the Global Health Research Initiative (GHRI), and dominates global population health research ethics literature. This definition is based on economic indicators of development in which lower- and middle-income countries (LMCs) represent the **South** and high-income countries the **North**. This breakdown is an attempt to reflect the economic disparities that exist between the two categories that limit the ability of Southern (**S**) researchers to develop and implement large-scale research initiatives. It is not intended to assign higher prestige to Northern (**N**) researchers, but rather reflects an evolving recognition on the part of N countries that they have a *global* responsibility for the status of human health that oblige them to bring equity into the research arena.

1.3 Overview of Report

The body of this report is primarily focused on providing a summary and synthesis of the main findings and recommendations from this exploratory study as a whole. The **Appendices** provide additional detail about the findings from each method, as well as the study instruments used. Thus **Section 1.0** provides an introduction to the main themes of the study and the main hypotheses guiding the work, **Section 2.0** outlines the theoretical framework used in this study, and **Section 3.0** provides an introduction to the conceptual framework developed and applied in this research study. **Section 4.0** used the Network of Ethical Relationships (NER) model described in the previous section to illustrate several key themes that emerged from the research project. **Section 5.0** reviews the capacity building elements of the project. In **Section 6.0**, the results of the applied ethics methodology are presented, while **Section 7.0** puts forward a series of key findings gleaned from this research study. The project's recommendations are presented in **Section 8.0**. The tables in **Appendix A** provides a brief summary of the literature review; **Appendix B** includes a detailed summary of the findings from each method employed (document review, on-line SurveyMonkey questionnaires, semi-structured interviews, etc.), as well as the CEHP case study and other methods. **Appendix**

C includes copies of the instruments used for data collection, as well as the raw questionnaire data from SurveyMonkey.

1.4 Background of Study Hypotheses

In order to better understand the causes of the ethical issues and challenges faced by North-South GHPR research teams, two reviews were initially taken:

- A. Review of the set of ethics models and moral principles currently used to provide the basis for research ethics
- B. Review of Northern and Southern understandings of moral obligations

Coming out of each of these reviews were the following two hypotheses:

A. Review of the set of ethics models and moral principles currently used to provide the basis for research ethics

The Canadian Tri-Council Policy Statement (TCPS), which provides the research guidelines employed by all Research Ethics Committees in Canada, primarily aims at ensuring that researchers' activities do not harm research participants. The United States has similar guidelines based on the same aim. These published guidelines are explicitly anchored on the four basic moral principles of bioethics namely, 'Respect autonomy,' 'Promote beneficence,' 'Do not harm,' and 'Satisfy justice requirements.'¹ These principles and the primary areas of concern expressed in these guidelines, namely, risks to study participants, consent of study participants, confidentiality for study participants, and protection of non-moral agents indicate clearly that the guidelines are devised based on a particular type of research activities.

The bioethics literature contains some critical discussion of what are deemed the relevant moral principles and how they apply in research. Among Northern academics who define ethical research practice and control its implementation, there is general agreement about the relevance and scope of the above mentioned four principles and areas of concern. Several decades of agreement has led to the firm establishment of the medical research paradigm as the one to be used in all cases. As a result, current confidence in the biomedical-based ethics paradigm's adequacy has led to its widespread support and use in other evolving research domains and practices. One such new research domain is global population health research (GPHR). The question that has arisen is whether the ethical issues and challenges faced by GPHR researchers can be adequately addressed by the dominant bioethics-anchored paradigm.

Presently, the prevailing approach to understanding the moral requirements of all researchers is based upon a bioethics model and a particular

¹ The justice principles, which are assumed by the guidelines, include equality, fairness, and impartiality.

understanding of the fundamental ethical issues of bioethics. The starting point for moral reasoning in bioethics is typically a patient-doctor relationship in which the relationship is understood as between two autonomous individuals. The relationship between these two persons is essentially detached from the network of relationships of either person. This individualistic starting point has favoured and generated moral discourse about research practice that is explicitly and implicitly grounded in human rights theory. At the level of theory, a human rights theory takes the rights of individuals as the basis for assessing actions as right or wrong. A moral theorist can easily provide a reasonable account of the dominant paradigm's four moral principles and its primary areas of concern in terms of human rights theory. At the practical level, legal rules covering research practice and REB guidelines both demonstrate a fundamental commitment to protecting the study participant's human rights, especially the right to one's person and the right to choose.

The dominant bioethics paradigm's principles regarding 'Autonomy' and 'Justice' can also be explicitly associated with the moral human rights theory. Although the 'Do no harm' and 'Benevolence' principles can also be shown to be consistent with human rights theory, from an historical perspective, these principles have deeper roots in the medical paradigm rather than the human rights theory. Their relevance and role was well established before the notion of human rights was employed in moral discourse. Whereas the medical profession's commitment to 'Do no harm' and 'Benevolence' is as old as the Hippocratic oath, human rights, a seventeenth century discovery or invention, only recently entered and gradually came to dominate the bioethics paradigm. Arguably, this dominance was the natural consequence of according very high moral value to human rights and the fact that human rights violations became the primary characterization of morally wrong medical and research practice. Since those who created codes of ethics for doctors and research ethics guidelines for researchers had as their primary aim protecting patients and research participants from doctors and researchers respectively whose practice intentionally or unintentionally violated their patients/study participants rights, the discourse that called for these ethics tools and determined their content was largely informed by human rights theory.

Although the four moral principles as adopted by the current bioethics paradigm can be explained in terms of human rights, the 'Do no harm' and 'Benevolence' moral principles are also explicitly employed by other moral theories. Consequently, there are various accounts of these principles in the literature. Critically, not all interpretations are equally consistent with human rights and several of these interpretations do not work well within the dominant bioethics research paradigm.

While knowing these facts is important for moral theorists, for researchers, REB members and funders the ethical dilemmas experienced when the bioethics paradigm's moral principles are interpreted as requiring different actions in the same situation are potentially far more significant. As an example, the principle of 'Benevolence' may be understood as requiring

involuntary vaccination of study participants but respecting ‘Autonomy’, i.e., the human right to choose, requires the study participants’ consent. In global population health research (GPHR), conflicts between these principles are probably the rule instead of the exception given the nature and primary focal endpoints (communities, populations) of this type of research. Whereas human rights and the bioethics-anchored research paradigm require the researcher to focus on his/her relationship with a study participant as an *individual*, in GPHR the researcher is fundamentally focused on a *population*. This doesn’t mean that GPHR researchers do not care about the individuals (participants) involved in their research programs, but the nature of the research is such that the good for which it aims is the well-being of the whole (population). Without being dismissive of the moral value of individuals, it is understood that the well-being of the whole community has greater moral weight than an individual member of the community. It is recognized that a particular study may benefit the participants’ community more than participants themselves, since ‘population’ and ‘community’ refer to non-static entities that exist into the future and whose members change over time.

Each study participant in a GPHR research study is an individual representative of the population and they understand that their participation will primarily further the good of the community. While no ethical GPHR researcher will ever propose a research study that harms or violates the rights of community participants, the aim of GPHR research is by definition the future good of the population rather than the present good of the participants. Since a human rights theory accepts Immanuel Kant’s categorical imperative² that persons are always to be treated as ends never merely as means and since GPHR can be interpreted as using some individuals to benefit many other individuals, one can reasonably anticipate conflict between the dominant bioethics research paradigm and the GPHR type of research.³ As the longstanding debate between moral theorists committed to human rights and utilitarianism attests to, ethical dilemmas based in a conflict between the rights of the individual and general welfare are the most difficult to resolve. On the face of it, the dominant bioethics paradigm avoids these conflicts by interpreting the ‘Do no harm’ and ‘Benevolence’ moral principles in terms of individual participants and leaves the issue of general welfare out of moral reasoning regarding ethical research practice. Unfortunately, this means that it cannot provide an appropriate context for addressing ethical issues related to GPHR type of research.

Although there is consensus that the four basic moral principles of bioethics are relevant to assessing human actions in general and the actions of researchers in particular, a renewed interest in virtue ethics, as well as

² Immanuel Kant, *Groundwork for the Metaphysic of Moral*, 1785.

³ Theorists who express this concern typically explain it in terms of ‘using persons’. However, in the context of GPHR research this notion is problematic since participants will have consented to participate and their consent will frequently be based upon their desire to benefit their community. These research participants do not see GPHR as devaluing them since they do not dissociate their well-being from their community’s well-being.

the emergence of an ethic of care and environmental ethics, has resulted in growing recognition of the limitations of these four principles, particularly with respect to GPHR research. This is partly because the model that provides the basis for moral reasoning is criticised as misrepresenting the interdependency and complexity of human relationships, and partly because of increasing demand for a more comprehensive basis in moral theory for understanding obligations in human relationships.⁴

Argued for, interpreted, and applied in the context of a bioethics model which is now under fire, the four bioethics moral principles which ground the North's prevailing approaches to research ethics seem to be providing an inadequate set of guidelines for ethical research when this research takes place in a context very unlike the model of the researcher-patient upon which the guidelines are based. While acknowledging that the bioethics paradigm is appropriate for some types of research, given the significant differences between medically anchored research and GPHR research, as well as the ethical issues experienced by the Teasdale Corti (TC) teams and other similar global health research team collaborations, a new model is required to provide a firm basis for conducting ethical global population health research.

In this report, a core argument is made for the development and use of a **Network of Relationships (NER)** model and to identify the key moral principles and values that should be employed with it. Additionally, an evaluation is provided to determine whether the dominant bioethics paradigm's fundamental moral principles are relevant to this new proposed model and whether the new model requires new interpretations of the old principles or even additional fundamental principles.

In summary, the ethical issues that have arisen for North-South teams point to the possibility that in the circumstances common to this type of research there are morally relevant considerations that are not adequately addressed by current research ethics guidelines based in the predominant model and fundamental moral principles of bioethics. It has become apparent that what is needed is a richer understanding of the basis of moral obligations in order to understand and resolve these issues and provide meaningful and adequate guidelines for ethical actions. The literature examining research ethics when coupled with the experience of researchers conducting global population health research both suggest that it is possible that some of the ethical issues faced by the TC teams are caused by inadequacies in the conceptual moral framework presupposed by the bioethics anchored

⁴ In most anthologies for courses in bioethics there is an introductory chapter which explains the Utilitarian principle and its concept of common good and also virtue ethics. Both of these moral theories imply a more complex understanding of the obligations required of medical professionals and the researchers than just the four principles of bioethics. If the newest moral theories were to be added to the context of understanding moral obligations, namely environmental ethics and the ethics of care moral theory, a much fuller understanding of the extent of moral obligations emerges. An analysis of the ethical issues investigated from the more comprehensive perspective of these moral theories is not provided in this report, but rather an assessment is made of the strengths and weaknesses of the dominant bioethics paradigm's moral principles in the context of the new paradigm presented in this report.

research ethics guidelines. It is possible that it is ethically problematic to employ the North's prevailing understanding of the ethical requirements of research activities (requirements generated in the context of the doctor-patient relationship and Western philosophy's moral theories) to the research activities of North-South teams engaged in global population health research. This thus led to the generation of our first hypothesis:

Hypothesis #1: The standard bioethics model generating the moral principles that anchors and justifies the North's ethical guidelines is not an appropriate model for North-South population health research. Therefore, the moral principles generated by the bioethics model cannot by themselves provide an adequate set of ethics guidelines for North-South population health research.

B. Review of Northern and Southern understandings of moral obligations

It is commonly assumed that there are significant differences between the North's understanding and the South's understandings of moral obligations which putatively give rise to ethical issues and disagreements. For this research study, an *a priori* assumption that this is true was not made. Rather, empirical data about ethical issues was gathered from the review of all TC teams that consented for us to review their team's documents, an in-depth analysis of the Caribbean EcoHealth Programme's (CEHP) TC team, online questionnaires administered using SurveyMonkey, follow-up interviews, and an international workshop, were used to assess the accuracy of this assumption.

Based on an analysis of the data collected, a determination was made as to whether or not there was sufficient evidence to support the conclusion that there are significant differences between the North and the South in terms of moral values and moral reasoning. If the evidence did not support this assumption, further explorations were made to determine if a better explanation for the ethical issues and challenges that arise in global population health research could be found in power differences between the North and the South in terms of development and resources and/or whether any lingering effects of colonialism still impacted the way some individuals and some communities reacted to the North.

The empirical data gathered in this research study were also used to assess the extent to which actions of researchers and ethics review boards were consistent with North-South ethics guidelines. The CEHP TC case study was used to provide knowledge and insight into these important entities and to further clarify whether the fundamental moral values of the North are commensurable with the fundamental moral values of the South. Data from the CEHP case study was also used to explore how efforts to reconcile ethical disagreements between members of multi-disciplinary research teams and research ethics boards, as well as research teams and communities participating in the research were addressed and handled. For the above reasons, the CEHP case study analysis has potentially

significant capacity building. It produced new knowledge which may better enable everyone involved in North-South global population health research to engage in ethical activities and thereby ensure that everyone shares in the benefits of ethically appropriate research. These findings support our second hypothesis:

Hypothesis #2: The moral values of the North and South can be a source of ethical disagreement when the North's moral values are understood narrowly as the four bioethics derived moral principles which are the basis for the North's research ethics guidelines. When a richer understanding of the fundamental moral values of the North is incorporated into the discussion of the ethical issues, the moral values of the North can be reconciled and ethical issues resolved.

1.5 Study Methodology

For this research study, the research methods used for empirical data gathering were combined with a social sciences and the philosophical method of applied ethics method of analysis. As shown in **Figure 1**, empirical data collection methods were used to capture and synthesize the experience of several North-South research partnerships. The literature review provided the background for creating online questionnaires and follow-up in-depth interview instruments for gathering the empirical data.

This study employed a unique interdisciplinary methodology which was based on the humanities and social sciences. The mixed method approach proved invaluable in helping to create a rich understanding of the complex issues under investigation. Mixed methods research requires an ontological and epistemology approach that values a wide range of knowledge. In this case, the so-called transformative-emancipatory ontology provided the basis for pursuing a mixed methods line of inquiry. According to Mertens (2003), this ontological position "holds that there are diversities of viewpoints with regard to many social realities but that those viewpoints need to be placed within political, cultural, historical and economic value system to understand the basis for differences. And then, researchers need to struggle with revealing those multiple constructions as well as with making the decisions about privileging one perspective over another" (in Clark and Cresswell, 2008:75), the techniques of triangulation, complementarity, development and paradox (Greene *et al.*, 1989) were used to bring together the findings of the study for Discussion in **Section 4.0**.

Concurrent with this activity, the key ethics review guidelines employed by North and some South EBs were analyzed to identify the explicit moral principles and values and the implicit moral theories upon which they are based. The extent to which the North's biomedical paradigm dominates North and South REBs was also determined.

The literature review focused on discussions of ethics review processes and ethical conflicts and challenges experienced by N-S research teams. The

results of this essentially philosophical inquiry formed part of the context for the analysis of and reflection upon the empirical data collected in this study. These data were then also analysed using qualitative and quantitative methods. Consequently, the recommendations that have come out of this research study are normative judgements based upon philosophical argumentation, respond to documented ethical issues, and they take account of morally relevant empirical data.

The methods that were employed to collect the empirical data utilized in this research study are listed below:

- Literature Review
- Document Review of consenting TC teams
- On-line SurveyMonkey questionnaire survey of all TC Researchers
- Semi-structured interviews of selected TC researchers
- On-line SurveyMonkey questionnaire survey of REB members
- Semi-structured interviews of selected REB members
- Case Study of the Caribbean Ecohealth Programme (CEHP)
- International Ethics Workshop

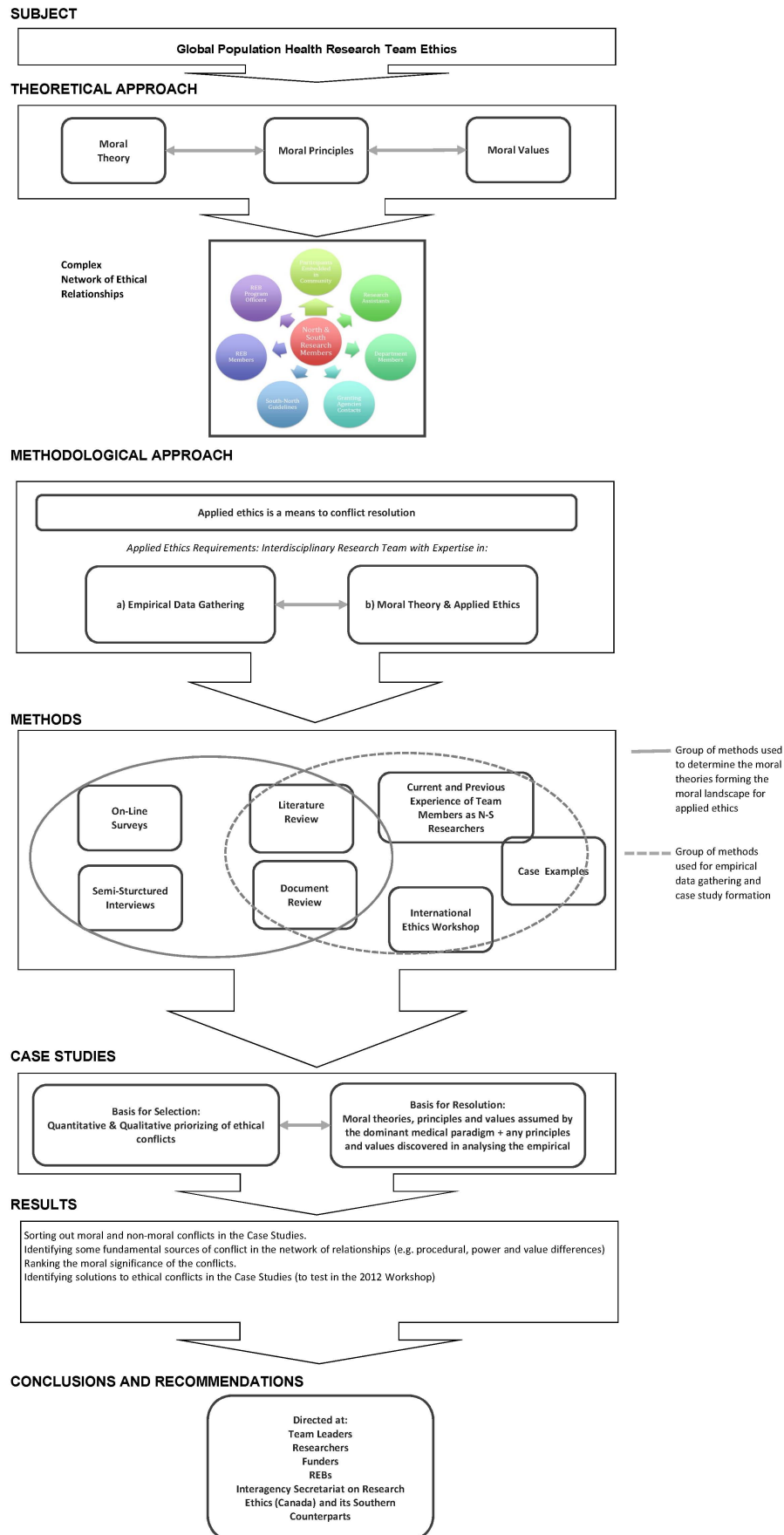


Figure 1 Overview of research hypotheses and methodology

1.6 The Research Team: SAMKET+H+L

As indicated in **Figure 2**, an initial four-person core research team—Drs Sandra Tomsons, Angela Gomez, Martin Forde, and Karen Morrison—collectively provided the skills and experience to undertake the variety of research activities required by our methodology. The team’s expertise covered applied ethics, moral theory, global population health research, eco-health research, international research collaboration, and research in developing countries. This team had both North and South researchers, members who were involved in North and South REBs, and members who were actively engaged in global population health research collaborative efforts. Added to this four-person core (SAMKET: **S**andra **A**ngela **M**artin **K**aren **E**thics **T**eam) were two graduate students—Heather Watson-Burgess and Laura ‘Peggy’ Rising—who helped conduct the literature review and do some of the data analysis respectively. Thus, the acronym **SAMKET+H+L** is used on the cover of this report to indicate all of the key sources of information and authors of this report.



Figure 2 Overview of SAMKET (Sandra-Angela-Martin-Karen Ethics Team)

2.0 Theoretical Framework

2.1 Epistemology and Applied Ethics

Philosophical inquiry, like scientific inquiry, seeks knowledge (i.e. truth). From a Western (Northern) perspective, we claim that one engaging in **applied ethics** is engaged in a special kind of philosophical inquiry. A person employs one's knowledge of moral theory to gather knowledge of the morally relevant characteristics of a particular situation so that one is positioned to discover knowledge of what one ought to do in that situation. It should be noted that this account of the purpose of applied ethics, namely, the discovery of moral truth, is inconsistent with some of the claims about applied ethics in the literature. Some theorists argue that the notion of truth does not have application in this context and consequently they are focused on securing agreement or consensus rather than seeking truth. We see value in combining the search for truth and consensus.

Applied ethics is a particularly useful philosophical activity in circumstances in which a person has conflicting obligations or one's moral values appear to require them to both do and do not do an action. In such circumstances, persons who want and intend to do the morally right thing can (1) reflect on their moral principles, (2) determine which actions are options in the situation, (3) imagine the consequences of doing and not doing these actions, and (4) morally assess these consequences. As a result of this deliberative process, the person discovers what s/he ought or ought not to do. It should be noted that this deliberative process is one that employs our moral sentiments (for example, our sense of justice) as well as our capacity for reason. In morally complex situations, often our moral sentiments point us in the direction of what is right when we are unable to articulate the argument that justifies our belief.

The applied ethics methodology can be used to discover the morally appropriate action in a particular set of circumstances and provide a justification for claiming it is the morally appropriate action. While it can be done individually, as is true in scientific inquiry, many heads are better than one in the pursuit of knowledge. The more intelligent and creative the persons engaging in the above outlined four stages of philosophical activity, the greater the probability that the moral truth the group thinks they have discovered is indeed genuine moral truth. And, in the case of N-S research ethics, the probability of arriving at consensus and truth is greater if the dialogue is N-S.

2.1.1 Consensus and Truth

As in scientific methodologies, in applied ethics consensus about the truth of a judgment is not in itself sufficient evidence that the judgment is true. However, if we are explicit that the aim of applied ethics is knowledge, a group seeking knowledge about the truth or falsity of a moral judgment can be truthfully described as seeking consensus about this matter. This is because consensus is a 'symptom' or 'sign' of truth in all knowledge-seeking activities. Our agreement points to the fact that after engaging together in the four stages



"The aim of science is not to open the door to infinite wisdom, but to set a limit to infinite error."

-Bertolt Brecht in *The Life of Galileo* (1939)



of applied ethics inquiry, this moral judgment has emerged as a judgment we all agree is morally justified. The best evidence that we bring into our discussion of the truth of the judgment justifies/supports our assertion that it is true. Our agreement, that is, our consensus does not constitute proof that the judgment is true or evidence that it is true. However, if four people arrive at the same conclusion in the context of philosophical dialogue, in which the four participants critically engage each other's

arguments, it is reasonable to view the conclusion as having greater support than if the same four people arrive at this conclusion alone in their offices.

Consensus after applied ethics inquiry is a sign of truth but it does not guarantee truth. Just as all methodologies take consensus as a sign of truth, all methodologies lack a truth guarantee. Applied ethicists, like scientists, concede that a conclusion supported by the best available evidence may actually be wholly or partially false. In either science or ethics, there is the possibility of making false knowledge claims at the end of one's reasoning activity. Even the brilliance of those employing these methods cannot absolutely ensure all data relevant to knowledge seeking is included in the reasoning justifying the conclusion. However, until someone discovers a piece of information missing from but essential to the reasoning which supported the consensus that the judgment is true, applied ethicists, like scientists, will be confident in their evidence-based conclusion.

For practical purposes, in ethics and in science, moral judgments and scientific judgments resulting from applied ethics reasoning and scientific reasoning are treated as moral truths and scientific truths. The inherent fallibility of both applied ethics and all science methodologies make ethicists and scientists alike open to the possibility that their truth claims will be proven false. The discovery of relevant truth creates epistemic responsibilities for truth seekers. So, for example, an applied ethicist must revisit his or her arguments supporting their moral judgments and determine whether their confidence in their truth status changes in light of this new knowledge. Openness to the possibility of error is an epistemic requirement of all philosophical inquiry. Arguably it is an epistemic virtue to be encouraged in all knowledge seekers in the light of human fallibility and progress in Western (Northern) science's understanding of the world and Western (Northern) philosophy's understanding of our moral obligations.



"The best we can say of a theory is that it has not (yet) been refuted. Thus there is no room for dogmatism in science; modesty is the only sensible attitude. Science consists of conjectures that have not been rejected, not of accepted facts derived from observation of the world."

-Colin McGinn on Karl Popper in NYRB Nov 21, 2002 p46



2.2 Moral Theories Employed In Dominant Research Paradigm

The applied ethics inquiry approach adopted in this study and hence resultant assessments of global population health research (GPHR) type activities and proposed solutions began by taking as its starting point the four fundamental moral principles and values of the West's (North's) dominant biomedical-based ethics paradigm. Recognizing that this paradigm is anchored in Western philosophy, we tried to avoid being constrained by this paradigm's metaphysical or normative framework. However, it is used as a starting point since the ethics review process for all Teasdale-Corti teams included Canadian ethics boards.

The combined requirements of N-funders and N-EBs are such that all N-S research teams had to submit their projects to N-EBs and hence satisfy the guidelines and procedures as outlined in the TCPS and variously interpreted in the requirements of N-EBs across Canada. Hence, these requirements imposed (most likely unconsciously and unintentionally) the North's philosophical understanding of research ethics (i.e. the dominant biomedical paradigm) and its four fundamental principles on S-researchers, S-participants, and S-countries. Furthermore, these requirements meant that TCPS's interpretations of other moral values such as consent, privacy, and data ownership are also, in practice, imposed on S-researchers, participants and countries.

Since Canada's *Tri-Council Policy Statement* (TCPS) is the document that grounded the ethics review process, we based our analysis of the North's dominant biomedical paradigm on its content. So, for example, our account of the dominant paradigm's explicit and implicit use of moral theories is based on an analysis of TCPS's Chapter 1, **Ethics Framework**. Since, for the most part, policy statements in other N-countries are analogous to TCPS, we are confident that our analysis can be generalized to the policy statements of other N-countries even though TCPS is country-specific.

We recognized from the outset that using the dominant bioethics paradigm's principles and values meant that we were replicating in our study the tendency of N-funders, N-EBs and N-researchers to impose the dominant research paradigm on the South. However, as it turned out, it is because we used it that we were able to discover some of the paradigm's most serious weakness. Whenever our empirical data was inconsistent with or could not be accounted for on the basis of the content of the dominant paradigm, we were able to identify a problem for using it in N-S research collaboration. So, by employing the 'research ethics interpretation' of the several Northern moral theories that ground ethical and political understanding of right and wrong in Western societies, we were able to show the narrowness of the dominant paradigm's interpretation of these theories and its problematic individualistic metaphysics. On the basis of the empirical data collected during this study and the subsequent analysis of the data, our goal was to add

to the North's dominant paradigm's normative ethical review framework elements that would make it more relevant and inclusive of the needs of researchers engaged in GPHR collaborative research efforts.

The applied ethics analysis approach used in this research study accepts and applies the new *Tri-Council Policy Statement's* core principles, namely 'Respect for persons,' 'Concern for welfare,' and 'Justice' and the subsequent values that are derived from these principles. In this study's analysis, however, the terms 'benefit' and 'harm' will be used to interpret 'Concern for welfare' thereby employing the four fundamental principles which provided the basis for the guidelines in the earlier version of the TCPS and most other N-policy ethics statements.

Initially, the decision to employ these four principles was partially based upon evidence in the literature⁵, subsequently, it was confirmed by our data that supports the conclusion these N-values are not contested by S-researchers, EBs, or S-participants. Further, our data provides some support for concluding that the fundamental values of the medical/ bioethics paradigm that provide the basis for N-research ethics guidelines are not in themselves the source of ethical disagreement and ethical issues faced by N-S research teams.

The literature review and analysis of the data collected in this research study regarding N-S research team interaction with team members, ethics boards (EBs), and funders suggests that by requiring all projects to satisfy the guidelines and procedures as outlined in the TCPS, all of the Teasdale-Corti teams imposed (most likely unconsciously and unintentionally) the North's philosophical understanding of the four fundamental principles on S-researchers, S-participants, and S-countries. Furthermore, the TCPS's interpretations of other moral values such as consent, privacy and data ownership are also, in practice, imposed on S-researchers, participants and countries.

2.2.1 Deontological/Human Rights Moral Theories

The TCPS's fundamental moral values and principles do not explicitly mention human rights but rather focus on providing a human dignity account of intrinsic and moral value that typically provides the basis for human rights claims. Thus, TCPS explicitly requires researchers to respect human dignity rather than respect human rights. Nonetheless, its presumption of the biomedical paradigm's one-to-one relationship between researcher and participant and its emphasis on autonomy, consent, privacy and

⁵ For example, representatives of the Ugandan Ministry of Health, AIDS Commission, National Council of Science and Technology, National Chemotherapeutic Laboratory and Makerere University took part in 5-day symposium. Participants concluded: The principles of autonomy, beneficence, non-maleficence, and justice are relevant to research in Uganda. However, their implementation must reflect the circumstances and cultural context unique to Uganda. (Loue, Okello, & Kawama, 1996)

confidentiality means that human rights and human rights theory underlie its understanding of research ethics. All of TCPS's requirements and recommendations, as well as its accounts of human autonomy and dignity, and the fundamental values respect, harm, concern for welfare, and justice belong to the human rights type of moral theory. On the other hand, some of its accounts and moral requirements are inconsistent with some interpretations associated with other moral theories that are explicit and implicit moral theory components of the dominant paradigm. Human rights theories demand respect for all human beings, prohibit harming humans in some ways (those ways which violate rights) and some of these theories prescribe benefitting human beings.⁶ From the perspective of human rights theorists, human rights violations are the most serious injustices. This high ranking of human rights is reflected in TCPS's discussion of moral principles and values and some of its application sections. And, ranking human rights highly is particularly relevant in N-S contexts since the literature and our empirical data show that some moral issues are based in a conflict between individual rights and community rights. In explicating its multifaceted notion of justice, TCPS explicitly and implicitly expresses an understanding of justice belonging to and emanating from human rights theories.

Even if one rejects an individualistic notion of human nature and the one-on-one understanding of ethical relationships that attaches to negative theories of human rights and the dominant research ethics paradigm, it is important to acknowledge that a human rights theory does provide a key component of most normative frameworks for understanding moral responsibility. Many S-countries join N-countries in their acceptance of human rights as an expression of the moral value of human beings. Around the world, this notion is used to protest and explain the unjust treatment of individuals, groups and peoples. Given that the empirical data collected in this research study does not justify the disuse of this moral notion or show that N-S disagreements about the nature and content of human rights give rise to moral issues in N-S research teams, we are continuing to employ this moral theory as one source of the normative framework providing the backdrop for the applied ethics methodology used in this research study.

Although human rights theory has an important place in this study's analysis, since we allow for other moral considerations such as the common welfare and social and global justice, these additional moral considerations by

⁶ A theorist who provides a negative interpretation of human rights, that is, claims that to have a human right entitles one only to non-interference from other human beings and governments, will disagree with the theorist who claims that having a human right entitles one to more than non-interference. These positive rights theorists maintain that having, for example, the human right to life means that humans or governments are as requiring to put in place the conditions necessary for human beings to be able to exercise their rights. So a child's right to life means the child's parents have the duty to feed and supply the other conditions of life for the child. Or, analogously, the right to life of adult humans means that society (often understood as governments) is morally obliged to put in place the economic and service institutions (education, health) that are the conditions of being able to live.

default result in a reducing or diminishing of the importance of the content of an individual's 'human right package'. Thus, in the context of global population health research, we reject the view of human nature presupposed by most human rights theories and the negative interpretation of human rights that is often presupposed in discussions using the biomedical paradigm.

2.2.1.1 Human Rights Theory and Human Nature

Western (Northern) philosophers such as Thomas Hobbes, John Locke and John Stuart Mill have created the notion of human rights embedded in the dominant paradigm. Today, human rights theorists continue to try to revise their theories so as to take into account the new and different social, economic and political context typical of most Western societies.

For the most part, contemporary moral and political philosophers who build their human rights theories on Hobbes, Locke and Mill do not challenge the metaphysical underpinnings of their theories. For the purposes of this research study, the following statement summarizes the core assumptions about human beings presumed in human rights theories: A human being is essentially autonomous, rational, self-interested, independent and self-reliant. Equally important, human beings are 'sinners', that is, they transgress divine law by committing immoral acts.⁷ While most contemporary human rights theorists typically disconnect human rights from religion, especially the religion that most influenced the Western tradition, namely, Christianity, many continue to maintain human beings have a tendency to pursue their selfish interests even if doing so will disadvantage others.

In Western societies, pessimism about human nature is sufficiently prevalent to make recognition of human rights and implementing ways to protect them of foremost importance to the moral and political theorists who develop human rights theories. It appears that such suspicion about human dispositions seems to be shared by the creators of research policies for whom protection of study participants is the primary goal. The TCPS requirements and Ethics Boards' procedures to implement them can be construed as attempts to guarantee the practice of ethical research by preventing more powerful, self-interested researchers from violating the rights of vulnerable participants who cannot, by themselves, protect their self-interest.

2.2.1.2 Human Rights Theory and Negative or Positive Interpretation of Human Rights

Much of current N-S research collaboration, of which the Teasdale-Corti initiative is a prime example, presupposes an understanding of the obligations of the rich to the poor that is inconsistent with a negative interpretation of human rights. A positive interpretation is also required for a human rights theory to provide an adequate interpretation of concern for welfare. Without a positive interpretation of human rights, a human rights

⁷ The Oxford English Dictionary provides the definition of sinner.

doctrine will explain concern for welfare in terms of not harming (i.e. prohibiting malevolence); however, it will not require actions to benefit (i.e. benevolence). Moral and political theorists still debate whether human rights should be understood as negative or positive; however, moral theorists generally agree that benefit has moral value and harm has moral disvalue. For this study, the aim was to construct a normative framework for applied ethics that acknowledges the values all human rights theorists agree upon and also recognizes the moral value of benefits and harms that may or may not be included in all human rights moral theories.

2.2.1.3 Human Rights Theory and Individualism

As important as it is to acknowledge and allow room for human rights, sometimes N-S research collaborations reveal the need for transforming the Western (Northern) understanding that human rights are possessed by individuals.

The context of global population health research where the focus of research studies is communities/countries and the aim of the research is to benefit resource poor communities/countries rather than individuals, this provides a good fit for the notion of community or group rights. In this context, human dignity provides the basis of asserting group (rich) obligations to other groups (poor). N-S research teams also might discover in the context of community-based research that community consent instead of or as well as individual consent for a study to go ahead would be more ethically appropriate. The new context makes the Western (Northern) notion of human rights seem morally problematic. The notion of group human rights emerges and appears to be the most ethically appropriate right to satisfy.

Human rights theorists are still working on the relationship between individual rights and group rights and attempting to resolve the conflicts between these two related yet distinct types of human rights. This area of research activity is about the same age as N-S research collaborations. The moral foundations of global health research and our empirical data made it necessary to incorporate both community human rights and individual human rights into the normative backdrop for our applied ethics methodology. By doing so, we recognize that we are employing a new notion of rights that is missing from the dominant biomedical paradigm. Consequently, our normative framework for applied ethics is different from and larger than the normative framework for most research ethics discussion. We also recognize that the new notion of group rights cannot just be added to the paradigm without making changes to the individualism presently inherent in it.

Presently, there are still more questions than answers in the literature as to how to resolve conflicts between individual and collective human rights. For the purposes of this research study, we have not assigned more moral weight to one type of human right than to another. However, we recognize that Western philosophy's longstanding acceptance of individual human rights and the newness of the notion of group human rights may favor N-assigning

more weight to individual rights. On the other hand, the strong sense of responsibility to the community evidenced in some S-countries may support more weight for group rights.

2.2.2 Consequentialist Moral Theories

Consequentialist theories morally assess actions and policies on the basis of their consequences as determined by a pleasure-pain or benefit-harm calculus. These theories are grounded in concerns about human welfare. They may assign primary moral value to individual-welfare or community-welfare. The focus of N-research ethics policies on research participants (e.g., not harming, seeking informed un-coerced consent, and protecting privacy) means, for example, that the TCPS is consistent with consequentialist theories that assigns high moral priority to individual-welfare. The TCPS's silence about community well-being in the moral principle and value discussion means that it for the most part excludes consequentialist theories, notably utilitarianism, which assess actions as right and policies as morally appropriate on the basis of whether they will maximize benefit and minimize harm for the greatest number of those involved. Such consequentialist theories regard the welfare of the community as having the greater moral weight than individual well-being.

Given the nature of this research study, it was anticipated that some moral issues arising in N-S research collaborations could arise because some Southern participants perceive themselves as embedded in their community and, as a result, feel some sense of responsibility to that community. This Southern sense of responsibility to the community could possibly conflict with the TCPS's placement of prime importance on persons. A Southern community-utilitarian interpretation of concern for welfare would conflict with the TCPS's individual-human rights interpretation. Moral theorists have engaged the debate about individual vs. community well being for many decades. This debate is very important and it would be relevant to this research project if one of the competing moral theories seemed likely to emerge as a clear winner. However, it is not likely that this will happen in the near future since there is no consensus about which theory is better and no basis for declaring a victor. Furthermore, as is demonstrated by the arguments which politicians in Western societies use to defend their actions and policies, these societies value both human rights and the welfare of the community.

The use of the utilitarian principle in this research study and the assigning of moral value to community well being will distinguish the applied ethics methodology utilized in this report from the dominant paradigm. Although 'Beneficence' and 'Non-maleficence' have been extensively discussed in research ethics literature, since, for the most part, these discussions assume the researcher-participant relationship is analogous to the physician-patient-relationship, they will be woefully inadequate to provide an account of the moral issues arising in the complex network of human and institutional

relationships which define the standpoint from which N-S researchers engage in ethical decision-making.

2.2.3 Justice

Justice is central to the TCPS and this core moral principle is particularly relevant in N-S research collaborations. The notion of justice is associated with several justice principles and the TCPS explicitly and implicitly uses fairness, equity, and equality. In N-S research collaborations, resource-rich N-funders and researchers partner with resource-poor S researchers and institutions and the collaboration is based on an acknowledgment by N-partners that justice requires them to address an unjust distribution of resources. This acknowledgement that a principle of social justice underlies research in some contexts enlarges the justice framework for research ethics beyond the TCPS's notion of justice.

The TCPS's justice discussion recognizes that power imbalances create justice issues; however, for the most part, it ignores inequalities in the material conditions of the researcher and participants. It does not, for example, require researchers to engage in research activities that address wealth-based inequalities (e.g., a differing health status). However, from the standpoint of justice, several principles support a requirement to address these inequalities. Furthermore, some N-S research collaborations like the Teasdale-Corti initiative presume not only that the N-S distribution of wealth and material resources is unjust, but they enlarge the notion of social justice so that it is perceived as global justice. Hence, N-S research collaborations stretch justice requirements so that responsibility extends beyond national boundaries. This larger notion of justice opens the door for conflicts with the TCPS's much narrower understanding of justice requirements.

In the analysis conducted in this research study, a broader account of justice is used than that employed by the TCPS. Theories of justice developed by moral and political philosophers are used to explain principles of justice related to self-determination (individual and community), equality, equity, desert, fair distribution of benefit and burdens, and protecting vulnerable individuals and groups. It is anticipated that this analysis will importantly inform the dominant biomedically anchored paradigm's understanding of justice's multiple requirements in N-S research collaborations. Further, it is anticipated that a broader social/global notion of justice will be assigned a high moral value in the moral backdrop for applied ethics reasoning in the context of N-S research collaboration. This high value makes it likely that our expanded notion of justice will overrule competing values in the dominant paradigm and will feature predominantly in our explanations and proposed solutions to the moral issues identified in this study.

2.2.4 Virtue Ethics and Environmental Ethics

We believe virtue ethics and environmental ethics are additional ethical theories that would be useful to those seeking to explain and obtain resolution to the moral issues that arise in N-S research practice.

In this research study, the empirical data did not provided a basis for employing environmental ethics. With respect to virtue ethics, however, the empirical data collected in this study, as well as the development of the network of relationships and resultant more holistic understanding of the nature of research practice clearly demonstrated not only the need for virtuous persons but supports the conclusion that virtue ethics needs to be explicitly brought into the discussion of ethical research practice. At this point, the empirical data collected in this study has not been analyzed in terms of virtue theory. However, we are confident that virtue theory belongs to the normative backdrop for our applied ethics methodology. Further, we remain open to the possibility that future research will establish that ethical theories developed from the perspective of the environment must also be included. Several TC programs, including the CEHP, focused explicitly on the relationship between population health and the development of the fundamental ecological programs that support it (see also, Millennium Ecosystem Assessment, 2005).

2.3 Prevalent Moral Issues in N-S Research Collaborations

The applied ethics analysis approach used in this research study builds upon and expands on the literature's analysis of the ethical/moral issues faced by N-S GPHR research teams. The literature review identified moral issues arising in the network of relationships in which researchers on N-S teams are situated (see **Appendix A**). The empirical data collected in this research study provided a source of information about specific types of ethical issues some of which formed the basis for the case examples which were constructed for the applied ethics exercises.

The objectives of the inquiry were: (i) to enable researchers to be confident about what is morally required of them when involved in GPHR types of research, and (ii) to determine whether there are ways to engage in research practice or restructure the researcher's relationships with participants, ethics boards, and funding agencies that would make it unlikely that ethically problematic situations would arise.

2.4 Applying Applied Ethics

There are various types of challenges commonly encountered by N-S research teams. Some are clearly ethical in nature, for example, a team member lies or fails to complete his/her share of the work. Other ethical challenges arise against the backdrop of N-S cultural differences, for example, a N-member of

the N-S research team treats a S-member in a way that the S-member regards as disrespectful but the N-member regards as morally permissible. Other challenges are more complex because they are based in a milieu of ethical principles, cultural norms, legal rules, and institutional procedures. For example, moral principles requiring that potential participants be respected and exercise their right to choose to participate in research might conflict with cultural norms of the same potential participants which sanction the practice of husbands providing consent for their wives. Further complications arise if, in the S-country where the study is being conducted, men have legal rights supporting this cultural norm, yet the researcher has to employ guidelines of both S & N EBs that require that the woman's consent be obtained and secured.

According N-S research ethics literature, ethical conflicts involving women's rights are a major ethical challenge for N-S research teams. These conflicts are not unique to N-S research collaborations. However, since N-researchers come from social contexts which recognize and legally protect women's rights, but in the S-country where the research is being implemented neither may be the case, the N- researchers find themselves in morally problematic circumstances. Powerless to change these circumstances; they may nonetheless attempt to generate discussion about women's equality and rights. S-researchers on the team may be in agreement with N-team members regarding women's equality and rights but realize that changing local traditions not only takes time but the changes must come from within. Using economic or research benefits to push communities into changing their beliefs and practices results in greater resistance, thereby impeding rather than promoting the hoped for change.

Promoting women's equality, including their right to self-determination, is sometimes an explicit and primary objective of the research. Furthermore, women's inequality in S-countries is frequently a primary moral concern for N-funders, EBs and researchers. However, the N's moral concern to ensure research practice respect and promote women's human rights can conflict with N-responsibility to respect the values and self-determination of S-researchers, EBs and participants. The moral principles of respecting dignity and autonomy constrain N-researchers and agencies in their activities to promote women's equality in S-countries. It must be remembered that although women's equality is currently upheld by N-participants in N-S research collaborations, not too long ago Canada's cultural norms, legal rules and institutional structures were explicitly inconsistent with fundamental moral principles in the dominant paradigm. For example, women were not legally respected as persons and were not protected by many of the justice principles belonging to the paradigm's notion of justice. At that time, violations of women's human rights (i.e. moral rights) were consistent with society's dominant beliefs and values. Hence the conflict between what was legally permitted and women's equality and human rights was invisible and undetected.

Society's beliefs, values and laws changed slowly. Today, in Canada, women's legal rights are more consistent with Western philosophy's understanding of their moral rights, but there are still beliefs and values supportive of sexism in Canadian society. As assessed by the dominant

research paradigm's understanding of gender equality, Canada has addressed inconsistencies between moral and legal rights, nevertheless, sexism is, still real in Canada. There are many sources of beliefs, values and attitudes embedded in worldviews in our society that are supportive of women's inequality, for example, Christianity and other religious perspectives. It is the axiologies of S-philosophies and philosophical inquiry that will determine the shape that women's equality and human rights will take in S-countries. If there are fundamental differences between N and S understandings of the relationship between individual and community human rights, then it is reasonable to anticipate these differences may be reflected in differences in N and S accounts of gender equality. Our study's empirical data does not provide the basis for drawing any conclusions about this important question. However, our enlarged normative framework for N-S dialogue about moral conflicts may facilitate an applied ethics inquiry that more satisfactorily explains and addresses this ethical conflict.

One of the advantages of our applied ethics methodology is the way it promotes clarity in discussing N-S ethical challenges by imposing a distinction between genuine ethical dilemmas and apparent ethical dilemmas. All our sources of empirical data establish that N-S researchers and N-S EBs can mistakenly classify the situations in which they find themselves. For example, there is a tendency to regard any issue with an EB as an ethical issue. Hence, when an ethics review takes a long time and delays research, this may be perceived as an ethical issue even if it is only an efficiency issue. Placing the issue in the applied ethics context makes it obvious that the issue is only an ethical issue/challenge/conflict if moral values and moral principles are involved.

The following sections outline some of the background knowledge and structures that can guide researchers through the applied ethics methodology.

2.4.1 Thinking about Moral Values

'Things' can be assigned a value based on different dimensions: economic, aesthetic, self-interest, hedonistic, moral, etc. We morally value and disvalue 'things'. For example, the bioethics model values autonomy, equality, human rights, honesty, and privacy and disvalues disrespect, harm, injustice, and rights violations.

When one says that one values human dignity or autonomy one is pointing to characteristics of human beings that provide the basis for our moral obligations. Some philosophers and Canada's TCPS claim that it is the dignity or autonomy of members of our species that justifies claiming human beings as having intrinsic value and hence moral value. Given the nature of the call for proposals that led to this study, it is doubtful that its primary audience doubts that human beings have moral value. Thus, no attempt will be made to justify this claim.

When one says, "Tom is honest" (or dishonest), that person is morally assessing Tom. They are praising or blaming him for his actions. When one

says “Tom is a good businessman”, they may be praising his moral goodness, but it is just as likely that they might be praising Tom for engaging in the activities or having personality traits that make one a successful business person. These actions and personality traits may or may not make one a morally good, i.e., virtuous person.

Other ‘things’, for example, such as capacity development, are not ordinarily listed as a moral value yet can be interpreted as such. If one explains capacity development in terms of empowerment, one connects capacity development with valuing autonomy and thereby values it as a means to a morally good end. To see capacity development as morally required because of unjust distribution of ‘benefits and burdens’ is to explicitly connect it with the moral value justice and one or more justice principles.

2.4.2 Thinking about Moral Principles

Whereas moral values are things we value, moral principles are very general statements that identify fundamental moral obligations (duties, responsibilities). They are commands.

The biomedical based ethics paradigm provides the context for most discussions of research ethics. The dominance of this paradigm is demonstrated (and sustained) by worldwide policy statements upholding it and by worldwide ethics codes, institutional guidelines, and procedures built upon these policy statements.

The core moral principles in dominant biomedically-anchored research ethics paradigm are:

- 1 Respect persons
- 2 Do not harm persons
- 3 Benefit persons
- 4 Treat persons justly

Moral principles provide the means for moral assessment and moral decision-making. Each principle identifies a value(s) we must consider when figuring out what we ought to do. By pointing us in the direction of a value or disvalue, they enable us to classify courses of action as right and wrong. Three of the fundamental principles point to the moral value of persons (1), benefitting (3) and justice (4) whereas “Do not harm persons” points to what we morally disvalue, namely, harm to persons. Moral principles also point to things we implicitly value or disvalue. So, for example, we disvalue disrespect (1), non-persons (1), burdens (3), and injustice (4). In this set of principles, the value of persons is the underlying moral value that confers moral value on benefitting and justice and that confers moral disvalue on harm.

For a scientific audience it might be helpful to think of moral principles as ‘moral indicators.’ The values named in moral principles are indicators of some basis for moral obligations. Moral principles supply moral assessment tools because the presence or absence of the values they point to indicates situations are morally okay or morally problematic.

When human beings are in good relationships, it is likely that most of their interactions can be described as consistent with respecting the values connected to fundamental moral principles.

The generality of moral principles makes it necessary to engage in a lot of moral deliberation/reasoning in order to figure out how to obey them; and/or to act in ways consistent with them. *Moral reasoning* connects other moral values with those named in the fundamental moral principles. For example, the values human dignity, autonomy, and honesty are associated with respect and persons; equality, human rights, and equity are associated with justice; economic sufficiency and health are associated with benefit/well-being.

2.4.3 Moral Reasoning Requirements

The generality of the obligations identified by moral principles makes it necessary to figure out more precisely what the obligations are. This deliberation activity can be referred to as “moral reasoning”. Since we all engage in the moral assessment/evaluation of people, laws and institutions, it is fair to say we all engage in moral reasoning. Like other forms of reasoning (for example hypothesis development, data analysis) it can be done well or not so well.

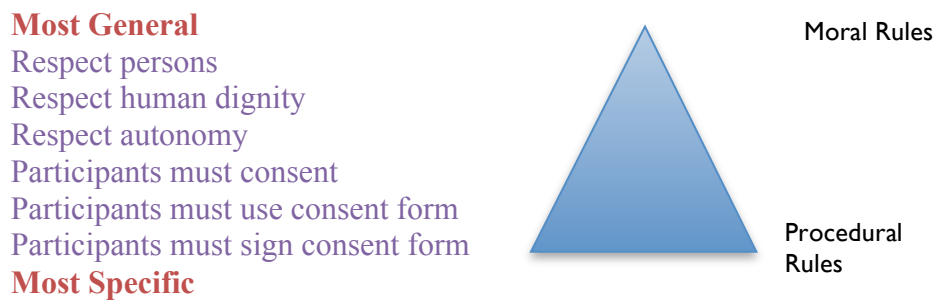
Moral reasoning skills are essential to the production of ethical guidelines and procedures and they are useful whenever we are asking: What ought I to do? This is a question we normally do not ask unless there is an ethical problem or dilemma.

In moral reasoning at the level of decision-making (i.e. applied ethics or practical reasoning) we aim to discover the course of action in the situation in which we find ourselves that we can justifiably regard as morally justified. This is the course of action consistent with the moral principles and moral values that we ought to follow in this particular set of circumstances in order to do what is morally required of us. Applied ethical reasoning points the way to morally right actions and how to avoid or respond to moral dilemmas. As the means to grounding our choices in moral principles, it allows us to claim that we have evidence that our choices are morally acceptable. Applied ethics allows one to more confidently assert: “I am doing what I ought to do.” Or, research team members to say collectively: “This is the right thing for us to do.” Equally important, we can have the peace of mind that comes from knowing we are not doing something wrong. Research teams members will not only experience peace of mind individually but team solidarity rather than dissonance.

2.4.4 Levels of Generality of Moral Commands

The notion of hierarchy has two applications in the context of moral commands. On the one hand there is a hierarchy of generality ranging from the most general rule to the most specific rule and on the other hand, there is a

hierarchy of moral significance attaching to moral rules. Both hierarchies are illustrated below using the dominant paradigm's underlying moral principle.



Commands in the hierarchy are in a means end relationship. The ones below a most general principle (fundamental moral principles) identify the kinds of actions that are consistent with the fundamental principle. These actions are morally required because they are the means to satisfy the more general principle's command. Hence, less general rules are interpretations of the requirements of a general principle and identify ways to implement it. In the example, there are three context specific commands in the hierarchy (Participants must consent; Participants must use consent form.; and Participants must sign consent form.). This is to say that in the case of these three commands the context in part determines whether they are moral requirements. In some contexts, obeying these commands may violate the moral principle "Respect persons." For example, in some contexts, it may be morally wrong to require participants consent or that participants use a consent form or sign a consent form. The status of "Respect persons" as a fundamental universal moral principle is not challenged when the universality or moral acceptability of one of the three particular rules is rejected. The challenge only demonstrates that, for example, "Participants must use consent form" or "Participants must sign consent form" are not unconditional, universal moral rules. Indeed, it would be best to say that they are not moral rules at all but rather they are *procedural* rules that in some contexts enable researchers to respect persons.

2.4.5 International Ethics Codes, National Policy Statements & Ethics Board Procedures

All documents that provide moral prescriptions for the ethical practice of research have as their ultimate end the implementation of fundamental moral principles in research practice. They typically focus on the relationship between the researcher and participants in the research study and declare the protection of the study participant to be their major objective. The rules and procedures that they put in place are to ensure that researchers' interaction with participants is in compliance with the four moral principles (and attendant values) that are regarded as underlying ethical research practice. When researchers submit proposals that satisfy these requirements, for the EB, this indicates that the researcher's treatment of potential participants will be morally acceptable.

At all levels (international, national, and institutional), the rules, procedures and processes specified are typically worked out assuming the backdrop of a

particular set of social, economic, and political circumstances, namely, those prevailing in N-countries. For the most part, the practical moral reasoning that produced the rules, procedures and processes does not take into account the social, economic, and political circumstances of S-countries and is not informed by S-participation.⁸ Nor can N-EBs be credible experts commenting on the cultural nuances and differing moral philosophies of our complex global village. Societal and cultural specificity is a possible source of disagreements about how to treat S-participants in a way consistent with the fundamental moral principles (and values).

The literature review conducted for this research study as well as the empirical data collected provide evidence that circumstances in N-countries are the basis for ethics review and demonstrate the kinds of ethical conflicts and challenges that result. For example, as most N-S teams have experienced in carrying out their research, in S-countries to respect potential participants in a study it may be necessary to:

1. Convey information in a group rather than to each individual on a one-on-one basis.
2. Eliminate the consent form as a means of conveying information since the content of a consent form does not explain what they need or want to know.⁹
3. Forgo using signed consent form as an indicator of voluntary participation that respects participants.

Blindly following lower level rules is not wise and may result in the violation of moral principles even if the rules are called moral rules and viewed as standard ethics review procedures. If following the rules that have been created by well-meaning and well-intentioned groups of researchers does not respect potential participants, then researchers are not morally required to comply with them. Given the primacy all codes, policy statements and EB procedures accord fundamental moral values, in theory they support the researcher or research team that refuses to comply with them on the grounds that compliance would not respect the participant in this set of circumstances. However, in practice, researchers and research teams find themselves in an ethical dilemma with no easy way out because in practice in the ethics review process conducted by EBs there is insufficient reference to the moral principles in order to resolve the conflict between N & S requirements and procedures. A morally inappropriate priority assigned lower level rules has become an obstacle to seeing the need to engage in the applied ethics reasoning that would unpack what the moral principles require in this particular context. Consequently, N-EBs are not able to discover that in the context of S-country, a new set of procedures and guidelines are required to serve as indicators that

⁸ Although it adopts the fundamental moral principles of the dominant paradigm, it is worth noting that the South African Medical Research Council's *Guidelines On Ethics For Medical Research: General Principles* (1996) specifies that context is morally relevant and that their guidelines focus on South African needs. It employs the distinction between individual and community human rights and the notion of distributive justice in its formulation of ethical research requirements.

⁹ Although the signed consent form is not an unconditional requirement in the TCPS, sometimes N-S research teams encounter N-EBs which treat it as a requirement

researchers are appropriately and correctly respecting potential study participants.

2.4.6 Complex multicultural context and unjust inequalities

N-S research teams work in complex, multicultural settings with a intricate myriad network of relationships and framed by circumstances characterized by inequalities that are deemed unjust by the principles of social justice. The injustice inherent in material and human capacity that underlies all researchers' relationships has significant implications for ethical research practice. It is generally understood that unjust inequalities can create power imbalances that are a burden for S and benefit for N. Less understood are the ways these injustices are related to prevalent ethical challenges N-S teams face.

A person's response to morally problematic situations may be limited by the situation in which it arises. As an example, a N-S research study might establish that an intervention will greatly improve the health in a S community. However, neither the individuals nor government in the S-country have the financial resources to continue the intervention proposed by the study. For the individuals and institutions based in the S-country, actions based upon reasoning employing only the fundamental moral principles (i.e. context empty) are not part of the set of options available. They lack the resources to do the morally right thing. N-countries may have the financial capacity to supply the resources, but neither the researcher nor the funder can supply the long-term funding required. This moral dilemma is an extremely important one that demonstrates the need for applied ethical reasoning and shows that ethical research practice, like social justice, requires an applied ethics dialogue at the national and international levels.

However, even in the context of limited options, it is important to realize that there are moral requirements. Fundamental moral principles do not disappear so that a researcher (or the Team) is permitted to lament the injustice in the world and proceed to complete the research study as usual. In unjust circumstances, all of the moral principles band together with justice to protest 'business as usual.' Simply focusing on how to best comply with Ethics Boards' requirements will not suffice. There is an opportunity in the context of unjust inequalities to do the morally best of the morally problematic courses of action available. Applied ethics dialogue is the only means to finding out what is the morally best research practice in these unjust circumstances.

2.4.7 Sandra Tomsons' Approach to Applied Ethics

Philosophers who claim to do applied ethics would respond differently to the question: How is it done? To this query, some will tell you how they do it. Others will even tell you how it ought to be done. It may, however, be more useful to think of applied ethics as an "emergent methodology." Like other methods in the social sciences, it is always under construction and deconstruction.

Tomsons has specialized in practical ethics and applied philosophy since the publication of her dissertation, *Property and the Doctrine of Human Rights*. That work is, in fact, best classified as applied politics. Her work teaching

medical and environmental ethics added applied ethics and research on the rights of Canada's Indigenous peoples expanded these ideas of applied politics. Even her epistemology research is applied epistemology. Components of Tomsons' approach to doing applied ethics include:

- i.* Employing philosophy's methodology
- ii.* Being explicit about the normative nature of inquiry
- iii.* Being explicit about searching for knowledge
- iv.* Addressing the objective and relative nature of moral claims
- v.* Undertaking a conceptual analysis
- vi.* Collecting evidence for claims
- vii.* Assessing evidence
- viii.* Acknowledging the role of 'common sense' morality
- ix.* Acknowledging the role of moral sentiments
- x.* Using narratives for epistemological and motivational reasons
- xi.* Accepting the relevance of empirical data
- xii.* Focusing on dialogue not monologue

All researchers engaging in research do so in a complex context. This complexity is greatly multiplied when the researchers are part of N-S research teams engaged in global population health research. The researcher's many relationships are all ethical relationships. Although the ethics review process in the N and the S might make it appear that researchers are only in an ethical relationship with their participants, the fundamental moral principles make it clear that they apply to all person-to-person relationships.

In all of their relationships, researchers are required to obey the fundamental moral principles. However, their actions are also expected to conform to many types of institutional requirements that may or may not be consistent with their ethical obligations, for example:

Funder's	Proposal criteria and accountability procedures
EB's	Protocol requirements
Countries	Legal requirements

From a moral point of view, it is always the moral principles that are the most important and they provide the basis for assessing the other types of requirements and ultimately should be the basis for action.

Recognizing that ethical research practice encompasses all persons in the complex network of relationships enlarges the scope of moral decision-making in research practice. Now every interaction and every stage of research activity is recognized as involving moral decision-making. Applied ethics is part of the ongoing business of doing research from beginning to end. Ethical research practice does not mean getting ethics approval for proposed research protocols.

2.4.8 Key Ingredients and a 'Slice of Life'

To engage in applied ethics one must bring together the following key 'ingredients':

1. Theoretical knowledge of:
 - Moral theories
 - Literature related to applying ethics in relevant area
2. Empirical data
 - Knowledge of the social, economic, and political characteristics providing the backdrop for that which gave rise to the moral question being addressed and are relevant to answering it.
 - A 'slice of life' example, a narrative, or case example
3. Engage the activities of philosophy's methodology in the company of at least one other person.

Examples of 'slices of life':

1. **Small slice:** Overcommitted, overworked N-researcher offered opportunity to participate in an exciting N-S research project. What should s/he do?

Different values would support different choices:

- | | | |
|--------------------|---|-----|
| ○ Economic values: | research supports promotion | Yes |
| ○ Self-image: | prestige (department, university) | Yes |
| ○ Professional: | promote his/her marginalized specialization | Yes |
| ○ Moral | help change the world | Yes |
| ○ Family duties | even less time for them | No |

What should s/he do? S/he said 'Yes.'

2. **Larger slice:** S-researcher explains to team that it will be unable to conduct research in a particular community if they insist on using a lengthy consent form and satisfy all the requirements of N-EB. The question for the N-S research team: "Should we use a shorter form?"

- | | |
|---|-----|
| ○ N-EB requires the long form. | No |
| ○ S-EB will not approve the long form. | Yes |
| ○ No one will agree to be a participant if the long form is used. | Yes |

Note: None of the team's reasoning outlined above so far engages fundamental moral principles. Nonetheless, it is relevant to doing applied ethics.

If researcher values:

- | | |
|--------------------------------|-----|
| ○ Knowledge (project's output) | Yes |
| ○ Funder approval | Yes |
| ○ N-EB's approval | No |
| ○ S-EB's approval | Yes |

- Doing the morally right thing ?

When the team's reasoning is about knowledge and agency approval, the team has not yet begun to engage in applied ethics reasoning. The team is not addressing the question in a manner that answers the "What is the morally appropriate way to document participant consent?" Addressing the question of moral requirement is necessary in order for the team to be reasoning at the level of applied ethics. In order to find out what is the morally right thing to do, the research team needs to put their options and the fundamental moral principles into a context of real people in their particular circumstances. However, this 'slice of life' does not contain sufficient information to find out what the morally right thing to do is. Those who engage in the dialogue need to have understanding of the life experiences and moral expectations of the people they are in the researcher-participant relationship with, and the two consent forms. Only with a richer set of information can the N-S applied ethics dialogue determine what fundamental moral principles and values require researchers to do. Researchers can assume from the outset that they are morally required to act in accordance with these principles. They should not assume from the outset that they are morally required to make participants endure the longer form.

3. **Example of Best 'Slice of life':** Ntombi's story

- *Source:* S. R. Benatar "Reflections and recommendations on research ethics in developing countries" *Social Science and Medicine*, 54 (2002) 1131-1141

Benatar tells the story of a potential participant in a N-S research study. He provides a snapshot of Ntombi that reveals her personal, social, economic, and political circumstances in a S-country and brings us into her experience as she is faced with the decision of whether to participate in the study or not. Without Benatar's story, an N-researcher or N-EB member could not and would not begin to imagine the burdensome nature of the decision the researcher has asked Ntombi to make. In Ntombi's story, the N-researchers discover that "not all, and especially those who are disadvantaged or who have been exploited, will see the world through the same lenses..." The vivid contrast between Ntombi's lived experience and that of N-researchers makes self-evident the need for N-S teams to do a lot of applied ethics before and throughout N-S research projects. Moreover, it is in Ntombi's story that we discover that a commitment to human rights is empty without a commitment to social justice - a justice notion that, for the most part, does not have a voice in research ethics discussion and consequently has not been given a role to play in decision-making.

The methodology used to apply the applied ethics methodology in this study is summarized in **Appendix A.2**. The 'slice of life' narratives created to practice this process are included in **Section 6.0** of this report.

3.0 Conceptual Framework: The Network of Ethical Relationships Model

The **Network of Ethical Relationships (NER)** model (**Figure 3**) provides a useful mechanism to organize and understand the wide variety of ethical relationships that individuals are navigating over the course of their research projects. The names of the people (and in the real world, these are individual people, not ‘institutions’) involved, and the key roles identified in the circles may change from one research project to another, but the overall model seems flexible enough to be applied to a wide range of international research activities.

The NER model developed in this study was used to succinctly convey the idea of the dynamism and complexity (**Section 2.4.7**) of the relationships that researchers involved in North-South (N-S) global population health research navigate before, during, and after their research programs (see also **Section 4.2.2**). It features importantly in our analysis of our empirical data and our critique of the dominant biomedical paradigm. Further, the NER diagram was used to structure the applied ethics stories in **Section 6.0**, as well as provide the structure and analytical framework for the Caribbean EcoHealth Programme (CEHP) case study (**Appendix A.2.6**).

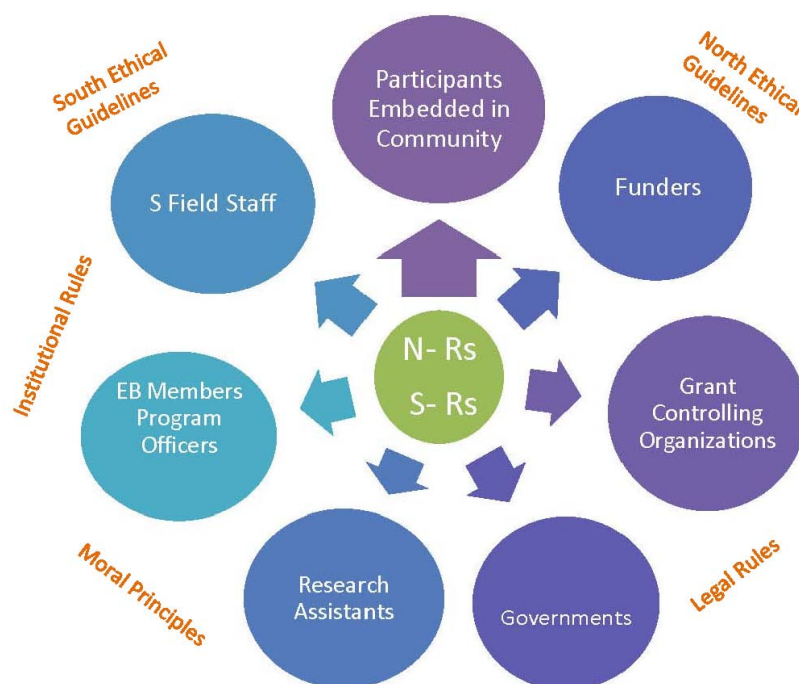


Figure 3 Network of Ethical Relationships Model¹⁰

¹⁰ Although the NER diagram is based on our research findings, the following should be noted: (i) the nature of other non-TC N-S research team's project may make it necessary to add more circles in order to accurately represent all the relationships contributing to implementing their research, and (ii) the types of rules (moral, legal, cultural, institutional) that N-S research teams must take into account in their decision-making and research practice are placed in the backdrop of the Network of relationships. We do this to make the rules visible and display the complexity of the normative network for N-S research collaboration.

3.1 Key Features of NER Model

Key features of the NER model diagram are highlighted below:

- The wider arrow indicating the dominant concern of the researcher for the participants in the research initiative;
- The notion that the circles represent people with multiple identities, including that of serving as an officer of the organization they represent – over the course of their projects, and careers, researchers maintain short- and long-term relationships with a variety of individuals from these groups;
- In the context of the TC research teams, the inner circle represents the close and on-going relationship between the N and S researchers themselves, that is, the TC team. Intra-team dynamics are a key element of a successful research initiative. This theme was explored in greater detail using the mini-SAMKET case study, outlined in [Appendix A.2.8](#).
- Moral principles, N and S ethical guidelines, legal rules and institutional rules are made the backdrop of the relationship diagrams because they provide a complex normative framework for researchers' network of ethical relationships.

3.2 Network Complexity

As indicated in [Figure 3](#), the idea of a complex network of relationships was a key guiding concept for this research study. For this reason, a brief introduction to the complex systems literature is relevant and appropriate to this report. The complexity lens is becoming increasingly more prevalent in academic work in a wide range of disciplines and fields, including the health sector (Pourbohloul and Kieny, 2011; Zinstagg *et al.*, 2010; Duit and Galvaz, 2008; Antonacopoulou and Chiva, 2007; Rouse, 2000). It is a meta-narrative guiding the exploration of themes such as: the determination of the boundaries of a system (determined by the researchers), spatio-temporal scale, non-linearity, path-dependence (the importance of knowing the history of the system), incomplete knowledge and uncertainty, emergent properties, and the need for a new transdisciplinary understanding explored from a wide range of different perspectives. It leads to recommendations for flexible and adaptive approaches and investments in reflectivity and social learning. Understanding systems from multiple perspectives and scales, and thinking about how they change over time, are fundamental tenets of systems approaches.

Systems thinking has been described as a type of inquiry focused on “patterns, processes, relationships and context” (Capra, 2005). The latter two components are most certainly relevant to this study, while identifying the former is a way to look for useful points of intervention in N-S research systems that could serve to change the future trajectory of the system, i.e., the way in which N-S research is defined, discussed, and conducted. Thus, the complexity lens is useful for identifying changes to policies and practices that seems useful in the context of this project. Indeed, Patton (2002) notes that:

1. A systems perspective is becoming increasingly important in dealing with and understanding real-world complexities, viewing things as whole entities embedded in context and still larger wholes;
2. Some approaches to systems research lead directly to and depend heavily on qualitative inquiry; and
3. A systems orientation can be very helpful in framing questions and, later, making sense out of qualitative data.

As illustrated in the following quotes, in the fields of health research and ethics, complexity is well recognized:

Health systems defy simple representation. They call for novel ways of thinking to improve our ability to predict and control individual and population-based health outcomes. A holistic framework is needed to capture disparate diseases and health conditions and their intricate relationships into a unified platform. Such frameworks are developed using complex network analysis (Pourbohloul and Kieny, 2011).

The strategic vision of the Office of Behavioral and Social Sciences Research (OBSSR) at the National Institutes of Health (NIH) is rooted in a collaborative approach to addressing the complex and multidimensional issues that challenge the public's health. This paper describes OBSSR's four key programmatic directions (next-generation basic science, interdisciplinary research, systems science, and a problem-based focus for population impact) to illustrate how interdisciplinary and transdisciplinary perspectives can foster the vertical integration of research among biological, behavioral, social, and population levels of analysis over the lifespan and across generations. Interdisciplinary and multilevel approaches are critical (p.1) ... How can the growing understanding of complex adaptive systems be used to better understand the process of decision making in health at the personal and systems levels? (p.7) (Mabry et al., 2008).

While the need for approaches that take complexity into account are increasingly commonplace, the role of ethics (i.e. participation of moral theorists and practical ethicists) in this discussion is relatively limited. As in global population N-S health research, complex systems thinking is predicated on the dynamic discussion that emerges from bringing together multiple perspectives. How to manage that dynamic and how to proceed with the discussions, debates, and inevitable disagreements in an ethically informed way is an on-going challenge.

It is interesting to note that the complex theory frame advocates for the use of stories and narrative as a means of communicating complexity, both to the public as well as between researchers of different kinds. In addition, scenario-based thinking is a key element of the complexity dialogue. Thus, there are interesting parallels between this framework and the applied ethics methodology that was used to select, inform, and develop the stories put forward in the applied ethics section ([Section 6.0](#)).

4.0 Analysis of the Network of Ethical Relationships (NER) Model

This Section builds on the previously discussed conceptual and methodological frameworks of this exploratory research study and the hypotheses that guided their development. Considering the interrelatedness of the various elements of the study and its findings, this section represents an attempt to discuss the findings following a sequence that allows a clearer illustration of the complexity of the conceptual Network of Relationships (NER) model as it played out in real life, and explore how this complexity generated ethical and other types of challenges. It incorporates the findings of the empirical and mixed methods research as summarized in the Appendices of this report.

Firstly, the two hypotheses that guided this study are addressed. Secondly, additional themes that emerged from the research are then explored. These include setting out the N-S context within which the research and implementation collaborations took place, followed by the unfolding of the network of relationships that developed and what they mean to the individual researcher and the collective, i.e., the team. Following this, the focus shifts to a discussion of the ethical approach used in biomedical research and its appropriateness for global population health research (GPHR). Part of this discussion looks into the need to apply the fundamental moral principles in ways that expand the “ethics box” in order to better address social justice issues. But the ethics box cannot be appropriately expanded without considering the rights and responsibilities of the various social actors, the interplay of individual and bureaucratic power, and the distinction between procedural and relational types of tensions.

This Section is closed with the recognition that to understand and resolve the ethical and procedural challenges faced by N-S GPHR research teams, the emergent and non-static nature of culture and of human relations calls for a collaborative approach that is flexible and invites those involved to reflect upon the ways in which they deal and respond to these fluctuations. To be more precise, this is a clarion call for collective practical moral reasoning. This includes the recognition that given the evolving nature of human societies, perfect systems cannot be constructed. Hence, in order to prevent ethical challenges and to avoid wrong-doing, it is more realistic and reasonable to think about ways in which individuals can contribute to make the systems within which they operate less rigid, more ‘humane’, and hence potentially more ethical.

4.1 Study Hypotheses

The initial call for proposals indicated that N-S research collaborations faced persistent, unique ethical issues and challenges. In our LOI, we agreed that we would attempt to provide an account of the nature and sources of these ethical issues. It is commonly assumed that there are significant differences in North-

South understandings of moral obligations which putatively cause ethical issues and disagreements. We have not, *a priori*, assumed that this assumption is true. We rather used the empirical data about ethical issues gathered from our case study, questionnaires, and International Ethics Workshop to assess the accuracy of this assumption.

Based on an analysis of data collected, we determined whether or not there was evidence to support the conclusion that there are significant North-South differences in moral values and moral reasoning. When the evidence did not support this assumption, we explored whether or not a better explanation for the ethical issues and challenges that arise in population health research was to be found in power differences between the North and the South in terms of development and resources and/or whether lingering effects of colonialism still impact the way some individuals and some communities react to the North.

The empirical data gathered in this research study was used to assess the extent to which actions of researchers and ethics review boards were consistent with the fundamental moral values and principles of the dominant paradigm. The CEHP TC case study was used to further clarify whether the fundamental moral values of the North are incommensurable with the fundamental moral values of the South. Data from this case study was also used to explore efforts to reconcile ethical disagreements between members of multi-disciplinary research teams, and between research teams and EBs, funders, and communities participating in the research.

Realizing that the ethical issues that arise in N-S GPHR could come from several sources, at the outset of the study, two hypotheses were developed to guide the collection of empirical data in ways that it was thought would provide some understanding of whether (and the extent to which) fundamental N-S ethical differences were the primary source of N-S ethical issues.

The call for proposals as well as a preliminary review of the literature, both suggested that the dominant biomedical paradigm currently widely used for research ethics could be limited in its application to N-S global population health types of research. Given that the biomedical paradigm is a N-construct, it seemed possible that it might have excluded S-ethical thinking, S-moral values and principles and that this exclusion could be used to explain observed ethical conflicts seen in N-S GPHR research efforts. Thus, a prime objective of this research study was to collect empirical data from N-S researchers as well as members of ethics boards from both the N and the S which would provide insight into whether (and the extent to which) the N's biomedical paradigm was the primary source of the ethical issues.

4.1.1 Hypothesis #1

The standard bioethics model generating the moral principles that anchor and justify the North's ethical guidelines is not an appropriate model for North-South population health research. Therefore, the moral principles generated by the bioethics model cannot by themselves provide an adequate set of ethics guidelines for North-South population health research.

The following ‘premises’ explain the foundation upon which *Hypothesis #1* was constructed and the ongoing support we found for it:

- i. The account of N-S research teams’ experiences of ethical conflicts in the initial call for N-S research ethics proposals and the corroboration of this account by SAMKET’s two Teasdale-Corti team members.
- ii. The current dominant biomedical model which is used to provide guidance on the nature of ethical research and is used as the basis for most discussion of ethical research practice is firmly embedded in Western (Northern) metaphysics and axiology. Hence, N-philosophy (worldview) is by default presumed to provide the appropriate context and content for discussion of all types of research practice. This implies that if there are different philosophies (worldviews) in S-countries that contain metaphysical and axiological content that do not map perfectly onto N-philosophy, ethical disagreements are a predictable outcome.
- iii. The N-S biomedical paradigm that is embodied in N-country ethics policy statements and implemented in the processes and procedures of N-EBs does not allow for or facilitate inclusion of notions such as social justice and community autonomy in discussions of ethical research practice since these notions are absent from and inconsistent with parts of its normative framework. Hence, it is reasonable to anticipate that the literature’s discussion of ethical research generally, and N-S collaborations in particular, would make invisible or marginalize S-philosophies. During the LOI preparation stage of this study, prior to the conducting of a detail literature review, SAMKET’s collective experience lead the team’s N & S ‘ethics experts’ to conclude that the biomedical paradigm and the N-philosophy underlying it are effectively silencing S-philosophies.
- iv. Early in the literature review, it became obvious that S-philosophies (worldviews) were either absent from the literature (invisible) or marginalized by being mislabelled as cultural differences. With few exceptions (e.g., Solomon Benatar), most authors did not consider the possibility that S-countries have a philosophy(ies) that might materially differ from the philosophy(ies) accepted by N-countries; philosophy(ies) having metaphysical and axiological differences that played a significant role in explaining the ethical challenges and conflicts N-S collaborations were experiencing.
- v. For more than two decades, the primary research area of SAMKET’s N-‘ethics expert’ had been Indigenous philosophy and Aboriginal rights of Canada’s Indigenous peoples. She was therefore familiar with the extent to which non-N-country philosophy, especially the philosophies of Indigenous peoples, can be incommensurable with Western (Northern) philosophy’s fundamental metaphysical and axiological theories that are embedded in N-societies. Since Indigenous people were study participants for some of the TC N-S collaborations and most TC studies typically involved vulnerable groups and communities in S-society,

SAMKET thought it possible that axiological differences, that is, N-S differences in fundamental moral values and principles were at the root of the ethical conflicts confronting N-S teams. Therefore, SAMKET decided to focus its empirical data gathering on identifying similarities and differences in N-S fundamental moral principles and values.

- vi. If any significant axiological differences in N-S understanding of moral principles and values were discovered, it would be reasonable to conclude that the N-country's imposition of their dominant research ethics paradigm is an unintentional component of N's contemporary (unintended and generally unperceived by N-researchers) colonization project. In the literature, this contemporary form of the N's ongoing colonization project, which constitutes a new form of oppression, is called 'scientific colonization.'
- vii. If any evidence could be provided that the N is (or is not) intentionally or unintentionally imposing the dominant research ethics paradigm upon S-countries lacking the academic resource capacity to recognize or respond to the imposition, then the N-S oppressive practices would have been made visible. Furthermore, this would justify the claim made in, Hypothesis #1, namely, that the standard bioethics model generating the moral principles that anchor and justifies the North's ethical guidelines is not an appropriate model for North-South GPHR research. Nothing in the metaphysics or axiological theories that are the basis of the biomedical model, and nothing in the N's articulation of the model's fundamental values and principles prohibits imposing this model on those who do not share N-philosophy (worldview). Yet, N-researchers have done nothing to justify their assumption that the N-model is '*the* model.' In other words, they have not proven they have discovered the gold standard for research ethics practice.
- viii. If the N-assumption that the N-model is '*the* model', an assumption frequently shared by S-researchers educated in the N, then the possibility for a philosophical dialogue in which S & N work out together the appropriate content for a research ethics paradigm for N-S collaboration is shut down. The dominant N-biomedical paradigm is unquestioningly adopted. Ongoing ethical challenges and conflicts are symptoms of a problem; but there is no way for members of the research team experiencing these problems to locate the problem in the axiology of the dominant paradigm. Indeed, it might seem more reasonable to explain the ethical problems using the more general, and hence more vague, notion 'cultural differences.' If the problem is explained in terms of N-S cultural differences, the dominant paradigm is off the hook so to speak. It does not come under the scrutiny that its N-genesis makes necessary. Once it is recognized that Northern philosophical and scientific inquiry created and revised this paradigm over time, and that it has not been informed by S philosophical and scientific inquiry, it becomes clear that any epistemological assumptions about the universal applicability of this paradigm are unwarranted. There is no justification for believing that the

model, by itself, provides an adequate set of ethics guidelines for N-S research collaborations.

Since the empirical data collected in this research study and a careful analysis of the literature lends support to the conclusion that reason requires N researchers to question the appropriateness of assuming the truth and universal application of the dominant bioethics paradigm ('premise' vi), given the possibility in 'premise' iii of incommensurable differences in S & N axiologies, SAMKET invoked the precautionary principle in its endorsement of the following recommendation in Hypothesis #1: *"...the moral principles generated by the bioethics model cannot by themselves provide an adequate set of ethics guidelines for North-South population health research."*

4.1.2 Hypothesis #2

The moral values of the North and South are a source of ethical disagreement when the North's moral values are understood narrowly as the four moral principles that are the basis for North's research ethics guidelines. When a richer understanding of the fundamental moral values of the North is incorporated into the discussion of the ethical issues, the moral values of the North can be reconciled and ethical issues resolved.

The following 'premises' explain the foundation upon which *Hypothesis #2* was constructed and ongoing support for it:

- i. When formulating the LOI, SAMKET was uncertain about the extent to which the S and N researchers ascribe the same and/or different fundamental moral principles and values. However, the literature and SAMKET's collective experience provided some support for asserting that the dominant bioethics paradigm reflected in N policy statements and N-EBs procedures and requirements employed a narrow interpretation of the moral principles and values they uphold.
- ii. As explained above, each of the four fundamental moral principles upon which the bioethics paradigm rests points to *the* fundamental value of one of the significant and competing moral theories in the western philosophical tradition. The paradigm initially was using deontological theory's respect for persons based upon the intrinsic value of human dignity and/or autonomy (values upheld by human rights theories) and utilitarian theory's valuing of benefit and disvaluing of harm. Only recently did it explicitly acquire a notion of distributive justice requiring fairness in distribution of benefit and burdens. The paradigm's amalgam of competing theories and values that can be interpreted as requiring different actions in the same situation leaves the door wide open for ethical disagreement, even within the N context in which it was constructed; -especially, since the paradigm has an underdeveloped notion of distributive justice and does not provide an account of the priority or relative moral weight of the fundamental and secondary values it contains thereby leaving the impression that all values are absolute, of equal moral value and apply universally.

- iii. Given the extensive philosophical literature analysing competing moral theories in the Western philosophical tradition and explanations and attempts to resolve the disagreements and dilemmas generated by conflicts between their competing values, the matter of fact presentation of the fundamental moral values and principles in N-policy statements such as Canada's Tri-Council policy is as puzzling as it is misleading. However, arguably it takes a new context for reflecting upon research practice, such as N-S research collaborations, to discover the assumptions, strengths and weaknesses of the dominant paradigm.
- iv. In the context of N-S collaborations our data showed N-S researchers were sufficiently accepting of the dominant paradigms fundamental moral values and principles to claim them as their values; nonetheless, they frequently maintained that N-guidelines that N-EBs created to implement these values were too restrictive and/or inflexible to successfully implement the fundamental values in the context of S-countries. So, for example, while accepting respect persons and valuing autonomy and also the consent requirement based upon these fundamental values, researchers from the N and S agreed that N-practices of individual consent and signed consent forms are not the only practices that can be used to implement these fundamental and secondary moral values in research practice. Indeed, in some S-contexts, N-practices are morally unacceptable and the dominant paradigm's fundamental values support S-secondary moral values and consent practices.
- v. The theoretical and normative framework of the dominant biomedical paradigm does not contain all Western philosophy's moral theories nor utilize all aspects of Western philosophy's normative framework. So, for example, it ignores virtue theory and environmental ethics and only partially uses human rights theories and theories of justice. What is missing is important because it is possible that excluded theories and concepts could contribute to reconciling S-N axiological differences by establishing there is more commensurability than incommensurability between S and N philosophies. Until there is extensive philosophical dialogue between S and N philosophers critically assessing both what is in and left out of the biomedical model's ethics box that is morally relevant to ensuring N-S research teams engage in ethical research practice, it will be impossible to ascertain the extent to which N and S axiologies can be reconciled.
- vi. Premise v in combination with our empirical data and our analysis of the moral foundations for N-S research collaboration provide some basis for the optimism expressed in Hypothesis 2: *When a richer understanding of the fundamental moral values of the North is incorporated into the discussion of the ethical issues, the moral values of the North can be reconciled and ethical issues resolved.* We believe that N-philosophers, in their critiques of liberal theory's individualism and narrow understanding of justice have introduced into N-axiology and metaphysics some beliefs about human nature, character development

- and notions of justice that make all N-participants in N-S research collaborations (i.e. funders, researchers and EBs) more receptive to changes in the dominant paradigm. Furthermore, the literature's discussion of research ethics conflicts/issues shows that N-scientists and N-researchers participating in N-S research teams are experiencing the need for changes in the dominant research ethics paradigm. So, for example, how-to research textbooks now discuss N-S research collaboration and philosophers who provide accounts of the moral theory undergirding the paradigm now include a brief discussion of the notion of social/global justice and acknowledge human rights demands based on it.
- vii. As our study evolved and we confirmed the extent to which the dominant biomedical paradigm is an N-construct embodying N-philosophy and that its evolution has primarily remained in the hands of N-institutions and researchers, we became increasingly concerned that S-philosophy is not adequately represented in discussions of N-S research ethics. N-researchers and institutions continue to control the content of and revisions to the dominant biomedical paradigm.¹ For example, in its recent revision of TCPS, Canada's Tri-Council includes an important chapter "Research Involving Aboriginal Peoples in Canada" (Chapter 9). This chapter holds some promise for contributing to N-S research ethics discussion, in particular when N-S research takes place in Indigenous peoples' communities. However, this chapter's rationale for researchers' responsibility to engage communities in design, consent and dissemination processes and its unique moral value content (i.e. moral values missing from the Ethics Framework discussion) stand out in stark contrast from the content of other chapters. Because the content of this chapter is not anticipated in Chapter 1's account of the Ethics Framework, not only are the requirements identified in this chapter disconnected from TCPS's account of fundamental moral values, principles, and moral theory, but the TCPS's understanding of what constitutes ethical research practice appears incoherent.

Our empirical data and analysis indicate that N-S researchers can only expect to fully understand the genuine ethical conflicts and challenges they encounter when their applied ethics N-S dialogue becomes an established research practice. It is this dialogue that will reveal the extent to which S-metaphysical beliefs and fundamental moral values have been excluded from N-S research ethics discussion and the rationale for revising and enlarging the dominant paradigm. It will also reveal the extent to which N-S axiologies and metaphysics are commensurable. Only N-S philosophical dialogue can verify either of our claims in Hypothesis #2. It is when S-researchers, especially philosophers, contribute to the N-S philosophical dialogue that empirical data will become available that will establish whether, as our hypothesis #2 claimed "When a richer understanding of the fundamental moral values of the North is incorporated into the discussion of the ethical issues, the moral values of the North can be reconciled and ethical issues resolved."

This N-S philosophical dialogue provides the only means to discover whether N-philosophy has an account of human nature that matches S-understanding and whether N-philosophy has a rich enough account of fundamental and secondary values to adequately express S-axiology. En route to establishing the commensurability or incommensurability of S-N metaphysics and axiology, the N-S philosophical dialogue will also verify the first part of Hypothesis #2, namely, whether: The moral values of the North and South are a source of ethical disagreement when the North's moral values are understood narrowly as the four moral principles that are the basis for North's research ethics guidelines. We urgently recommend N-S philosophical dialogue at the level of moral theory and practical ethics because we are confident that it has the potential to facilitate a richer understanding of N and S moral values and provide knowledge to enable N-S researchers to reconcile their value differences and prevent/resolve ethical challenges/conflicts.

4.2 The Complex, Dynamic Network of Ethical Relationships

In this research project, the complexity frame provided a useful structure for thinking about both the boundaries of the 'network of ethical relationships' (NER) that researchers appear to be navigating, as well as the ways in which these relationship change over space and time. The tension between scales – in this case the individual and the collective – was a key theme. Additionally, since at different times in the implementation of research, there are significant differences in the scale of the activities conducted by different partners, it was discovered that the complexity and reflective lenses were useful for identifying relevant changes to ethics policies and practices.

4.2.1 Network of Ethical Relationships (NER) Model

In the context of our research, the complex network of relationships for collaborative global population health has several layers of complexity that are particularly relevant. For the purposes of this research study, the prime focus was on the fundamental moral principles and values of persons in the network. However, in every society there are non-moral values and requirements (rules) based upon them that are competing with and sometimes confused with moral requirements. The NER diagram identifies in the types of rules it places in the background some of the sources and some types of requirements that individuals (whether researcher, participant, team employee, grant administrator, EB member or funder representative) take into account in their decision-making and actions. Individuals live in a complex normative world consisting of legal rules, cultural norms, institutional requirements, and, last but not least, moral rules. The complexity of this normative network creates a context in which conflict between moral requirements and other types of rules is almost inevitable, even if legal and cultural norms are shared. In the context of N-S research collaborations in which the individuals in the team bring into the network of relationships differing legal rules, cultural norms, and institutional requirements, the complexity of the normative framework is multiplied at least by two. Also, the potential for conflicts among the various types of rules in the framework is proportionate to this complexity.

Consider the following hypothetical example: A N-S research team will be carrying out the same study in Jamaica, South Africa, and China. The team discovers that the legal requirements for participant consent in Canada conflict with the legal requirements in Jamaica, South Africa, and China. Similarly, the EBs they interact with in these countries all require different methods for collecting consent. In the field, after securing approval to conduct the research from the N and S EBs, the researchers discover, when potential participants refuse to be part of the study, that in some countries the consent process is not consistent with cultural norms.

Because of the various types of requirements that apply to researcher decision-making and researcher activities, as well as a tendency not to distinguish them clearly from moral requirements, the potential for misunderstanding and misnaming the type of normative challenge one is facing is great. For example, Canada's TCPS sometimes blurs the distinction between legal and moral requirements and may suggest that researchers attend more closely to legal requirements. The following quotation illustrates both the blurring and the ranking problem. "Researchers may face situations where they experience a tension between the requirements of the law and the guidance of the ethical principles in this Policy. In such situations, researchers should strive to comply with the law in the application of ethical principles. Researchers should consult with colleagues, the REB or any relevant professional body, and if necessary, seek independent legal advice to help resolve any conflicts between law and ethics, and guide an appropriate course of action." (TCPS, 12) In a statement of the ethical framework for research practice and a policy statement providing an account ethical conduct for research involving humans, we think the Policy Statement should specify that applied ethics reasoning is required and seeking the advice of an applied ethics expert is as important as 'independent legal advice to resolve conflicts between law and ethics. Moreover, the expression 'an appropriate course of action' is too vague if the expertise recommended is 'independent legal advice'. Legal experts can be expected to recommend complying with legal requirements. However, from a moral standpoint, the only reasoning that can possibly determine the 'appropriate course of action' is applied ethics/practical reasoning. This reasoning should not ignore legal requirements, but, it cannot rank these requirements above fundamental moral principles that assess the legal requirements as morally acceptable or unacceptable.

It is necessary to be explicit about this point, because TCPS's tendency to collapse the distinction between moral and legal requirements is embedded in N-societies. Because there is a tendency in N-societies to perceive the legal framework as morally justified, (i.e. we are living in a morally just society) there is a corresponding tendency to identify moral requirements and legal requirements. As a result, there is a N-tendency, evidenced in TCPS, to give legal obligations and moral obligations equal standing. This does not pose a problem when a legal requirement mirrors a moral requirement. However, if legal requirements are inconsistent with fundamental or secondary moral values and principles, as our empirical evidence indicates they can be, then TCPS's claiming, for example, "...researchers are responsible for ascertaining and complying with all applicable legal and regularity requirements with

respect to consent and the protection of privacy of participants (see Chapter 5).” (TCPS, 12) is morally problematic. It does not encourage applied ethics N-S dialogue to resolve ethical conflicts in this area but rather encourages compliance with legal rules. When the N-S legal rules conflict not only with moral principles, but, with each other, N-S research teams find themselves in a catch-22 situation. Moreover, TCPS does not point these teams in the only directions that can enable them to make their way out of it, that is, (i) their engagement in S-N moral theory and/or applied ethics dialogue or (ii) their consultation with N-S experts who engage these dialogues on their behalf.

An example will illustrate the blurring of the distinction between moral and legal and moral rules that can take place in N-S research collaborations. In many countries the same rule ‘Do not steal’ is a moral rule, a legal rule, an institutional requirement, and a cultural norm. In such circumstances, since all other non-morally anchored rule sources support rather than conflict with the moral requirement, the normative network itself is neither a source of confusion nor moral conflicts. However, source complexity can result in conflicts and confusion about the type of conflict so that conflicts that are essentially moral conflicts are labeled as institutional or cultural conflicts and vice versa, conflicts that are really legal, institutional or cultural are mislabeled as moral conflicts.

To illustrate this mislabeling and resulting confusion, consider how in N-countries, for centuries during which moral reasoning was evolving towards the establishing of the equal moral value of men and women, legal rules permitted and cultural norms condoned the morally unjust treatment of women. Actions that were just legally in N-countries were morally unjust. Hence, mislabeling of actions and confusion in decision-making would result unless ‘just’ was qualified by either ‘legal’ or ‘moral’. This mislabeling and confusion was reinforced by procedures and processes of N-societies’ social, economic, and political institutional structures which, for the most part were consistent with legal rules and cultural norms and inconsistent with what is morally just.

Consequently, it is not surprising that it was easy for many persons in N-countries who identified legal or cultural norms with moral requirements and believed legal rules were morally justified to falsely believe that their position was supported by moral reasoning. Seeing the complexity of this normative network and how most of its components lent powerful support for the perpetuation of women’s inequality can help one to understand why it took such a long time to reconcile the many kinds of requirements in the network with the reality that metaphysical accounts of human nature and fundamental moral values and principles justify acknowledging and protecting women’s equality.

It is noted that cultural and institutional value revisions happen very slowly. It is easy for those with the power to change legal rights so that they mirror moral rights to resist such change when those who protest injustice are struggling against the slow pace of cultural and institutional change. The above example also reveals how moral principles and values and the moral reasoning based on

these can be a catalyst for change when an entrenched normative network creates systemic injustice that is resistant to change.

According to the literature discussing ethical challenges/issues in N-S global population health research, the ethical issues collaborative teams face may be explained by differences in moral values in N-S countries. If fundamental moral principles and values differ, or they are the same but ranked differently, or they are the same but are interpreted and therefore operationalized differently, then in any of these circumstances moral conflicts are highly likely to occur. The probability that there will be conflicts increases with the number of ways in which there are differences in N-S understanding of the basis for determining moral responsibility.

In N-S research collaborations, women's inequality sometimes is an ethical challenge for N-researchers. While all parts of the N's normative network (i.e., legal, institutional, and cultural rules) now support the moral rule that woman must have access to the benefits research provides and they must consent to be involved in any research study, analogous conditions are not established in all S-countries where N-S collaborative research takes place. Thus, for example, if a legal rule in a S-country's normative network prohibits women from consenting to participate in a study, since the legal system gives the legal right to consent for women to fathers or husbands, and, if this legal rule and attendant legal rights are supported by cultural norms and traditional practices, then this N-S difference in the normative network will be a source of significant ethical challenges for N-S research teams. It will also create ethical challenges for N-institutions supporting N-S research either as funders or by providing ethics review. Women's inequality has deep roots and where it is systemic the beliefs, attitudes, and practices that created it ensure its ongoing existence. Hence, although it will not be easy to implement, it is morally necessary for N-S researchers and everyone else in their network of relationships to participate in the N-S philosophical dialogue (at the level of moral theory and applied/practical ethics) that is necessary to resolve the N-S standoff on this issue. N- participants in N-S research collaboration cannot claim the right to impose their metaphysical and axiological on S- participants. Only by engaging in the S-N dialogue we recommend can those who play a role in N-S research determine whether either or both sets of legal rules and cultural norms are consistent with fundamental moral principles. This dialogue is the only means to ensure that N-S research teams have the capacity to make decisions about morally appropriate research practice.

In the literature, both N & S scholars situate N-S disagreement about women's equality and rights in a justice context, namely, the oppression of women or the violation of their human rights. Therefore, from the N-perspective, in the morally unacceptable hierarchy, this particular ethical challenge is at the top. From a S-perspective, justice principles deem unjust the North imposing its values and understanding of the content of human rights on S-countries as a condition for S-country acquiring the benefits that come with N-S research collaborations. So, this ethical challenge is also at the top of their morally unacceptable hierarchy. What this N-S standoff on this question points to is a difference in the understanding of moral principles and values that, on the face

of it, seems to be inconsistent with N-S researcher and EB member agreements regarding the fundamental moral principles and values. From a N-perspective, all these values and their principles support equal respect for the autonomy of all human beings and equal treatment. From a S-perspective, there may be no disagreement with the notions or valuing of autonomy, equal respect, and equal treatment. However, there might be disagreement about how to understand what being autonomous means. So, for example self-determination cannot be dissociated from group (i.e. family or community) self-determination. Further, 'equal respect' might not be interpreted as identical treatment and 'equal treatment' might not mean the same treatment or the same set of legal rights. It is only in an ongoing N-S philosophical dialogue that the differences in the perspectives of the two domains—N and S—become clear and possible resolutions of the standoff reveal themselves.

Current training and the tradition of research practice incline most researchers to identify ethical research solely with the requirements of EBs. For N-S researchers it is particularly important to neutralize the potential for confusing EB requirements with moral requirements, especially since, typically, ethics review is the only one component of research decision-making and implementation that is associated with ethics.

While all EBs probably have requirements that are genuine moral requirements, they also have other types of requirements. For example, as indicated above, N and S EB guidelines typically require researchers to comply with legal requirements pertaining to research in the EB's country. Putting legal rules at the beginning of the list of possible confusions is intended to highlight the priority that legal requirements are accorded in ethics guidelines and in research practice. According to Canada's Tri-Council guidelines, researcher practice must conform to Canada's laws covering participant protection and intellectual property.¹¹ As explained above, like the other types of norms/rules, legal rules may or may not be consistent with moral rules. Incorporating legal rules into EB guidelines does not guarantee that they are moral since they may not be consistent with fundamental moral principles and values. The possibility of unjust laws is particularly important when S and N EBs have inconsistent legal requirements and researchers are trying to determine what they should do in order to ensure that their research practice is morally acceptable. Strict adherence to the legal rules of a S-country will result in research practice that cannot be approved by N-EB (since it is not legally permitted in N-country). However, from a moral point of view, it is more important to know whether that the practice legally required in S-country is consistent with moral requirements than whether it is consistent a N-country's legal requirement. The legal disagreement is morally irrelevant if the proposed research practice in a S-country is morally acceptable.

Legal requirements are not the only EB requirements that may be inconsistent with moral requirements. For example: The legal systems of two N-S countries involved in a research project agree that participants must consent to being part of the proposed research study. The general legal requirement that

¹¹ See for example Tri-Council p.23

potential participants consent to being part of a study is consistent with all of the fundamental moral principles in the biomedical paradigm and is upheld by S and N EBs, nevertheless, there are particular processes and requirements EBs put in place for collecting consent, which may materially differ among N-EBs. It is differences in these means of collecting consent that are frequently sources of ethical conflicts in N-S research teams. As an example, a S-country's social and collective understanding of consenting practice might reject a N-country's individual and solitary consent practices. From both perspectives, their understanding of consent practices is their internal best interpretation of the dominant bioethics paradigm's fundamental principles and values. Only in N-S applied philosophical dialogue can researchers and others in their network of relationships determine if the two different contexts for collecting consent make two different practices morally acceptable. Until the dialogue is engaged the perception that the ethical disagreement is an unresolvable moral conflict will continue

4.2.2 Individual/Collective

N-S research collaborations are instances of group rather than individual activities. A team designs and implements the project which means that for much of the decision-making and for many actions pertaining to the research project responsibility is collective, not individual. Unfortunately, the notion of collective self-determination and responsibility fits uncomfortably into N-moral theory generally and the bioethics research paradigm more particularly.

The starting point for all established moral theories in the Western (Northern) philosophical tradition are individual autonomy, self-determination, and responsibility. The bioethics paradigm is focused on individual researchers and their responsibilities to other individuals, namely, participants. Consequently, there is virtually no place at the theoretical level or in the paradigm's application of moral theories where research team or participant community decision-making, actions or responsibility can gain a foothold. This means N-S researchers do not have available to them an account of collective moral responsibility or guidelines pertaining to collective research practice or population health research.

Indeed, if they were to look for discussions of collective responsibility they would likely find that in the literature this notion is used to refer to the view that although they did not actively or intentionally collaborate, individuals are ultimately to be held responsible for other people's actions because they tolerated or ignored their actions. The collective is being held responsible for acts of omission. So, for example, German citizens are collectively guilty for Nazi Germany's atrocities under Hitler's leadership or Canadian citizens are collectively guilty of the federal government's oppression of Indigenous peoples. Philosophers have contested this use of the notion of collective responsibility since responsibility is being ascribed to a collective in which individuals acted (i.e. decided not to act) individually not collectively. In other words, there was no collective activity. In N-S research, the research teams and participants communities want to actually engage in collective decision-making. And, in these cases, there is no doubt that it is appropriate to understand responsibility as being collective rather than individual. When a

collective acts, it is morally wrong to hold a single individual solely/wholly responsible for the action.

However, in N, the default position for dealing with collective responsibility in N-S research is reducing collective responsibility to individual responsibility, for example, funding agencies require an individual, or in the case of N-S collaborations, two or more individuals (PIs) be responsible for the research project. TCPS, hence Canadian-EBs, also makes PI's individually responsible for all research activities undertaken by the research team. This approach of *assigning* responsibility ignores responsibility in the real world of decision-making and actions. In the real world, team members are decision-making and acting together or as individuals on the basis of their collective decision. Funders' and EBs' requirements impose/construct an individual responsibility that, by implication, denies the reality of collective responsibility. However, moral reasoning cannot ignore the fact of collective decision-making and action in accounts of moral responsibility. Moral responsibility is a moral fact; it cannot be created by fiat. In the case of Tri-Council's assertion, what appears to be an assertion about moral responsibility might actually be a statement about Canada's legal requirements. Nonetheless, from the moral standpoint of the policy statement's fundamental values, most especially justice, *to stipulate* that a single individual is responsible for the collective activity of a group is false and arbitrary. The stipulation ignores the multi-faceted collaborative nature of N-S research and in effect denies that the collective decision-making and activity were collective.

Since some funder and N policy requirements seem oblivious to how they engage research practice, N and S researchers belonging to N-S research collaborations could understandably be frustrated and/or confused by these requirements. They may even justifiably experience a sense of injustice as well as powerlessness. When research teams are comprised solely of N-researchers, the morally problematic nature of reducing collective responsibility to individual responsibility may not appear as self-evident as it does in N-S research collaborations. Reducing collective to individual responsibility is the common and accepted practice in N-societies; hence it is expected rather than questioned in N-countries' economic, political, and social institutions. Institutions act collectively, but, typically it is an individual who is held responsible and receives the praise when things work well and the blame when something goes wrong.

There is support in the literature for thinking Indigenous peoples have more fully worked out and reconciled the notions of collective responsibility and individual responsibility to the collective. Chapter 9 of the TCPS acknowledges that "Aboriginal entities" have developed research ethics documents "that emphasize collective rights, interests and responsibilities." (TCPS, 106) It recognizes that a community with shared identity and interests can have "the capacity to act or express itself as a collective." However, it represents Aboriginal peoples in Canada and Indigenous peoples in other countries as endorsing "collective decision making as a complement to individual consent" (TCPS, 110) implying that individual consent is prior and more important morally. This implication is one of many claims and

assumptions in Chapter 9 that could usefully be the subject of N-S philosophical dialogue that would be beneficial to developing greater understanding of the similarities and differences in S-N moral thinking

In some N-S collaborations, S-communities valued and requested a collective approach to consent that would be in keeping with the notion of collective interests, decision-making and responsibility TCPS associates with Canada's Aboriginal peoples and Indigenous peoples in other countries. This valuing and the request would strongly conflict with N-researchers' valuing of individual autonomy and assumptions about individual responsibility. It is likely that S-N collaborative philosophical dialogue about individual and collective responsibility could produce results that would contribute to N-S team building and more ethical interaction with potential and actual research participant communities and participants. Furthermore, such a dialogue could contribute to N-capacity building since it would provide the opportunity for N-participants to fill gaps in Western philosophy's account of responsibility and thereby address moral problems created by the gaps. Ultimately these dialogues should also assist Tri-Council in fulfilling its commitment to "the continued evolution of this Policy" (TCPS, 105).

4.2.3 Exploration of Selected Relationships in the NER Model

The Network of Relationships (NER) model provided a useful framework in which to explore particular relationships. As previously mentioned, this study was unable to do full justice to the relationship with participants, and many other relationships that were identified to be important (e.g., governments, grant controlling organizations, field and research staff) were not explored in detail. The following sections explore the Researcher-EB, inter-team, and Researcher-Funder relationships which were of particular interest in this study.

The complexity of the NER in the context of global N-S population health research is demonstrated by the number of actors represented by the NER model when applied to the case of the CEHP. In **Figure 4**, below, the contextual complexity within which the CEHP case study is embedded is illustrated.



Figure 4 An overview of the complex Network of Relationships being navigated in the Caribbean Ecohealth Programme (CEHP)

4.2.3.1 Researcher/Ethics Board Relationship

This research study attempted to collect data about N-S researchers' relationships with several of the components of the network of relationships, namely, team members, Funders, EBs, team employees, and participants. SAMKET team members with experience in global health research concurred with the literature that located some of these conflicts in N-S research teams' relationships with EBs. Since a comparison between N & S EB guidelines and practices would facilitate a comparison of N-S moral principles and values, it made sense to focus our efforts in exploring the researcher-EB relationship. A comparison of N-S EBs would also permit us to gather empirical data that would address the LOI's primary concern, that is, that TCPS employs a paradigm based upon clinical research. Because of this, TCPS's discussion of ethical conduct for research involving humans does not explicitly address questions pertaining to population health research. Hence, it provides little guidance about infringing on autonomy in order to protect the welfare of the community not does it address ethical issues that may be unique to this type of research. Thus, the questionnaires and in-depth interviews used in this research study were designed for and completed only by researchers and EB members. For the most part, questionnaires and in-depth interviews were focused on eliciting the perceptions of N-S researchers and EB members regarding the nature of the researcher-EB relationship. The goal was to gather empirical data that would reveal from both ends of the relationship the level of satisfaction with the relationship and the conflicts that arose in it. Also, the questionnaires were designed to elicit researcher and EB member opinions about the sources and possible resolution of conflicts that had arisen.

It became clear, however, that even in focusing on this single relationship in the network that the relationship could not be understood without bringing into the discussion other relationships, such as the relationship between the researchers and study participants, S-communities and institutional relationships, and the funder to name a few. In N-S collaborations, researchers' good relationships with persons in one circle in the network (for example, with EB members) presuppose that researchers are in good relationships with those in other circles in the network.

4.2.3.2 Inter-Team Relationships

As this study evolved, it became clear that Teasdale-Corti teams do not share an understanding of research team in the sense that there are clear boundaries dictating who is in and who is out of the team. In most teams, a core group of N-S researchers exercised shared managerial responsibilities for the research project. In TC groups, S-researchers who were 'on the ground' where the studies were implemented had more interaction with other circles in the network of relationships than N-researchers. S-members of the managerial team, because of their familiarity with local culture as well as their location, interacted as necessary with S-institutions and N & S researchers, S-technicians and S & N students who directly encountered and form relationships with the circle of communities and potential and actual participants.

In some sense, everyone who contributed to implementing each of the components of these large research projects could be understood as being in the circle of N-S researchers at the center of our network of relationship diagram. Everyone had a role to play in successfully implementing the project. However, as the NER diagram indicates, in practice, those who created and managed the projects, that is, a small group of N-S researchers (variously referred to as the managerial group or executive committee) occupied the center circle. Collectively or in part (typically the S part), this group was in relationships with most of the other circles in the network. Even S-researchers in the center circle may not have established relationships with the community circle and potential and actual participants in the study. Generally, because of N's narrow understanding of the notion of researcher, it is unlikely that N-researchers in the center circle, would view either the community or participants as team members. However, some S-researchers and both N and S researchers on teams doing participatory research would have included the community and participants in their understanding of team members.

A holistic approach to defining the team fits with a community perspective on research practice. From this perspective everyone in the network of relationships has a role to play in the research and is part of the project's research community. When the community perspective is taken, the notion of collective responsibility is at least as important to creating good relationships in the network as the notion of individual responsibility. Individuals have a sense of responsibility to a whole (a community) that in turn is responsible for individuals; and, everyone with a role in the research has a sense of being recognized as part of the whole rather than giving a small contribution to a small piece of a much larger project.

Teams doing participatory research involved the community in all aspects of the research project, including project design, implementation and knowledge dissemination. For these teams, efforts to build relationships with the community were as morally significant as efforts to build relationships with the N-S researchers 'managing' the project.

The empirical data gathered in this research study indicates that N-S collaborations tend to run smoothly when the persons in the center circle are equally committed to the project; have known each other for a number of years *or* have 'worked' at getting to know one another; have mutual respect for each other's scholarship and potential contribution to the project; and, at the outset, establish procedures for working together and resolving conflicts. Members of these teams are 'ethics conscious' and possess virtues that support good personal relationships. If members of the center circle are disrespectful of others, or their decisions and actions are self-serving rather than for the good of all team members and the project, their morally problematic actions create a disharmony that can threaten team viability and the whole research project. Hence, although virtue theory was not featured in this study's data collection, it would be valuable to collect data about the extent to which virtues (and vices) contribute to a team's successes (and failures). Although the bioethics research paradigm is about principles and rules that command action or inaction, it is silent about the virtues and vices that dispose one to act rightly or wrongly.

Nonetheless, we can count on virtuous researchers to generally do the right thing and they can serve as experts who can often provide insights into how to resolve ethical issues that inevitably arise in research. N-S philosophical dialogue about N-S understanding of virtues and vices, that is, good and bad persons, could provide useful information about the expectations of ‘the other’ to N-S team members. It would be a useful exercise if it only served to clear up stereotypical thinking on the part of both N and S researchers.

Inter-team relationships varied according to the roles and responsibilities of the members and the phases of the project. In general the PIs maintained solid lines of communication among themselves, which allowed them to share information, plan activities, address common concerns, and to monitor the implementation of the project. PIs represented the project’s management team, which also included the project’s manager. Some of the PIs meetings also included the funders and representatives from other collaborating agencies that also had a stake in the project.

Generally, the researchers, technicians, data collectors, students and participants did not participate in the management team meetings, unless it was deemed necessary. The PIs came in contact with these team members to discuss specific aspects of the project implementation, mostly on a need to basis. The relationships among TC PIs were cordial and respectful. While N-S PIs shared a common cultural and/or disciplinary background they learned to work with each other and to appreciate everyone’s contributions.

The researchers, technicians, and data collectors established closer relationships with each other, regarding one another as peers, who had similar duties and responsibilities and in some cases shared the same working space. These individuals worked with individuals who mostly shared their own culture and professional training. Core team members were usually the only ones invited to participate in the larger meetings or international conferences.

Participants only came in contact with the core research team during data collection and, in some instances when results were reported back to communities. Data collectors shared the cultural background of the participants, which facilitated the data collection process and prevented conflicts from emerging.

Most team members functioned within specific clusters where they implemented specific aspects of the project. The clusters were effective in making their contributions to the larger project. While this type of arrangement worked in terms of meeting the goals of the TC project, some of the team members who were not part of the management team stated that they would have liked to receive more information about the overall project and to be linked to other members of their teams.

4.2.3.3 Researcher/Funders Relationship

SAMKET’s time and financial resources meant that we had to limit our data collection. Our initial proposal focused on the Researcher-EB relationship, but as we began to collect data, it became clear that some morally significant

ethical issues were located in the relationship between the researchers' and funders' circles. This issue arose because of funder requirements and the consequences of delayed release of funding. Researchers expressed the same delayed research concerns when they discussed the length of time it took to get their research proposals reviewed by ethics boards. However, in the case of their relationship with funders, they reported that funding delays created justice problems since there was no money to pay S-employees. This example demonstrates the need for relationship building between researchers and funder representatives that deals with researcher-fears of funder disapproval and funder-fears about researcher reliability.

4.2.4 Changes in Network Relationships over Space and Time

When viewed through the complexity lens, there are several variations on the NER diagram that lead to additional observations about these networks:

- i) Key relationships change over time, with certain relationships having more influence over decision-making (and behavior) at different times (**Figure 5**);
- ii) Different actors in the system have different NERs that they are accountable to/responsible for (**Figure 6**);
- iii) These relationships are dynamic and adaptive.

Systems theory supports the idea that networks are important for understanding the organization of living systems (Barabási, 2002). The temporal evolving nature of global N-S research is well-illustrated by Allen (2010) in her 'bicycle diagram.' This diagram, which so vividly conveys how research moves 'through time' and involves ethical decision-making with every movement, also highlights the (relatively) short duration of researchers' engagement with each component of the network, for example, research ethics boards (EBs), in their on-going navigation of ethical decision-making requirements.

In addition to time, the spatial dimension of global N-S research is also important. By definition, researchers in N-S collaborations reside in very different places and increasingly rely on electronic modes of communication to create projects and to do the work of research together. Short field visits are the norm, and the proximal and distal relationships between parties are quite different, and evolve differently, between the researchers on the research team. Moreover, the spatial dimension impacts how extensively core researchers and persons in other components of the research network are able to interact and feel they are able to participate fully in the research program. Bringing everyone into the same room requires great financial resources that are typically unavailable to N-S collaborations. Funders may permit allocation of funds to creating N-S partnerships; but once the project is underway, funding is for implementing the research rather than ongoing team maintenance and/or development.

Empirical data gathered from the CEHP case study, the Researchers' semi-structured interviews, and to a lesser degree, the EB's semi-structured interviews gave evidence both of the scalar nature and the variable duration of the moral relationships established for the purpose of implementing the CEHP

and other programs within the GHRI. Following are some of the patterns of those relationships and the benefits and limitations within them.

For the purpose of this discussion we will start the flow of relationship building from the time the funder posts a request for proposals that clearly delineates an emphasis on collaboration and the integration of research partners at various levels and in different geographical areas. While the types of relationships required in order to successfully respond to a request for proposals might not be explicitly defined by the funder, interested researchers are implicitly prompted to identify potential partners with whom they have or think they can have a working relationship and to shape the structures within which those relationships would operate.

Since the Global Health Research Initiative (GHRI) called for the creation of N-S collaborations aimed at improving global health and increasing the research capacity of less developed countries, N researchers (and in some cases, S researchers) reached out to S (N) universities, and professional and government institutions in order to identify collaborators. This team building process followed a snowball approach in that interested researchers began by identifying peers who could be potential partners and who in turn identified others who could be part of the collaborative effort. In this manner potential team members were identified and team structures were defined based on the expertise and leadership needed to conduct the research, and by the experience and networks of researchers and happenstance.

In general the structure of a TC community consisted of principal investigators, program managers and coordinators, different types of researchers (i.e., laboratory based, community based, etc.), data collectors, technical support staff, trainers, and students. Some TC teams implemented participatory research in which participants were included. Except for the participants, there was representation of N and S members within each team category. The role played by team members determined the strength of their links with other team members, the funders, and other external bodies such as the ethics boards.

Approval of the research proposal marked the beginning of an ongoing relationship between the project's PIs and the funder's Program Manager. The intensity of this relationship fluctuated based on the stages of the research and any emerging needs. As the research initiatives were being launched, the Program Manager and the PIs work together to insure compliance with and a good understanding of the funder's contracting guidelines. The Program Manager also insured that all grantees comply with EB's research requirements, and any other requirements imposed by the researcher's country (legal rules), as well as by universities and the funder (institutional rules). The Program Manager then stepped back to allow the research process to unfold and was ready to respond to any funding or programmatic issues that might arise with any of the grantees. The relationship between the funder and the PIs usually intensified when grantees were expected to submit progress reports in order for funds to be released, when arranging grantee meetings, and when final reports were due.

The approval of the research proposal also marked the beginning of an exchange between the projects' PIs and the EBs responsible for the approval of research activities. These relationships were typically intense during the approval process, which can be lengthy and then become almost non-existent until the time when yearly reports and/or final reports are submitted, unless changes are made to the approved project that require EB approval. As previously stated, the PIs were usually the ones who initiate these relationships and were responsible for supplying all documentation to EBs and served as indirect links between the EBs when the approval of more than one EB was required.

In some S countries EB boards were non-existent or were located within health ministries or government agencies. In these cases, PIs had to establish a relationship with representatives from these institutions to seek proper approval of the research effort. In some cases, this involved helping the country to create and set up an EB to review the proposal – a process that could take as long as a year.

Figure 5 A Hypothetical Example of the change in the Network of Ethical Relationships over time.

A. The grant writing/initial collaboration and negotiation stage

B. During the REB approval stage and preparation stage, often includes multiple REBs (may take 6 months to a year)

C. During the Field Stage, assuming all is going smoothly.

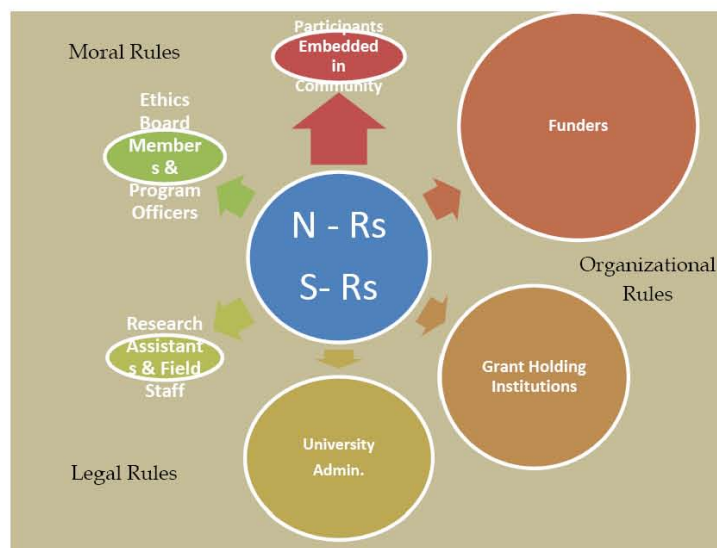
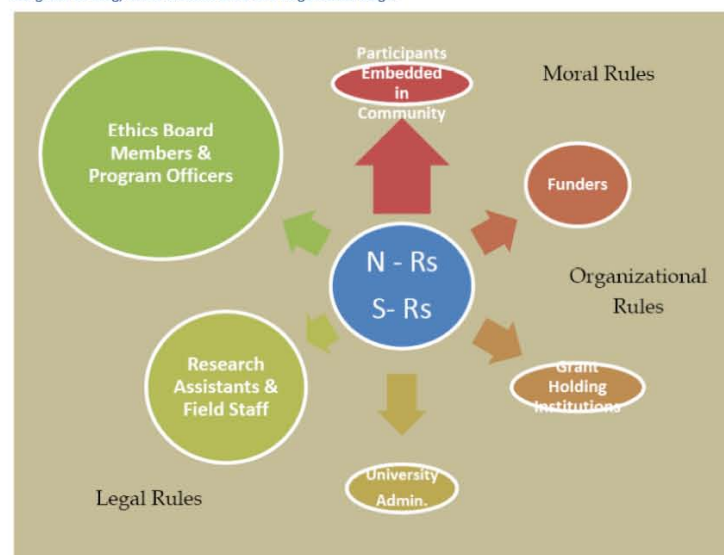
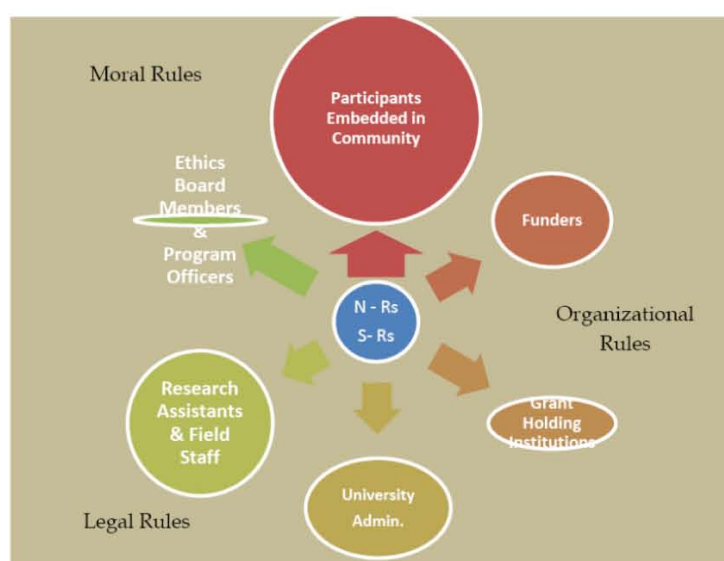


Figure 2. A Hypothetical Example of the Change in the Network of Ethical Relationships Over Time. The grant writing/initial collaboration and negotiation stage.



During the REB approval stage and preparation stage, often includes multiple REBs ... may take 6 months to a year.



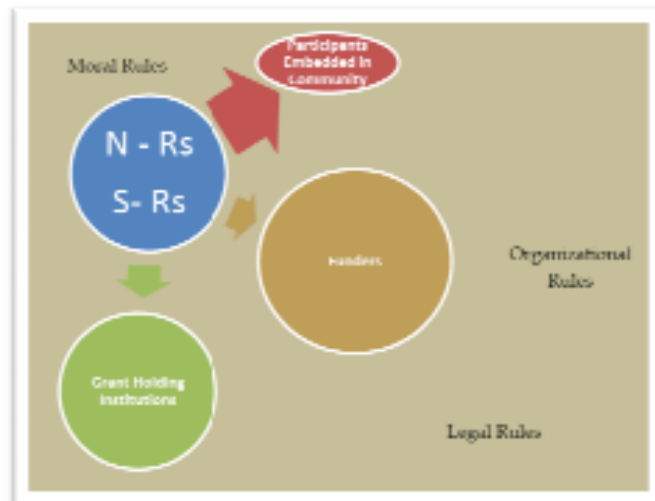
During the Field Stage ... Assuming all is going smoothly.

Figure 6 Changing the Focal Point of the Network of Ethical Relationship Diagram

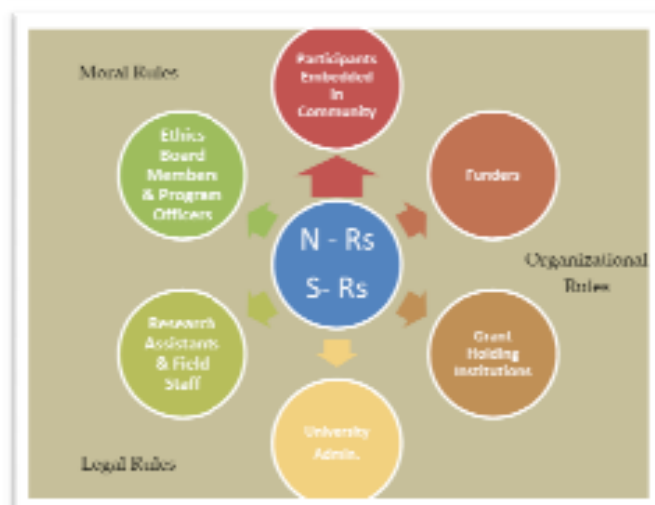
Top: Funder-Centered: The funder has a primary relationship with the Principle Investigators (PI), and an indirect one with the Grant Holding Institutions and the Communities

Middle: The PIs are at the centre of a myriad of relationships, including those among the PIs themselves

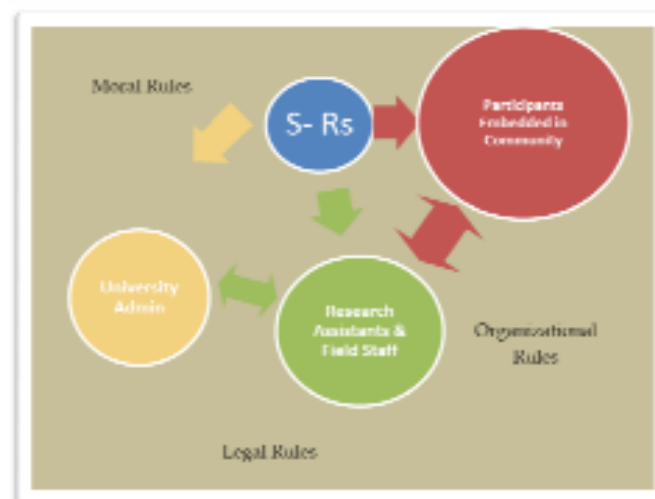
Bottom: The Southern researchers may have the most direct contact with communities, as well as research assistants and field staff.



a. Funders Network of Ethical Relationships for the Individual Program



b. Researchers' Network of Ethical Relationships



c. Research Assistants and Field Staff's Network of Ethical Relationships

4.3 Additional Themes

4.3.1 Cultural Differences

The need to recognize the socio-cultural, economic, and political aspects that shape the life experiences of researchers and research participants is embedded in the reality of N-S- research practice. This is a complex and open-ended task considering that the socio-cultural aspects of any society are interwoven with the political ideologies and established hierarchies and that rigid bureaucracies determine the systematic distribution of power.

Researchers involved with the GHRI dealt with cultural differences within their own socio-cultural environment as well as between the various cultural settings in which they established research collaborations. The scope of these differences was manifested in the institutional culture of the various academic, government, and non-government organizations associated with their projects; the diverse traditions, languages, beliefs and values that are part of the world view of all cultural groups; and the interplay of these elements with the geo-political pressures that have become a constant shaping force throughout the world.

4.3.2 Review of the Bioethics paradigm appropriateness in the N-S Context

During the construction of this study's research proposal, it became clear that for many reasons the bioethics paradigm was not likely an appropriate model for N-S research. The following facts in particular led to the initial hypothesis that this dominant paradigm was inadequate:

- This model is a N- construct that is not informed by S-philosophy;
- The bioethics model focuses on protecting study participants versus communities or population, that is, it is individualistic in its understanding of research;
- The bioethics model is narrow in its understanding of research practice.

Although it was not anticipated that it would be necessary to discard the bioethics model, we did speculate that it would require radical transformation, revisions significant enough to be regarded as a paradigm shift.

4.3.3 Expanding the 'box' of Ethical Principles

One of the findings from the synthesis of empirical data and philosophical analysis done in this research study is that the bioethics paradigm needs revision at the level of its fundamental values and moral principles and in its metaphysical underpinnings, that is, its assumptions about the nature of human beings and their interaction.

The 'ethics box' for N-S research collaborations will likely require several additions, however, the most significant addition is a new justice notion, namely, social/global justice. Social/global justice cannot merely be placed side-by-side with the justice account currently contained in N-policy statements. It is not simply a matter of adding a new principle. This addition has implications for understanding and implementing the current occupants of

the biomedical ethics box. So, for example, adding a social/global justice component has implications for how the justice notions in the ethics box are to be understood and the kinds of actions that are currently thought of as being appropriate implementations of the justice requirements.

The addition of a social/global justice notion to the ‘ethics box’ will also require a rethinking of the relationship between human and collective rights and deliberation about the moral weight of social/global justice relative to N-self-interest. Hence, the addition of the notion of social/global justice requires philosophical inquiry at the level of moral theory to provide a coherent theoretical basis for the research ethics policies. Since this deliberation will significantly impact the moral theory component of N-policy statements, it is reasonable to predict that it will lead to significant changes in research ethics policies and requirements. We are confident that these changes have the potential to benefit N-S research collaborations since they will have a theoretical basis that includes the justice notion that provides the moral foundation for this type of research.

4.3.3.1 Fundamental Moral Principles

It is being recommended that significant changes be made to the contents of the bioethics paradigm’s ethics box. However, it is important to note that the empirical data collected in this research study supports a cautioning note that the baby should not be thrown out with the bathwater. This study’s findings support both transformative revisions **as well as** not discarding any of the fundamental moral values or principles in the N-paradigm’s ethics box. The point is that N-ethical deliberation regarding research ethics at the moral theory and applied ethics levels has evolved and progress has been made since ethics review of research became a legal requirement in N-countries. However, the epistemic value of N-S collaborative knowledge gathering in the areas of both moral theory and applied ethics must be recognized. Furthermore, if this research activity is to happen, N-S ethics collaborations must be initiated and be given financial support so that this research activity becomes as integral to the development of research programs as knowledge gathering is in the natural and social sciences.

Philosophical inquiry in the form of N-S critical dialogue in the context of seeking to understand ethical conflicts in N-S research collaborations can contribute significantly to knowledge gathering about moral theory and its application to research practice. This research activity promises not only to contribute to revising the bioethics paradigm’s ethics box but also to contribute to understanding the moral foundations of N-S research. By providing a N-S account of the moral foundations of N-S research, it will provide tools for assisting N and S governments, N-S research ethics policy makers and implementers, S and N-funders, and N-S researchers to more self-consciously understand, support, and engage in ethical research practice in N-S research collaborations.

4.3.3.2 Rights and Responsibilities

One of the aspects of moral theory that will require a great deal of N-S deliberation is the new understanding of moral obligations/responsibilities of

individuals, institutions, and nations that the notion of social/global justice introduces into moral decision-making. This deliberation will have to examine the relationship between human rights and collective rights and attempt to reconcile the conflicting obligations that can be present when both types of rights are recognized. As indicated above, the dominant bioethics paradigm is primarily committed to a negative understanding of human rights, meaning that one is prohibited from acting in a way that would violate human rights. However, with the inclusion of the notion of social/political justice, there will be support in the ethics box for an understanding of positive human rights, meaning that governments have an obligation to put in place the conditions which make it possible for human beings to exercise their human rights.

The understanding of justice underlying N-S research collaborations, that have S capacity-building as their ultimate goal, is more consistent with a positive understanding of human rights than a negative one. Justice is understood to protest a global distribution of benefits and burdens such that N-countries' capacity exceeds human well-being requirements whereas S-countries' have a deficit in human-well being requirements. Hence, justice does not only require that we do not interfere with, i.e. violate, the rights of others (old paradigm), rather justice requires that those who are capacity-rich share their riches to put in place the necessary conditions for human well-being globally, not only in resource-rich countries. When justice provides the basis for these obligations of N-countries, the giving to support S-capacity is not an option and it is not charity. It is a duty that is as morally binding as the duties to respect autonomy and not to harm.

4.3.3.3 Power

N-S research collaborations acknowledge from the outset there is an imbalance of power in N-S relationships and that the research being undertaken should contribute to correcting this imbalance. This research study did not focus on this underlying power imbalance and the obstacles it creates for ethical research in N-S collaborations and just treatment of any S-person having a role in the research project. The just treatment of S-persons problem exists for S-PIs, S-institutions (including universities and government agencies), S-EBs, S-community leaders, and S-participants. In the data gathering done for this study, some of the ethical conflicts were thought to arise because of the N's power. And it seems that the N is always in the position of power in N-S collaborations, unless a N-person who holds the power consciously and deliberately decides not to exercise it but engage in decision-making that neutralizes the power imbalance.

A N-S research team in implementing their project encounters numerous power imbalances that are embedded into the complex network of relationships. However, although we did not construct our data gathering instruments to enable analysis of the extent to which power differentials are a source of ethical conflicts, the relevance of power differences is manifested in our data. Researchers expressed awareness of the power of: EBs to disapprove research protocols and thereby prevent the implementation of studies; Funders to cut off funding and make it unavailable in the future; and S and N institutions administering grants to control the release of funds as they saw fit. Hence, in their relationships with persons in these circles in the network, their decisions could sometimes be based in a sense of powerlessness and even fear.

It would seem that the only way to avoid these undesirable motivations for decision-making would be N-S philosophical dialogue between the researcher circle and those in the power-holding circles. These dialogues would allow researchers to express their legitimate concerns and give those in the other circles in the network (whose primary aim is to facilitate researcher activities) an opportunity to dispel researcher concerns.

Researchers also expressed awareness of being on the other side of the power relationship: N-PIs with greater academic status or experience than S-PIs who 'bowed' to their opinion; PIs offering opportunities and benefits to vulnerable participants and their communities. In order to avoid S-PI or participant deference and promote S-PI and participant self-determination, it is necessary that there is an ongoing N-S dialogue between PIs that ensures S opinions are 'on the table'. And, PIs need to engage participants and their communities in an ongoing conversation that builds a relationship of understanding and mutual trust.

4.3.4 Recognition

Canadian philosopher Charles Taylor has formulated a critique of liberal theory and its inherent individualism that is relevant to an analysis of N-S ethical research practice. According to Taylor, liberalism fails to acknowledge the role that social recognition plays in self-identity. The self is not as autonomous and self-determining as liberal theory or the account of autonomy and dignity in N-research policy statements would suggest. Acknowledging societal constraints on decision-making is perhaps more relevant in the context of N-S collaborations than when a N-researcher conducts research in a N-country or a S-researcher conducts research in a S-country. However, since there are minority cultures in most N and S countries, Taylor's discussion has relevance for these contexts as well.

For our purposes, the important insight in Taylor's account of recognition is that recognition of persons belonging to another culture must originate in actual respect for the other culture. This respect has epistemological, moral, and political implications that are relevant to our analysis. Epistemologically this means that respecting another culture requires N and S researchers be open to the possibility that the beliefs of the other culture are true, even when there is inconsistency between N-S beliefs. Hence, it requires epistemological humility, an attitude that their academic traditions do not encourage N-

researchers to display. From the standpoint of moral theory and ethical research practice, the respect that is the basis for recognition requires that N and S researchers seek to inform what is essentially an N-created biomedical paradigm with S-moral theory and understanding of ethical research practice.

4.3.5 Moral Assessment: Inequality of Moral Rights and Moral Wrongs

It became clear once the empirical data collected in this study was analyzed that not all of the examples of ethical issues were of equal moral importance. Since we ordinarily operate with the assumption that some right actions are better than others and some wrong actions are worse than others, this inequality supports rather than conflicts with S and N moral intuitions. However, there is very little guidance in N and S policy statements or in N-S EB procedures and requirements about making morally better or worse judgments. So, for example, since there is no indication to the contrary, the policy statements imply that the fundamental values are equally important in all situations and the group of values we call the secondary or derived values are also equal in their moral significance. Keeping with this implicit commitment to equality in the two groups of moral values, in examples illustrating the application of fundamental and secondary values, there is also no indication, for example, that respecting participant autonomy may sometimes have more moral weight than protecting the participant from harm, or that sometimes being a study-participant is morally more important than giving individual consent.

Using the above examples to illustrate that moral assessments should not be regarded as inflexible and independent of context, and the indication that the moral hierarchy of rights and wrongs should not be taken to imply that moral deliberation can deliver a set of universal rules and regulations to obey in order to engage in ethical research practice we offer the following diagram (**Figure 7**) to illustrate the continuum of moral wrongs that researchers face in the field. The misinterpretation or mis-weighing of ethical challenges can be a problem for N-S research teams. The moral nature of ‘irritating’ behaviours, for example, may be confusing to researchers and a source of interpersonal misunderstanding and conflicts. Behaviour that is considered rude in one societal context may be socially acceptable in another context. We all have trouble seeing actions we assess and experience as morally unacceptable as actions that are assessed and experienced as morally acceptable by others. We may know that this behavior is accepted practice in other places; but, our longstanding moral beliefs and sentiments mean we continue to experience the action as wrong and hence we are morally offended by the action. Context is thus vital to understanding and interpreting behaviours and open dialogue about one’s moral experience is the best means to resolve the interpersonal understandings and avoid conflicts. If there is agreement that “Respect persons” is the fundamental moral principle underlying research practice and human interaction, then dialogue about the experience of disrespect and the culturally accepted action will support persons from N-S countries to in mutually respectful interaction. Rude behavior may be irritating in some instances, and morally unacceptable in others. However, it is not morally acceptable for someone to knowingly harm someone, and if one has discovered that a colleague experiences an action as disrespect, one has discovered that

one ought not to repeat that action in the direction of that person. Context matters!

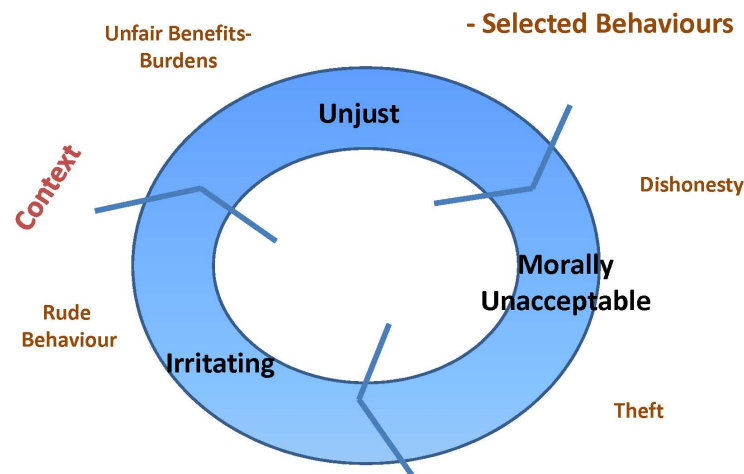


Figure 7 Continuum of Moral Wrong Doing, highlighting the importance of where context does and does not matter.

4.3.7 Shifting from Procedural to Relational Thinking

Very early in this research study's data collection, it became clear that inflexible regulations, whether they are part of a country's legal system or stipulated by a funder or an EB, could be a source of ethical challenges for N-S research collaborations. When a N-S disagreement is governed by two conflicting set of regulations and those regulations are absolute, then a N-S research team is caught in the middle and sometimes powerless to reconcile the two conflicting positions. Usually, changing a legal system is out of the question for the research team, even if there is N-S agreement on the team that the changes are morally required. However, when the N-S team is in agreement about what is morally required, taking this agreement to either the funder, or EBs, whose requirements, in theory at least, are not absolute, should hold some promise for resolving the regulation dispute in accordance with moral requirements. Procedural justice might have a small role to play in a full justice account for research ethics, however, presently, ethical conflicts can arise because EBs and funders sometimes presume it is the most important justice principle to apply in decision-making in research practice.

4.3.8 Emergence

The 'emergent' nature of many ethical challenges was a key finding of this study. Many researchers were confident that their personal relationships with other team members, funders, and other actors were solid. Many were, however, also conflicted by the choices that were put upon them at later stages of the research process by processes and procedures that seemed at odds with the overall purpose and spirit of the N-S study.

This research study found that some of the problems identified seemed to have 'structural' elements, imposed earlier in the process, that makes the ethical problem almost inevitable (**Figure 8**). The example of signed consent forms is an obvious example, described below.

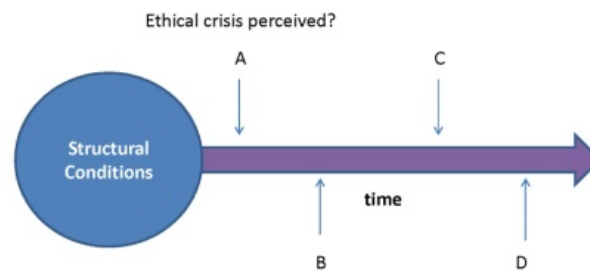


Figure 8 Structural conditions underlying ethical challenges in the field

An example of such structural conditions is as follows:

- **INPUT:** Researchers agree signed consent forms are inappropriate, they draft a proposal omitting signed consent, and including a different process
- N-EB rejects proposal, requires signed consent (A)
- Negotiation with N-EB unsuccessful (B)
- Researchers update N-EB with consent form, both EBs approve research (C)
- Target audience refuses to sign consent forms (D)
- **OUTCOME:** Research quality impacted by low response rate in target population

True emergence is, however, a non-linear concept that indicates that the end product (i.e. relationships) is a complex network which is ‘greater than the sum of its parts.’ Thus, while some ethical challenges can be traced back to structural conditions, others are as likely to emerge from the overall spirit of the team’s relationships as a whole. As Reidpath (2005) eloquently states:

There is information relevant to public health that can only be derived from the gestalt that cannot be ascertained from the sum of its parts.

These observations place importance on ‘getting the structures right’ for ethical relationships so that the process is sufficiently adaptive to not lead inevitably toward ethical challenges as researchers develop, implement, interpret, and disseminate their research findings. They also highlight the need to ‘get the attitudes right’ so that ethics is not considered the mandate of an EB, but rather is a key part of the culture of research implemented by N-S research teams. As indicated in the section that follows, we recognize that no perfect system exists, but believe that many elements of the current dominant paradigm are not well suited to promoting ethical N-S population health research team efforts.

4.3.9 No Perfect System

Data gathered through this exploratory study identified areas in which N-S research initiatives experienced challenges as well as ways in which diverse

research teams have learned to successfully work together. Collaborative and team work approaches are constantly evolving and reshaping themselves in order to respond to research conditions and the social, economic, and environmental contexts in which they operate. As such, these collaborations require great flexibility and the ability to adapt and transform, while still remaining true to their ethical and professional mandates.

A comparison between what might be considered as “Northern” and “Southern” approaches to ethical research showed there is richness in both, that both attempt to address the local concerns and needs, and that there are areas in which both could be improved. However, given the changing and evolving nature of societies the aim of institutions that regulate research activities should not be to create the “perfect system” by hoping to identify the “perfect procedures” to be followed according to a set of conditions. This will prove to be an unachievable goal because in order for procedures to be relevant to new emerging conditions they must also have flexibility built into them.

One way to create a more flexible system is by emphasizing the relational aspect of the research process rather than the procedural. This approach would require more dialogue between the regulating bodies and researchers, a greater understanding of the contextual conditions within which research is conducted, and the willingness to adjust the procedures accordingly. The current absence of procedural flexibility is illustrated in the challenges and conflicts that arose when researchers attempted to employ an individual model of obtaining consent from indigenous communities that followed a collective rather than an individual model of living. For some of the researchers participating in this study, in a “perfect system” it would not be necessary to have specific procedures to address the cultural nuisances of every indigenous group, because the system itself would have the procedural flexibility to accommodate without exposing these communities and the researchers to harm.

4.4 Complexity Lens

Complexity thinking in the context of this research study drew our attention to several interesting features of the data collected. The first was the need for multiple perspectives to inform the conversation. As noted in the Introduction, a flaw in this study was the very small voice given to participants and funders in N-S research projects. Some representation of these groups was provided from the CEHP case study, but that feedback was itself limited by having been provided during the execution of the CEHP itself, and before several of the participant and community feedback initiatives were implemented, and the end products of the work were clear. Another flaw in this study highlighted from the standpoint of complexity thinking, and mentioned above is the absence of S-philosophers and hence S-philosophy from the conversation. This flaw, which generally characterizes N-S research ethics discussion, was experienced early in this study by SAMKET’s N-philosopher. Her frustration that this crucial perspective is not adequately informing the conversation and recognition that without this voice it is impossible to fully understand and resolve N-S ethical conflicts underlie many of SAMKET’s recommendations.

Complexity draws a great deal of attention to the issues of context and scale, and both of these were relevant to this study's findings. On the one hand, context is everything in studying ethical relationships – not only insofar as it affects the relationships of the actors themselves and the power dynamics inherent in those relationships, but also it shapes the weight those different ethical principles and values are given by the extended research team. This weighting is shaped both by the character (and virtues and vices) of the researchers themselves, as well as their previous experiences, training and preponderance to 'reflectivity' in terms of thinking through the ethical implications of their actions. Scale is important here too. Only a few people in the study network are well connected to the people involved. At the ground level where the work with communities takes place, graduate students and S researchers may be the most visible connection to the research effort. At higher levels, the role and attitudes of the PIs is central, and at even higher levels, the structure, function, mandate, roles and attitudes of funders, EBs and University's have a huge influence on the work that ultimately takes place on the ground. Thus, taking a holistic view of the network of ethical relationships from a complexity perspective illustrates the overarching role of clear values in shaping the group effort. It also highlights the non-linear (or emergent/gestalt) nature of many ethical challenges (discussed above) and the need for flexible and adaptive processes.

Complexity thinking also highlights the need to understand the history of the system in question. The path-trajectory of the system over time is shaped in many ways by previous experiences. Thus, the ability of a N-S research team to work in certain communities may be heavily influenced by its previous experience with researchers. The emphasis in population health ethics on the Tuskegee experiments and on exploitative vaccine trials in the S demonstrates the ways in which unethical behavior among research teams can have large-scales consequences for all researchers. TC research teams also demonstrated that ethical behavior by research teams facilitates future ongoing research in communities. By establishing a relationship of mutual trust, ethical research practice has beneficial consequences for researchers and communities.

A final theme that the complexity lens helped elucidate is the chaotic, 'messy' nature of ethical relationships. They are typically unequal, constantly shifting, and may be ongoing and conflicting. They are affected as much by what the research team is doing as they are by the socio-cultural and political environments in which the relationships are embedded. They have better moments and worse ones. Thus the resiliency of the research team in the face of conflict, hard-times or strife is a feature of well-functioning teams. The ability of groups of researchers to debate, disagree, and still perform their research collaboratively and 'without fear' is undervalued in the current system.

Complexity thinking thus informed this research project in a variety of ways and helped create a robust interdisciplinary conceptual framework for thinking about this challenging topic.

4.5 Reflective Lens

Simultaneously with the process of collecting and analyzing the data for this research, the research team considered the importance of documenting the team's experiences as a micro-case study of the challenges and difficulties associated with the implementation of research involving N-S researchers. This was a reflexive process, which in addition to documenting the team's experiences served various purposes.

From a methodological perspective it served to maintain the rigor required for the various methodologies and to adhere to the project's design and purpose. This was in line with Mason's description of reflexive research as one in which "the researcher should constantly take stock of their actions and their role in the research process and subject those to the same critical scrutiny as the rest of their 'data'" (1996 p.6).

From an ethical perspective, reflexivity serves as a tool that reinforces the nature of ethics and that helps to understand and achieve ethical practice. In other words, it is part of the continuum between procedural and applied ethics. It bridges the two in a way that gives meaning to the procedural aspects that at times seem out of place in applied settings (Guillemin & Guilan 2004).

The implementation of this reflexive process responded to the call for researchers to be reflexive in their interactions with others as a way to maintain an ethical approach throughout the research effort and not simply to safeguard the methodological rigor of the study (Guillemin & Guilan 2004).

Following the completion of this study's data collection effort, which culminated with the workshop held in Ottawa in October, 2012, the research team gathered to reflect on the methodology and the overall implementation of the this exploratory research study. Regarding the composition of the research team (SAMKET+H+L), the team felt positive about its interdisciplinary nature. At the conceptual level, the team felt that the bridging of the humanities and the social sciences yielded positive results by using a more holistic approach in the analysis and interpretation of the data collected. The data could be reflected against social, cultural, and philosophical constructs. The absence of S-philosopher was lamented and remedy sought.

Time and funding limitations constrained some of the efforts considering that when the proposal was written the expectation was that only one project would be funded and as it turned out, the funding was divided into two distinct projects. The team maintained the scope of the project but had to limit the data collection approach. Amidst the funding limitations, the team was able to add a pre-med undergraduate student and a graduate student who significantly contributed to different aspects of the project: literature review (H) and analysis of the researchers' questionnaire (L).

Time constraints and the team's limited opportunities for face-to-face contact translated into less opportunities for the members to explore in greater detail

ways in which the interdisciplinary and mixed methodology approach could be articulated in order to enrich the study. Time constraints combined with the limited human resources meant that the team could not rigidly adhere to the anticipated data collection sequence. Ideally data from the Researchers' and Ethics Board Representatives' should have been collected and preliminarily analyzed prior to the implementation of the follow-up semi-structured interviews. Instead, the team's review of the responses served to shape the themes to be explored in the interviews.

In terms of the approach used for the implementation of the semi-structured interviews, initially the team hoped to be able to have two members pair-up for each interview for data reliability and validity. However, considering the multiple activities and responsibilities not only of the team members, but also of the interviewees, coupled with time constraints related to the varying geographical locations of both interviewers and interviewees, the coordination of this approach proved to be unrealistic and untenable.

In terms of the various methodologies implemented, the team felt they were appropriate given the exploratory nature of the study and the absence of a baseline. The sample sizes of the various data collection components adequately represented the researchers involved in the TC teams, but not the members of ethics boards and research participants. These limitations were largely due to the length of the project and limited funding. Most of the data collection took place via electronic questionnaires and Skype interviews. Only a few face-to-face interviews were possible. Further, funding constraints limited the face-to-face contact between team members, with research participants, as well as the possibility to hire other researchers.

Since our first presentation of our methodology and preliminary findings at an unexpected and hastily organized Brown Bag Lunch presentation in Ottawa (August 24, 2011) as part of SAMKET's first Team Working Sessions, we have been encouraged by audience response to our methodology, analysis and the new applied ethics approach we are bringing to research ethics discussion. The audience was unexpectedly large, and obviously interested. Its diversity meant that early on in the study, we had an opportunity to present our evolving methodology to many possible end users and receive valuable feedback. Opportunities at Montreal's Global Health Conference (November, 13-15, 2011) for Morrison and Forde to be part of a panel on global health research and Tomsons' poster presentation provided early opportunities for dissemination and feedback. This conference also provided SAMKET with its first opportunity to discuss our project and their project with the Michelle/Susan research ethics team and confirm the similarities in both teams' objectives and great differences in the two teams' methodologies.

Morrison and Tomsons presented the aim of the project and piloted our first applied ethics discussion of a Case Example at the Annual Conference of the Canadian Society for the Study of Applied Ethics in May 2012. Conference participants generously provided feedback on the information they thought was missing in the Case Example and their understanding of how to resolve the ethical challenge.

At the International Ethics Workshop, October 2012, following an interactive presentation on applied ethics, participants from the Teasdale Corti Symposium and others interested in research ethics were presented with two case scenarios: Story A: Conflicting N-S Ethics Board Requirements; Story B: Individual or Collective Responsibility?. In two groups facilitated by a philosopher whose expertise is practical philosophy (applied ethics and politics) they were asked to analyze and discuss a Case Example. The notes that Heather and Laura took on these N-S discussions of the Case Examples provided valuable feedback on the value of these discussion and the content of the Case Examples. The generally positive feedback Workshop participants provided on the applied ethics presentation and N-S discussion of the Case Examples on their evaluation sheets also provided valuable data. Many participants indicated that the content of the presentation was new and requested Tomsons' slide presentation. All participants indicated that they welcomed the opportunity to actively participate in the N-S applied ethics discussion and they found the discussion contributed to increased understanding of N-S ethical research practice

SAMKET also utilized the International Workshop to share and gain feedback on our interdisciplinary, multi-faceted study methodology, and our preliminary findings. Workshop participants were active during these presentations, providing constructive comments on our methodology and helping to corroborate the soundness of some of the themes that emerged from the data collected. This exchange also helped the team identify aspects of the findings that required more clarity or additional explanation.

In Spring 2012, Dr. Morrison tested Story B (Individual or Collective Responsibility? [Section 6.0](#)) in her public health lectures with Guelph's Master of Public Health students. Based on valuable student feedback, the Case Example was revised to provide additional morally relevant content.

It is important to mention that SAMKET is unified in its conviction that time proved to be the most challenging constraint throughout the duration of this study, since it is likely research delays more than any other single factor were likely responsible for the call for research proposals on research ethics. Time constraints were problematic throughout the duration of this multi-faceted project, but, they were most taxing in the last four months of the study. We found ourselves facing a moral dilemma that experienced N-S research collaborators on the team assured us frequently confronts N-S research teams. Our moral responsibility to provide the funder with the final technical report within the contractually established time frame conflicted with our moral responsibility to complete a data analysis process that would provide an accurate and comprehensive account of our findings and the set of recommendations promised in our LOI.¹² By gripping the horns of the dilemma and attempting to fulfill both complex moral obligations, SAMKET

¹² It is noted that these moral conflicts are framed within and compete with other moral obligations researchers have, such as family responsibilities, personal wellbeing (health issues), and so on.

knowingly opted to take on a brutal work schedule that brought us into the world of meeting unreasonable expectations experienced by many N-S research teams.

As each new 'drop-dead' date was replaced by another, SAMKET's capacity for collaborative research was repeatedly tested and demonstrated. Only mutual trust, respect, patience, good-will, and a sense of humor on everyone's part enabled each team member to 'keep pushing' to complete their part of the work-load. Without funder representative encouragement and support, SAMKET would have had to throw in the towel since personal integrity meant that no one on the team would submit a 'half-baked' final report. Team members did what had to be done in order to fulfill both moral obligations. However, in a study on ethical research practice, it is necessary to say that it is morally problematic that the time constraints placed upon researchers in N-S research mean that they are faced with a work-schedule that scarcely allows time to eat and sleep. N-S researchers typically do what has to be done because they think the work that they are doing is part of a large puzzle that will make the world a better place. SAMKET's response to time constraints was typical, but it knows that there is something morally wrong with a process that treats researchers like 'research machines' thereby not treating them with the respect due persons and harms rather than protects them from harm. In short, the time constraints the structure of funded research imposes on the N-S research process have morally problematic consequences for researchers. Engaging applied ethics analysis of these consequences reveals that the funding structure for research unintentionally violates all of the dominant biomedical paradigm's fundamental moral values/principles in its treatment of researchers.

5.0 Capacity Building in this Project

In addition to the internal capacity building of the SAMKET team, as it related to research ethics, applied ethics, and the nature of global population health partnerships, this project has built capacity in a number of somewhat unexpected ways.

Among the faculty involved in the research, one researcher (ST) was formally invited to sit on the N-EB of her institution in no small part due to the international recognition that this project has provided. Another researcher (KM) was asked by the program Director (and departmental EB representative) to take over the teaching of public health ethics in the Master of Public Health program.

The two graduate students involved in the project are continuing to showcase their work. One (HWB) now sits on the ethics advisory committee of the University of Manitoba's Medical School, where she is a student, and is the global health representative for reproductive and sexual health at that school. She was also heavily involved in the drafting of the Code of Ethics for her medical school class. LR presented in her university's student seminar series, and presented a poster and a talk at the SAMKET ethics workshop in Ottawa. These presentations focused on her work analyzing the researcher questionnaire for her MSc major paper that she will defend in the Population Medicine Department of the University of Guelph in 2013.

This research project extended the reach of its discussions through the presentation of its research and preliminary findings at a variety of forums (see **Box 1**) including:

Oral Presentations:

- IDRC Brown Bag lunch presentation, Ottawa, Canada, 2011
- Global Health Conference panel discussion, Montreal, Canada, 2011
- Canadian Society for the Study of Practical Ethics symposium presentation and applied ethics exercise, Social Science and Humanities Research Congress, Waterloo, Canada, 2012
- Global Development Symposium presentation, Guelph, Canada, 2012
- Ecohealth 2012 conference presentation, Kunming, China, 2012
- Canadian Political Science Association, 2013.

Poster Presentations:

- Global Health Conference, Montreal, Canada, 2011
- 57th Annual Caribbean Health Research Council Conference (full paper required), Georgetown, Grand Cayman.
- These presentations led to a number of useful interactions and discussion with researchers from around the world.

Tomsons, S. and K. Morrison. 2012. Paper, 'An interdisciplinary methodology for resolving ethical issues facing North-South population health researchers.' Canadian Society for the Study of Practical Ethics Meeting. *Congress of the Humanities and Social Sciences*. 28 May. Waterloo, Canada.

Morrison, K., S. Tomsons, M. Forde and A. Gomez. 2012. 'Ethical Issues and Challenges in Global North-South Population Health Research.' 6-9 May. Critical links between animal and human health. *Global Development Symposium*. Guelph, Canada.

Forde M., Morrison K. 2011. 'Ethical challenges facing North-South research partnerships', as part of panel 'Ethics and global health research: The place of ethics in the Knowledge-to-Action cycle of global health research,' *2011 Global Health Conference: Advancing health equity in the 21st Century*, November 13-15, Montreal, Canada

Tomsons S, H., Morrison, K., Watson-Burgess H, A. Gomez A, M. Forde. 2011. Research ethics reviews and North-South Research Collaborations: (Too much or too little ethics). Poster, *Global Health Conference: Advancing health equity in the 21st Century*, 13-15 November. Montreal, Canada.

Morrison KE, Tomsons S, Gomez A, Forde M, 2012, 'Ethical issues and experiences in global North-South population health research: implications for Ecohealth, *Ecohealth*, ' 2012, 15-18 October 2012, Kunming, China.

Morrison, K, S. Tomsons, Watson-Burgess H, Forde M, Gomez A, 2012. 'Understanding obstacles to ethical global health research,' *57th Annual Caribbean Health Research Council Conference*, April 19-21st 2012, Cayman Islands, *West Indian Med J*; 61 (Suppl. 2): 35.

Tomsons, S., K. Morrison, A. Gomez and M. Forde. 2013. North-South Research and Social Justice: A New Paradigm for Research Ethics. *Canadian Political Science Association Conference*. [abstract accepted].

Box 1 Academic Presentations of SAMKET research, 2011-2012

6.0 Applying Ethics

The two stories below are tools for engaging in applied ethics N-S dialogue in order to understand and find solutions to ethical conflicts arising in N-S research collaborations. The stories illustrate recurrent ethical problems and are teaching tools that demonstrate how good stories can be used to facilitate a N-S dialogue among researchers, EB members, funders, that can arrive at agreed upon conclusions based on moral values/principles. Since these two stories demonstrate common ethical issues that arise in many N-S research projects, many N-S researchers can easily recall similar stories and hence re-evaluate how they could have resolved them.

6.1 Story A: Conflicting N-S Ethics Board Requirements

Researchers' relationships with graduate students and N-S Ethics Board (EB).

Dr. Smith is a N-member of a N-S research team. He is supervising a S-graduate student (Shandra). Shandra's research project is a piece of a large N-S project and her fieldwork is in her country. The S-EB requires researchers to receive N-EB approval before initiating the review process in the South. The N-EB requests Shandra to make several changes to the letter of consent to make it consistent with the EB's requirements. Shandra makes the changes and the N-EB approves the protocol. This review process takes a month.

By the time the N-EB approved her protocol, Shandra was in her country ready to commence her fieldwork. She had three months to complete it. The S-EB review process was just beginning. It was unable to review Shandra's proposal immediately. After a month, it informed Shandra her protocol would not be approved unless there were changes to the consent form.

The S-EB indicated it is not open to negotiating the inclusion of a clause related to the confidentiality of responses when there is a small sample size. It was unfamiliar with the clause and had never used in other similar studies. It told Shandra that the clause is suitable 'for research in Canada, on Canadians; but not in their country'. The changes required by the S-EB would simplify the form and it would not contain some of the information that the N-EB had specifically requested Shandra include in her consent form.

Shandra has been limited to collecting secondary data for a month. She now has only two months to complete her fieldwork. She is a researcher in the middle of a disagreement between N & S EBs about ethical treatment of participants. She understands it is important that research practice be ethical and wants to be an ethical researcher. She knows she needs approval of both EBs to begin her research. Further delaying her fieldwork will compromise her research project and create a gap in the larger N-S research project

Shandra confers with Dr. Smith. He agrees with Shandra that she cannot satisfy the requirements of both boards. Dr. Smith indicates that in his experience with N and S EBs, both have insisted on compliance with their guidelines. Any attempt on their part to negotiate a compromise would take months.

They agree that the best course of action is the following:

- i. Since Shandra has N-EB approval, Dr. Smith will negotiate with the S-EB to determine whether it is open to incorporating any of N-EBs requirements for the consent form.
- ii. Shandra will incorporate into the consent form as many of N-EB's requirements as S-EB permits.
- iii. Shandra will not seek N-EB approval of the revised consent form.
- iv. Shandra will begin her fieldwork when they have the S-EB approval in hand to send to the N-EB.

Is the course of action Dr. Smith and Shandra have agreed upon morally acceptable?

6.2 Story B: Individual or Collective Responsibility?

N-S Research Team's relationship with S- employees and funders

Dr. Smith is a S-PI for a ten-member S-N research team. He has come to the team's regular monthly meeting believing that he has to convince his team has to do something to resolve a serious problem.

Last year, the team successfully competed in a fierce research funding competition. They were awarded \$2,000,000 to support their ambitious, multi-faceted research proposal for three years.

Dr. Smith's problem involves Don, a S-employee who coordinates several components of the research study. Don is the only full-time employee of the study and he has not been paid for a month, since the team submitted its 12 month financial and activity reports. The team's funder releases funds to the team to cover expenses for six months. Funding release is conditional on funder review of the team's reports. As a result, a team may not have its 6-month funding released at the beginning of the 6-month period the funds are needed to cover. The 6-month's budgets are fully allocated to employee salaries and study activities that the team needs to report on at the end of the 6-month period.

When funding release was delayed at the end of the team's first 6-month review, Don worked without pay for two months. Dr. Smith thinks it is unlikely that the team's last set of reports would take the funder any less time to approve. He was pretty sure that it would be at least another month before Don would be paid.

Dr. Smith believes that not paying Don is wrong. In the implementation of their research project, Don contributes a great deal to make implementation possible. Dr. Smith feels personally obligated to try to do something to fix the situation. He convinced Don to give up steady employment and sign on to this three-year research project.

Dr. Smith had expressed his concerns seven months into the project, after Don had been a month without being paid. In their discussion, his S & N team members agreed that Don was not being treated well. It was pointed out that the team had no money to draw on and the S-institution administering this part of their grant did not have the means to supply a buffer until the funder approved the yearly reports. Discussion ended with N-PI saying nothing can be done until the funder releases the money.

At the time, Dr. Smith reluctantly accepted the team's "There is nothing we can do" and "Funder is to blame" analysis of the situation. However, this month it became clear that by doing nothing, the situation would not change. Everyone on the team knew that Don was not being paid. Dr. Smith, who worked closely with Don, was the only team member who knew Don and knew how the stress he and his family were experiencing because he was not being paid. He believed his relationship with Don gave him an obligation to be his advocate since Don did not regularly participate in team meetings.

In putting together the proposal for their research project and in their implementation of it, Dr. Smith has been very impressed by his team's commitment to respecting and treating justly S-participants. Today, he will try to convince them that ethical research practice requires researchers to have the same commitment to respecting and treating justly S-employees.

What moral obligations does the N-S team have to Don?

7.0 Analysis of Key Findings

7.1 Moral Values and Principles

1. Both N and S researchers share the dominant bioethics paradigm's fundamental moral values and principles.
2. Both N and S researchers share the dominant bioethics paradigm's secondary moral values and principles.
3. The S applies some values such as justice principles of reciprocity and social/global justice that are not contained in the dominant bioethics paradigm.
4. The implementation of fundamental and secondary moral values/principles is culturally relative.

7.2 Analysis of findings in support of Hypothesis #1

Hypothesis #1: *The standard bioethics model generating the moral principles that anchor and justify the North's ethical guidelines is not an appropriate model for North-South population health research. Therefore, the moral principles generated by the bioethics model cannot, by themselves, provide an adequate set of ethics guidelines for North-South population health research.*

Conclusion: This hypothesis is highly probable based on the following evidence:

1. Literature review
2. Analysis of empirical findings supporting the Network of Relationships
3. Analysis of empirical findings about the type, nature, and sources of ethical conflicts
4. Analysis of the moral foundations of N and S Policy statements¹³ in the light of the moral foundations of N-S research collaboration.
5. Analysis of the theory of human nature and moral theories presupposed by the dominant biomedical research ethics paradigm in light of our empirical findings in (1) and (2).

7.3 Analysis of findings in support of Hypothesis #2

Hypothesis #2: *The moral values of the North and South are a source of ethical disagreement when the North's moral values are understood narrowly as the four moral principles which are the basis for North's research ethics guidelines. When a richer understanding of the fundamental moral values of*

¹³ N-Policy statements consulted: TCPS, Belmont Report; Declaration of Helsinki; National Institute of Health (USA). S-Policy statements consulted: South Africa: The National Health Research Ethics Council and Medical Research Council Guidelines on Ethics for Medical Research; China: *Reviewing Clinical Trials: A Guide for Ethics Committees*, editors, J. Karlberg and M. Speers, (2010); Caribbean: Pan American Health Organization website.

the North is incorporated into the discussion of the ethical issues, the moral values of the North can be reconciled and ethical issues resolved.

Conclusion: Nothing in our findings falsifies this hypothesis. The following provided some evidence to support it:

1. Literature review
2. N-S comparison of researchers and EB member's questionnaire data.
3. Analysis of empirical findings supporting the Network of Relationships
4. Analysis of empirical findings about the type, nature, and sources of ethical conflicts
5. Analysis of the moral foundations of N and S Policy Statements in the light of the moral foundations of N-S research collaboration.
6. Analysis of the moral principles (and values) presupposed by the dominant biomedical research ethics paradigm

7.4 Assessing the Biomedical Research Paradigm and N-S Policy Statements

At the outset of this research study, the aim was not to replace the dominant medically based bioethics paradigm, rather, the aim was to evaluate this paradigm's adequacy in the context of N-S GPHR collaborations. After an analysis based on the literature review done, review of several ethics policy statements, and the empirical data collected in this study, the evidence overwhelmingly supports recommending that a new paradigm be developed for N-S GPHR research which may or may not incorporate certain aspects of the bioethics paradigm which was primarily developed for medical type research.

The empirical data collected in this study provides a lot of evidence that in N-S research collaborations there are morally relevant values and principles to consider in decision-making and actions that are missing from the bioethics paradigm. Moreover, sometimes the missing values, in particular the missing justice principles, overrule the bioethics paradigm's moral values and principles and their implicit ranking in this paradigm.

Since many significant inadequacies in using the bioethics paradigm for N-S GPHR type research emerged from the analysis of data collected in this study, it is therefore concluded that mere tinkering of the bioethics paradigm will not resolve these problems. Nothing less than a paradigm shift is necessary. Again, please note that it is not being argued here that the dominant medically based paradigm does not have application in appropriate contexts, for example, the physician-patient relationship. However, this paradigm can be a source of misunderstanding, confusion, and ethical conflicts when applied in N-S research.

7.5 Inadequacies in the Biomedical Paradigm for Research Ethics

This study's analysis identified the following inadequacies in the dominant bioethics paradigm:

1. It is N-created and developed based on the dominant bioethics paradigm.
2. N-discussion and perspectives generated the understanding of moral needs and issues facing researchers and this specific worldview determined the content of most ethics policy statements (e.g., Tri-Council) and each EB's procedures and guidelines.
3. Although fundamental moral values of the bioethics paradigm are shared, there are N-S differences in the ranking and implementing of the values in research practice.
4. Not all S-fundamental values are included in dominant bioethics paradigm's ethics box.
5. N-EBs' procedures and guidelines may be ethically inappropriate in all or some N-S research contexts because S-fundamental values are missing.
6. The bioethics paradigm's focus on individualism ignores an individual's community embeddedness and relationships.
7. There is a narrow focus on duties to participant which ignores all other persons in the research team's network and thereby the researcher's duties to these persons.
8. The bioethics paradigm is grounded in several competing moral theories and their moral values and principles (the big four).
9. The bioethics paradigm presumes a negative interpretation of human rights and excludes the positive interpretation of human rights that is more consistent with the moral foundations of N-S collaborative research.
10. The bioethics paradigm has a narrow interpretation of justice that excludes notions of social/global justice and reciprocity that are part of the moral foundations for N-S collaborative research.
11. TCPS, EB guidelines and procedures, and discussion of research ethics in the literature tend to emphasize rule creation and following. Fundamental moral values are used to generate moral rules that will ensure researchers engage in ethical research practice. Consequently, researchers come to view rule following as the means to ethical research rather than being a virtuous character and N-S philosophical dialogue that justifies research decision-making on the basis of shared fundamental moral values.

7.6 Study Findings about Moral Conflicts and Their Sources

The two most significant study findings about moral conflicts were:

1. Research team – EBs conflicts.
2. Research team – Funder conflicts

7.6.1 Analysis of Research team-EB relationship Conflicts

The following researchers' perceptions of EBs were documented:

- i.* EB inflexibility.
- ii.* Participants and consent.
- iii.* Policy statements and EB requirements do not address all ethical relationships or possible conflicts.
- iv.* Sometimes, ethics is inconsistent with ethics review, that is, EBs requires morally wrong actions.
- v.* EBs are unfair.
- vi.* The EB has unchecked power, is punitive, and a threat to research and researcher.
- vii.* EBs appear to act in an arbitrary manner (different reviewers review the same proposal differently even those who serve on the same EB)
- viii.* EBs are inflexible about their processes and their requirements.
- ix.* EB members are inadequately trained and/or have inadequate experience to evaluate N-S population health research proposals.
- x.* EBs seem to act as though they are out to 'find something' in proposals.
- xi.* EB members seem to act as though they have 'to find something problematic' with any proposal submitted for review. A negative comment provides more proof of a careful read than 'It is fine.'
- xii.* EBs fear litigation and are more focused on legal rules than they are on moral principles.
- xiii.* EBs ultimately provide protection for 'the system' not necessarily the researchers, participants in research, or communities.
- xiv.* EBs rely on 'their university check-lists' and follow their rules and procedures. They are not engaged in applied ethics or basing their decisions on fundamental moral values and principles.
- xv.* The EBs Chair's leadership is essential to good relationships with researchers.
- xvi.* Most EBs are made up of researchers predominantly committed to following N-made rules.
- xvii.* Chairs of EBs occupy a role that forces them to taking a rule-based approach to research ethics, even if they do not agree with it.
- xviii.* Most EBs are overstretched and lack the time to adequately review all the proposals submitted to them for review. As a result, the outcome is sometimes sloppy work.
- xix.* EB members may be more motivated by self-interested than ethical research practice, for example, building up their CVs, getting ideas for research projects.
- xx.* N-EBs do not do enough to understand the values of communities or question the validity of the principles they are applying.
- xxi.* S-EB requests for payment or honoraria are morally unacceptable.

The following researchers' attitudes regarding EBs were documented:

- i.* Many feel wronged by EB processes and treatment.

- ii. For some researchers, perceiving EBs as unjust (v) powerful (vi) and inflexible (vii) creates a sense of fear, distrust and frustration regarding ethics review.
- iii. Some researchers expressed disillusionment with the motivation of EB members, for example, member of researcher's department on EB steals research ideas to promote his/her career.
- iv. Researchers expressed negative attitudes towards authoritarian and paternalistic actions of EBs.
- v. There is a pervasive fear of the ethics review process that is held by most researchers, that can be summed up best by what one researcher said: "the only certainty is that it will be difficult."

Navigating the set of ethical relationships in the N-S research network creates many opportunities for researchers to have ethical conflicts with EBs. Since typically in research ethics training, little time is devoted to engaging in practical/applied ethics decision-making, and since ¹⁴TCPS guidelines and EB procedures and requirements tend toward a rules-based approach to implementing ethical research practice, researchers and EB members can mistakenly come to believe that ethical research practice is about creating and obeying rules. TCPS and EB members are responsible for creating the rules and researchers are obligated to obey them. Since researchers fill the Tri-Council's committees that created the TCPS, and, for the most part, researchers fill positions on EBs, researchers in effect create the moral rules (requirements) that they and other researchers are required to obey. It is noted that there is virtually no discussion in the literature of the conflict of interest inherent in this practice, just as there is no discussion of the conflict of interest inherent in researchers 'policing' research practice.

It is also unlikely that research ethics training adequately addresses important epistemological issues about moral theory and practical ethics. Consequently researchers, and even EB members, may be cynical or skeptical about the objectivity of moral judgments and hence the value of ethics reviews. Since research ethics training does not address questions about the objective/subjective and absolute/relative nature of moral judgments, researchers may find themselves required to submit to an ethics review process that s/he believes is meaningless and a waste of time since ethical judgments merely express subjective opinions, i.e., not objective facts. From this epistemological stance, EBs are perceived as pretending they know what is right and wrong since no one can really come to know what is right or wrong action even if it is the case that actions are either right or wrong. The growth of ethical relativism in Western societies in recent decades makes it probable that many researchers have this set of epistemological beliefs. And, this makes it probable that they perceive EB processes and requirements as arbitrary attempts to do the impossible. Nevertheless, legally and institutionally (governments, universities, and funders) this unwilling researcher is required to submit to a process which s/he thinks is irrational and knows can be

¹⁴ Although we explicitly name TCPS in this paragraph, the discussion applies more generally to the approach EBs typically take to the policy statements they are obliged to implement.

obstructionist. In the case of N-S research team member, s/he may be cynical about EBs ability to “know all” about what is acceptable in the wide range of global research contexts. Ironically, after having declared moral judgments impossible, our data suggests that sometimes researchers who appear to have this epistemological stance on moral judgments will assert that the whole ethics review process is unjust (i.e. morally wrong). It is important to note that ethical relativism as an epistemological standpoint on moral judgments may be more common among N-researchers than S-researchers since in the S there may be greater assurance that we can know and do know what is right and wrong.

Researcher and EB member illiteracy regarding ethical terms and their multiple meanings can result in misunderstanding and confusion regarding ethical research practice. For example, justice, which is a fundamental value in the dominant paradigm, is associated with many justice principles even within the context of the paradigm. So, when an action is called unjust, it is not obvious which principle provides the basis for the claim. Also, researchers may not be familiar with all the justice principles relevant to N-S research, since neither N nor S policy statements provide a full account of justice notions that apply in this context. Similarly, researchers may not all be familiar with the various uses of the term ‘free’ in moral theory and applied ethics; - “free” applies to human nature (we have free will) and refers to a human right, name, the right to be free from interference. Since these justice principles and distinctions all belong to N-moral theory, these literacy problems are compounded in the context of N-S research collaboration. N-researchers and N-EB members typically confess ignorance as to whether fundamental moral values and principles are implemented the same way in S and N. However, this admission does not seem to dispose N-EBs to explore the relevancy and adequacy of the dominant research ethics paradigm for N-S research.

Major ethical issues can arise at all points of decision-making and action related to research and in the researcher’s relationships with persons in any of the circles in the network of relationships. Legally, institutionally and according to S and N policy statements, EBs only have a mandate to address ethical issues pertaining to researchers’ interaction with participants. A consequence of the silence about other relationships is that research ethics seems to respect participants more than all other persons in the network of relationships. The focus on participants in ethics review can create the mistaken impression that researchers have more obligations to participants than to other team members, members of EBs, or funders. However, according to the moral theory commitments in N-S policy statements, all persons have a dignity to be respected and are worthy of equal treatment. Hence, the silence in research ethics discussion about researchers obligations to those in other circles in the network is morally problematic.

We ask: Why do policy statements, EBs, and most research ethics literature presume that researchers are aware of how they should treat everyone other than participants? It is understandable that N-S research teams feel frustrated about an ethics review process that makes the protection of participants the only possible moral concern in research practice. In N-S collaborations,

researchers very quickly become aware that there are many other kinds of important ethical concerns and they are aware that research ethics discussion provides no guidance on how to deal with them since it is silent about them. Also, in procedural disagreements that arise between N-S EBs, N-S research teams may see an EB's negative moral judgment and develop resentment in the EB's excessive concern (and implied distrust) about their treatment of participants.

Researchers involved in N-S collaborations are very aware of the different societal and normative contexts for decision-making that are in play in their efforts to implement their research. So, sometimes, they are justifiably frustrated with an EB that takes a checklist approach to ethics review of their protocol. N-EB inflexibility that shows no understanding of circumstances in S-country or respect for S-researchers and S-EBs places N-researchers in difficult circumstances, especially since it seems reasonable to expect N-EB members to be committed to respecting human beings and their right to self-determination. Ongoing conversations/ dialogue between N-S research teams and EBs outside the context of resolving a dispute is almost non-existent. Consequently, problems in the relationship between researcher and EB frequently grow over time and researcher resentment and frustrations multiply rather than are resolved.

Our empirical data revealed that some of the key ethical challenges researchers face originate in EB requirements. So, for example, EBs put in place procedures and assume implicitly or explicitly that procedural justice demands compliance. N-EB preoccupation with consent form and confidentiality procedures illustrates the ethical dilemma that can result from an inflexible procedural approach to research ethics. Some N-EBs have decided that participant's informed consent requires a 15-page consent form. The researcher providing this example explained that the EB insisted on a detailed explanation of the intervention. The N-EB was not open to a discussion of how much information needs or should be provided to potential participants nor to considering the possibility of cultural differences in expectations regarding the information that should be provided. When a N-S team attempts to implement this EB requirement in a S-country, the team discovers that what N-EBs believe is morally necessary the S-EB believes is morally unacceptable. In such contexts, the weaknesses of the procedural approach, especially an inflexible procedural approach, becomes apparent and N-S teams discover why this approach is morally unacceptable in the context of their research collaborations. The applied ethics dialogue we are recommending seems to be one means to resolving this procedural impasse.

N-policy statements and EB requirements assign high priority to identifying ethical requirements for consent, confidentiality, and privacy. In the TCPS, much space is devoted to justifying their requirements pertaining to their values in terms of the fundamental moral values and principles. Unsurprisingly, placing such great emphasis on these values has the consequence that EBs, and subsequently researchers, ascribe very high moral value to each of these values and equally high value to the tools to implement them. Because of the great value assigned these values, guidelines and

procedures related to minimal risk assessment in ethics review focus almost exclusively on them. The upshot is a detailed set of guidelines to protect participants related to these values.

However, in N-S collaborations, S-communities and S-participants show that they do not assign the same high value to the notions of consent, confidentiality, and privacy valued in EB guidelines. For example, they may value oral rather than written consent. Moreover, they show that they value some things (for example, better treatment for diabetes) more than consent forms and other procedures valued so highly by EBs. When they want their stories to be told as *their* stories, they demonstrate they do not value confidentiality or privacy as highly as N-researchers and N-EBs. In S-countries, N-researchers are frequently confronted with the fact that privacy cannot be assumed to be a shared value.

Equally important to understanding the different ranking of moral values in N-policy statements and N-EB requirements, S-communities and participants sometimes claim an entitlement to more than consent, confidentiality, and privacy on the basis of their contribution to research. They sometimes claim they should have the benefit of the products of the research they supported by allowing the research team to conduct the research in their community. S-communities recognize the benefit of the knowledge they are making possible and sometimes these communities insist that their benefits match the benefit researchers and N-countries receive because of their participation. Although their claim arguably can be justified by some interpretations of the dominant research paradigm's fundamental values, these interpretations have not been employed in the literature and are missing from N-policy statements and N-EB requirements. And, N-researchers and N-EBs are disposed by N-research practice to be taken aback by such understandings of participant entitlement to benefit from research.

7.6.2 Analysis of Research team – Funder Relationship Conflicts

Although our study did not set out to fully explore the relationship between researchers and funders, this relationship was explored in our CEHP case study. We focused on the funders involved with the GHRI and the researchers online survey provided some relevant empirical data. It emerged in our analysis of our empirical data that funder issues were some of the most significant moral challenges for some N-S research teams. Funders were as likely to be perceived as 'a black box' as EBs. Unlike EBs with whom researchers interacting for brief periods as needed, funders have an on-going relationship with a N-S research team.

Funders begin their relationship with N-S research teams with their call for research proposals and the adjudication process resulting from it. The funder monitors the successful teams in the competition throughout their entire projects, including dissemination of results. (Note: Many researchers perceive the competition as brutal.) Like the EB ethics review process, funder monitoring is an evaluative process and, like EB approval, funder approval is a necessary condition for research to take place. However, unlike EB approval, funder approval must be secured repeatedly during the implementation of the

research project in ways that are funder determined. And, unlike EB procedures and guidelines, for funders there is nothing analogous to the Tri-Council policy statement that they must conform to and researchers could consult in order to determine the basis, specifically the moral basis, for funder requirements.

Funders, like EBs, have requirements, however, funder requirements are broader and ultimately more constraining on researchers since their requirements apply to the entire project and hence to aspects of research practice that EBs ignore. To illustrate this point, funders have requirements for project content (for example, capacity building), aspects of its implementation (for example, involvement with policy makers and government agencies), monitoring requirements (for example, regular technical reports), and accountability 'incentives' (for example, holding back funding until satisfied with interim technical report). They also may impose requirements on the structure of N-S teams and researcher interaction. The funder(s) control the size of a project and its timelines, and research teams are very aware of the funder's dictator-like power in their relationship.

Unlike EBs, funders may or may not be up front with their various requirements and may not provide the researcher with anything analogous to the EB's checklist. For researchers, the relationship with funders may be perceived as the most important and the least predictable. Unlike EBs, funders may be fully self-determining and not accountable to any other agency. Although the funder for the Teasdale-Corti program was very interested in and committed to ethical research practice, other funders may not be so committed. And, since the Teasdale-Corti program was solidly based on social/global justice and as a result committed to capacity building, N-S research teams were positioned to be in conflict with the dominant research paradigm from the outset. By being a Teasdale-Corti N-S research teams, they were committed to highly valuing moral values ignored by the dominant research ethics paradigm. Hence, they were inclined to value capacity building and benefit to S-countries well-being so highly that they would be inclined to dismiss some N-EB's concerns as morally insignificant and to judge harshly N-EB inflexibility.

8.0 Recommendations

8.1 A Paradigm Shift in N-S Research Ethics

The dominant North-derived bioethics paradigm silences S-voices. The theory of human nature and the moral values and principles embedded in the paradigm belong to the Western (Northern) philosophical tradition. Furthermore, N-scholars creating policy statements such as TCPS and N-EBs' requirements have narrowly interpreted the competing moral values in the dominant paradigm from the perspective of N-countries' political commitments to liberal theory. The result is a N-dominant research paradigm designed to reflect the N-worldview.

In practice, both S and N research ethics policy statements mostly reflect the dominant bioethics paradigm. Complying with these policy statements, N-EBs and many S-EBs implement the same policies in their requirements. This implicit acceptance of bioethics moral theories and values creates theoretical and practical problems for N-S teams. The result is ethical dilemmas and disagreements. Since the dominant paradigm assumes liberal theory's atomistic account of human nature, which S-countries do not uniformly accept, ethical dilemmas and disagreements are predictable. S-researchers, S-communities, and S-research participants cannot perceive their understanding of the relationship between individual self-determination and community self-determination nor their understanding of the relationship between a person's human rights and a person's responsibility to her/his community reflected in the dominant paradigm's account of persons and moral values and principles. Obviously, the S-perspective cannot be explained or understood without revising the dominant paradigm's account of human nature and without enlarging the set of values and principles in the paradigm's 'ethics box.'

These significant inadequacies in the dominant bioethics paradigm from the S-standpoint have unfortunate consequences for N-S discussion of research ethics. The paradigm does not provide S participants in this discussion the opportunity to speak from their standpoint since it is not fully represented in the paradigm's theoretical and normative structure. The paradigm does not permit S-participants to dialogue on their terms; it only permits N-participants do dialogue on their terms. Consequently, the dominant research ethics paradigm unjustifiably disadvantages S-researchers and S-EB members in discussions of ethical dilemmas and disagreements.

In this exploratory study, we took this dominant research ethics paradigm as our starting point for creating our empirical data gathering instruments because of its dominance in the S as well as the N creates the appearance of universal acceptance. The goal was to determine whether the bioethics paradigm's moral values and principles were in fact as universal as the paradigm's use implies. However, the focus on N-values throughout in our instruments may have resulted in some S-respondents experiencing the same exclusion from full participation they typically experience in discussions about the values and

principles underlying and implemented in N-S research practice. If they had fundamental values that are not in the dominant paradigm's 'ethics box', they could express these commitments only in the examples of ethical challenges they provided and in their in-depth interviews.

The S-understandings and values missing from the dominant research ethics paradigm contribute to an already great N-S capacity and power imbalance. Because the differences in N-S perspectives are significant, they establish the conditions for N-S ethical misunderstandings and disagreements. Since S-beliefs and values are not fairly represented in the dominant paradigm, it will be virtually impossible to arrive at N-S consensus. Moreover, the dominance of N-perspective in the paradigm makes it probable a compromised will favor N more than S perspectives. Only a richer expanded paradigm makes full S-participation possible research ethics discussion to resolve ethical disagreements and conflicts and a new paradigm is also required for genuine S-N discussion of the similarities and differences in N-S moral theories and moral judgments possible.

The empirical data collected in this study supports the conclusion that N-S researchers and EB members accept the dominant biomedical paradigm's fundamental moral values and principles. Similarly, both the N and the S share the dominant biomedical paradigm's secondary moral values and principles. However, as indicated in our instrument analysis, some S-researchers, communities, and study participants employ values to discuss their experience in research that are not components of the dominant bioethics paradigm. Since the missing values include justice principles, including reciprocity and social/global justice, and S-respondents indicated these values were ranked higher than some values in the dominant paradigm, what is missing explains some of the ethical dilemmas and conflicts, and supports both hypothesis #1 and #2.

We use reciprocity to illustrate the kinds of disagreements that can result from the missing S-values in the dominant paradigm and the silencing of S-voice that invariably accompanies the missing values. From the S-point of view, reciprocity is essential to good relationships and inherent in respect. So, for example, S-respondents reported that sharing ownership of study results is regarded as a form of reciprocity participants expect in their relationship with researchers. Moreover, the literature indicates S-participants' expectation that they would continue receiving treatment they took during a study if it proved beneficial was also expressed in terms of the notion of reciprocity. From the perspective of N-policy, EB requirements and N-research practice, these expectations on the part of S-researchers, communities and participants are extravagant and unrealistic. The dominant paradigm's 'ethics box' does not contain the tools for them to understand S-expectations as based on justice requirements.

Another example to indicate the role reciprocity plays in S-moral thinking and how it is silent in N-moral thinking about research ethics: N and S respondents in the on-line survey and in in-depth interviews identified the request for payment of some S-EB as an ethical issue. For the most part, S and N

respondents had a negative reaction to these requests, reporting they thought the EB's request was morally unacceptable. In N-country, and some S-countries (such as South Africa) the issue of payment for ethics review is nonexistent. N-EBs do not request payment for ethics review, and if EB members did so, their request would be morally unacceptable. Most EB members are faculty and they have contractual obligations to serve in the university's committee structure. Therefore, in effect, their salary pays them to serve on the EB. Typically, EB members external to the university receive an honorarium to cover their expenses.

In some S countries, where a lack of resources means very little research was and is undertaken, and since often there was no EB in place, serving on an EB was not part of faculty work-load. Moreover, since teaching loads greatly exceed those of N-researchers, other institutional changes might be necessary before EB service can be regarded as a morally acceptable expectation. However, it is important to note that if S- researchers, universities, and governments value reciprocity (as our data suggests they may) this justice principle justifies some requests for payment for ethics review. The social/global justice principle also supports this request. However, since the justice principles most obviously justifying the S-EB's request are excluded from the dominant paradigm's normative framework, and this paradigm provides the only moral context for research ethics discussion, it is unlikely that S justice-based justifications emerge in N-S discussion of the S-EBs request. In fact, our data indicate that both N and S researchers will take the dominant paradigm perspective, and at best regard the request as a conflict of interest and at worst perceive it as a bribe. S-moral values are disadvantaged in a context not employing their justice notions. Hence, S-EBs experience N- (and some S) dismissal of a value they rank highly, and S-EBs are unable to advance their perspective in discussion and decision-making.

The empirical data collected in this study suggest that some N researchers recognize that S-EB's request employs a justice notion, for example, reciprocity, which is at least as important as justice notions recognized in the dominant paradigm. When they attempt to explain and justify S-EB requests for payment, these N-researchers experience the same frustration as the S-EB. They too encounter the resistance of moral reasoning that does not include the justice notion they are employing. The normative framework for research ethics discussion does not allow them to communicate successfully with those standing firmly within the dominant paradigm. Since other N-participants in the dialogue are reasoning from values in the dominant paradigm and they and S-participants reasons from a value(s) excluded from the dominant paradigm and by implication disvalued, their arguments are dismissed. In such situations, N-researchers experience first hand the disadvantaged position their S-colleagues experience all too often in their research collaborations. Like their S-colleagues, these N- researchers may feel they are banging their heads against a brick wall that 'just doesn't get it.'

N-S research collaborations involve community research and this type of research implies relationships that have traditionally been ignored in N-policies and NEB procedures. This type of research exposes an important

weakness in the dominant bioethics paradigm, namely its individualistic/atomistic assumptions about human nature. Our network of relationship diagram recognizes participants are embedded in communities. However, one immersed in the mindset of the dominant paradigm might mistakenly interpret our NER diagram as representing persons in circles functioning as independent self-determining units interacting with other self-determining units. We reject being spokespersons for a new form of atomism since the empirical data collected in this research study supports different conclusions. For example, a member of the research team circle in the center of the NER diagram is a citizen of a country, a university faculty member, department member, and, sometimes, even an EB member.

In N-S population health research, the community is the object of study. Because it is community research, it requires of researchers greater community involvement than the dominant paradigm envisions. In the dominant paradigm, researcher involvement is individual in orientation and short-term. There is no notion of community involvement.¹⁵ A researcher is in a community solely as a recruiter of participants who are treated as autonomous individuals importantly dissociated from their communities. A quickly in-and-out (short-term) approach to community involvement satisfies the research community epistemologically. It supports the researcher's knowledge gathering objective well since 'the study' can be completed efficiently.

However, in N-S research collaborations, questions are raised about the moral acceptability of the paradigm's notion of short-time researcher community involvement. The empirical data collected in this study indicates that some S-communities feel that short-term involvement does not treat them fairly in the distribution of the benefits of the research. For these communities, researcher community-involvement must be long-term if the researcher community relationship is going to be characterized by mutual respect and mutual benefit. These communities perceive that reciprocity and social justice can only be implemented in research practice if the relationship is long-term.

An important inadequacy of the dominant bioethics paradigm is that it favors a follow-the-rule approach to ethical research practice rather than a N-S applied ethics dialogue approach. Policy statements and EBs tell researcher what the rules are and their moral obligation can be summed up as "Obey the rules." Consequently, when N-S research teams are faced with situations in which there are inconsistent rules among N-EBs, among S-EBs, or between N and S EBs, researchers perceive the rule conflict they are experiencing as an irresolvable ethical challenge. How can they obey two inconsistent rules? However, these rule-conflicts may not actually be ethical conflicts. Instead they may be rule conflicts that arise because EBs take an inflexible approach to their rules (which they believe implement moral values/principles). The dominant paradigm's directive "Obey the rules" hinders rather than points to a

¹⁵ TCPS's chapter on research in Aboriginal communities does take some steps to address researchers' obligations to communities. However, the requirements it identifies in this chapter seem at odds with the dominant research paradigm employed in the main body of the document. Also, nothing in TCPS's discussion of moral theory provides a clear justification for the different/special treatment of Aboriginal communities.

way to discover the nature of the conflict and resolve it. Our directive, engage in N-S applied ethics dialogue holds some promise of providing an account of the nature of the conflict and identifies actions to resolve it.

Recommendation: It is being recommended that a paradigm shift in research ethics, which recognizes that it takes the collaborative efforts of many individuals and institutions to make this happen, be made. We believe our detailed analysis of the inadequacies of the dominant bioethics research paradigm for N-S collaborative research that is supported by our empirical findings is a first step in the direction of creating a new paradigm. It can provide the basis for those with the power to make the needed changes to take the steps necessary to promote the N-S policy statements and EB guidelines.

8.2 Recommendations for Improving the Research Team – EB Relationship

Based on the findings garnered from all of the research instruments used in this study, the following recommendations for improving the Research Team – EB Relationship are made.

1. *Ethics training should be given to all researchers and EB members that works to transform the all too common researchers' perception of the ethics review process as an exercise in authoritarian paternalism into one that views this necessary activity as part of an ongoing process which supports them in their efforts to engage in ethical research practice.*

Rationale: Researchers and EB members are equally obliged to create relationships of mutual respect and, as needed, characterized by ongoing conversation rather than protocol submission on the part of researcher and evaluation on the part of EB. Since the literature and the empirical data collected in this study indicates that EBs are perceived as 'black holes' and the 'ethics police' who impede research and ultimately create ethical issues, it is recommended that EBs be proactive in educating researchers about how they can support them in their research. Since researchers perpetuate their perceptions of EBs in the students they mentor, it is further recommended that EBs create opportunities for students to serve on EBs thus allowing them to discover what EBs do and how they do it.

2. *Research ethics training should support and foster a trusting mutual-respect relationship between researchers and EBs.*

Rationale: The starting point for thinking about ethical research practice must be the firm confidence that most researchers do sincerely want to engage in ethical research practice. Research ethics training for researchers and EBs should be designed to increase their understanding of the scope of ethical decision-making in research practice and it should provide tools for and practice in ethical decision-making. This training should also examine the researcher-EB relationship, discussing the responsibilities of researchers and EB members to make it a mutually supportive relationship.

It is also important that training explain how the researcher-EB relationship fits into a larger network of relationships and the implications for this relationship of being part of the network.

3. *The ethics review process should be refocused and repositioned such that researchers and EBs both understand this process' mission as being geared to help train and support good researchers rather than one whose prime mission is to catch bad researchers.*

Rationale: Given the small number of unethical researchers, the fact that EBs cannot be 'ethics police' who identify and apprehend bad researchers, and the importance of ensuring those who aim to be good researchers have the necessary tools to practice ethical research, the primary aim of EBs should be training researchers well and producing good researchers (in the sense of virtuous persons). Although this means that EBs will not be focused intently on prevention of harm to research participants, if they have any success related to the aims that we believe they should be focused on, one of the results should be protecting research participants from harm.

Although some researchers regard EBs as the 'ethics police' and the actions of some EBs may create this impression, since EBs lack the means to collect evidence or apprehend unethical researchers, EBs cannot function as ethics police. A researcher who is prepared to harm participants or 'doctor' study results will not likely worry about lying to an EB in her/his protocol. Hence, EBs best support ethical research practice by:

- i. Ensuring research ethics training opportunities are available to researchers.
 - ii. Engaging in the applied ethics dialogue with researchers that will support researchers when they encounter ethical issues.
4. *Peer review and ethics review should be separate processes with peer review being completed prior to initiating an ethics review.*

Rationale: N-S researchers correctly believe that ethics review and peer review are very different processes. Since EBs are only mandated to conduct ethics review, many researchers maintain that EBs should not incorporate peer review into the ethics review process. Since EBs are not constituted for peer review, and peer review prior to ethics review ensures that EBs are not wasting time on epistemologically problematic protocols, in a perfect world, researchers are right, namely, EBs should refrain from peer review.

However, the world is not perfect and N-EBs sometimes encounter protocols which have either not been peer reviewed or are perceived by EB members to have been poorly peer reviewed. N-S policy statements and N- and S-EB members understand that protocol design is always relevant to ethics since 'bad science' has ethical implications. Researchers cannot claim the right to waste participants' time, and EBs who sanction research activity that does this are not fulfilling their moral responsibility to help

researchers respect participants. If a protocol is ‘bad science,’ probably it also unintentionally deceives participants by its false predictions about what it can contribute to knowledge or human well-being.

To address researchers’ frustrations with N-EBs who overstep their mandate, and acknowledge EB members’ moral concerns regarding bad science, it is recommended that researchers ensure protocols are submitted to robust peer review processes prior to EB review.

Qualification: Our recommendation throughout has addressed N-EBs. It has some application to S-EBs; however, in light of empirical data we have to acknowledge that in some instances, S-EBs must engage in peer review as part of their ethics review process because there is no institutional support for peer review. Since peer review is essential in order to know whether a proposal is bad science, and it is unethical for researchers engaged in research involving humans to practice bad science; if there is no peer review process in a S-country, it is recommended that S-EBs conduct the peer review process first and clearly distinguish this process from the ethics review process. Ideally, S-institutions should be supported to implement peer review processes, since the separation of the two processes makes for greater efficiency in ethics review and it would reduce the heavy burden the two types of review places on S-EBs.

5. *Research ethics training should clearly distinguish moral rules from legal rules and disentangle the blurring of this distinction in policy statements and EB requirements.*

Rationale: In N-countries, and perhaps most S-countries, some unethical research is illegal. For example, the TCPS indicates that Canadian law covers some of its requirements. Although some harms resulting from research activities are illegal in some jurisdictions, many harms that are part of research practice are not illegal in any jurisdiction. In every country, legal requirements are fewer in number than moral requirements, so researchers should be discouraged from thinking that abiding by a country’s laws means they are engaging in ethical research practice.

Like the TCPS and EBs, legal rules pertaining to research activities are restricted to the researcher-participant relationship. They do not apply to other relationships in the network. The legal systems do not fully cover morally acceptable treatment of research participants and no legal system covers either researchers’ deception of EBs or funders, or EB or funder wrong treatment of researchers.

Researchers and EB members especially need to understand the distinction between what is *morally* required and what is *legally* required in countries where unjust legal rules impinge on research practice. In situations of conflict between legal and moral rules, N-S research teams face serious moral challenges and their decision-making regarding ethical research practice will not be easy. Hence, it is recommended that this disconnect

between legal rules and moral wrongdoing be covered thoroughly in research ethics training.

6. *Research ethics training for N-S researchers, funders, and EB members assessing N-S research collaborations should be regarded as necessary tools for research practice and formalized in the manner of discipline training and the other research skills.*

Rationale: Our research demonstrates that N-S research teams have experienced serious ethical conflicts and challenges and our network of relationships notion reveals that ethical decision-making permeates all researcher relationships and the whole of research practice. Hence, ethical-decision making must be recognized as internal rather than external to practice.

Our data indicates that for the most part neither N-S researchers nor N-EB members have received much formal ethics training, especially training focused on N-S research collaborations. Since we have shown N-S population research requires a research ethics paradigm shift, it is particularly important that those involved in N-S research are aware of the inadequacies in the dominant research ethics paradigm and be trained to think in the larger ethics box of the new paradigm. They must also become familiar with and skilled in N-S applied ethics dialogue in order that they have the skills to avoid and resolve ethical challenges and conflicts they will encounter. In an imperfect world, N-S research teams will continue to experience ethical challenges and conflicts. However, appropriate research ethics training, provided by a team of N-S ethics experts, can equip N-S researchers to meet these challenges and respond in morally appropriate ways.

7. *A N-S team approach to research ethics training for N-S researchers and EB members reviewing N-S protocols is recommended. This training should cover the following topics:*
 - i. The historical and moral foundations of current research ethics policy statements and EBs.
 - ii. Discussion of the strengths and weaknesses of the dominant bioethics research paradigm and the characteristics of the new paradigm for N-S research ethics – including virtue and environmental ethics.
 - iii. Determining whether policy statements and EB processes and procedures are grounded in moral theories and moral values and principles.
 - iv. The aims and scope of ethical research practice and the narrower aims and focus of policy statements and EB ethics review.
 - v. The ongoing evolution of our understanding of ethical research practice, and what N-S research collaborations are contributing to this evolution.
 - vi. Applied ethics dialogue decision-making.

Rationale: N-S research ethics requires a new paradigm that needs to be developed by N-S research ethics collaborations. Until the paradigm is created and established in the literature and in practice, it is recommended that N-S research ethics training be in the hands of N-S research ethics team(s) that are doing the research necessary to construct the paradigm. N-S teams are necessary to ensure that S and N participate equally in the creation of the paradigm. For the same reason, that is, equal S and N participation, until the new paradigm is established, N-S research ethics training should be provided by N-S multi-disciplinary teams combining experience in the field and expertise in moral theory and applied ethics dialogue.

It is acknowledged that there are other possible important topics to cover in N-S research ethics training. Our list of topics above emerged from our research findings and it mentions topics that indicate the depth of research ethics training necessary to enable researchers and EB members to avoid ethical dilemmas, disagreements, and conflicts. The list demonstrates that N-S research ethics training cannot be covered as a small component of a methodology course.

8. *Funding agencies and universities should financially support their EBs so that they have access, as necessary, to the ethical expertise they need.*

Rationale: We recognize that EB members vary in their backgrounds and are not equally familiar with either the moral theory or applied ethics or the inadequacies in the dominant bioethics paradigm that would better prepare them to fulfill their responsibilities in reviewing N-S research protocols. Universities should recruit this expertise for their EB as they recruit other experts, such as lawyers. However, given the increased potential for ethical issues in N-S collaborations, we recommend funders make N-S ethics expertise available to research teams they support throughout the entire research project. Our data shows ethical challenges are not limited to ethics review but rather ethical research practice routinely requires access to ethics expertise. Since N-S researchers' training is based on the dominant bioethics paradigm that we have shown is inadequate for N-S research collaborations, N-S research teams cannot be assumed to have the required ethics expertise to respond to the ethical challenges they encounter. Hence, N-S ethics expertise must be regarded as one of the necessary tools for research implementation and become part of ongoing project management. The team of N-S experts would provide research ethics training opportunities in the classroom and 'in the field.' It should be separate from, and not accountable to the researchers EBs, in order to encourage a trust relationship and frank dialogue.

9. *It is recommended that N-funding agencies and N-S EBs work together with N-S researchers to build relationships of mutual respect.*

Rationale: "No one trusts anyone else." This statement by a N-PI identifies a major source of the most significant of the ethical challenges facing N-S research collaborations. Trust is an essential ingredient of any

good relationship and ethical research practice is impossible without a good deal of it on the part of the many people in the network of relationships diagram. However, for some researchers, distrust underlies ethics review and funder accountability requirements. And, some EB and funder interaction with researchers reinforces researcher views that EBs or funders do not trust them and will use their power as they see fit, whether or not it contributes to ethical research practice.

EB members and funders may both see their role as being to support researchers and their research. But, the power of EBs to reject a protocol in the ethics review process, and the power of funders to delay or cut off financial support for research means that from the perspective of researchers, EB members and funders are persons to please in order to conduct their research. When interactions between EBs and funding agencies become difficult because of their requirements, some researchers, because of their fear and distrust, perceive these institutions as obstacles to get around rather than persons with whom to dialogue to resolve the problem. Unfortunately, the way things are set up at present makes lying, avoidance, and resistance more psychologically possible than making the effort to engage in an applied ethics dialogue to resolve funder or EB problems. Although these morally problematic responses cannot be morally justified, a researcher in the circumstances described can rationalize these responses as the only way out of an impossible situation.

Open communication and applied ethics deliberation between N-S research teams and EBs and funders will not happen unless those whom researchers see as having power over them initiate the conversation and take steps to building the mutual trust that provides the basis for both. Therefore, it is recommended that EBs and funders take the first steps to engage N-S researchers in an applied ethics discussion of the moral challenges that N-S researchers have experienced in their relationships.

10. *It is recommended that N-S agencies creating ethics policy statements be active participants in the creation of the new paradigm for N-S research ethics.*

Rationale: N-S research teams typically have no contact with the agencies that create policy statements and this research study project was not designed to collect data from these agencies. However, we acknowledge that our study has benefited from the Tri-Council's active participation at a mid-study presentation of our project and at our International Workshop on Research Ethics. We regret that we did not have the opportunity to benefit from similar input from those who create and oversee ethics policy statements in the S.

Since N-S policy creating and revision agencies are responsible for embedding the dominant bioethics paradigm in N-S policy statements, we believe their active participation in creating the new paradigm for N-S research ethics will ensure that it is recognized in policy statements and implemented by N-S EBs in their guidelines and ethics review processes.

11. *It is recommended that the ability of N-EBs to override S-EB requirements be halted.*

Rationale: Current N-EB requirements give priority status to N interpretations of ethical research practice. N and S researchers are caught in a difficult, time-consuming, and frustrating role as intermediaries between different EBs. Connecting EBs is not feasible, given that some research projects may require upwards of 15 EB approvals, and that the process of going through the EB will take place at different times as the research gets underway in a new place or on a new topic. Enhanced dialogue, as recommended in this report, will help and rethinking the role of EBs will help a lot, but without removing the primacy of the N-EB approval for work in the S it will be insufficient.

12. *It is recommended that funders of N-S research collaborations support S-researchers in the explaining of S-moral theory(ies) and S-moral values and their application in N-S research ethics.*

Rationale: In our analysis of the literature's discussions of research ethics and ethical conflicts and challenges in N-S research and our empirical data we discovered a huge gap in research ethics. There is silence about S-philosophy. The literature contains virtually no articulation of S-moral theory(ies) or applied ethics methodologies. This silence is morally (and epistemologically) problematic in light of the literature's explicit/implicit acceptance of the N-research ethics paradigm. Consequently, N-moral theory and values dominate the ongoing discussion of research ethics and S and N researchers contributing to it may unintentionally impose a N-perspective that shuts out S-moral theory and values.

If S-moral philosophy differs in part or significantly from N-moral philosophy, the S needs a voice in research ethics construction. Our admittedly limited study suggests that many S-policy statements and S-EB procedures and requirements are copies of N-policy statements and what N-EBs do. For many reasons, the S is constrained by the N-model, not the least being that S-researchers receive N-research ethics training and the N-paradigm dominates research ethics literature and practice. Hence, it is not surprising that when S-researchers who belong to N-S research teams develop ethics review processes in S-countries they recreate the policies and ways of implementing them that have been developed in N.

Although S-researchers and S-EB members seemed accepting of N-values and principles in the lists in our on-line surveys, they also showed some variation from N-researchers and EB members in their ranking of the values. Also, in their examples of ethical conflicts, they introduced values, for example, community self-determination, reciprocity and social/global justice that are missing from the N-research ethics paradigm. Bringing S-moral theory and applied ethics based on an understanding of S-values into the context of collaborative research will empower S participants in N-S research collaborations. Furthermore, a dialogue containing S-moral

theory and values will be a capacity building experience for N-participants who will have the opportunity to be part of a genuine S-N research ethics dialogue. Genuine S-N research ethics dialogue has the potential to transform N-understanding of ethical research practice in N-S collaborations.

Since some types of ethical disagreements and conflicts that arise in N-S research collaborations also surface in N research collaborations, for example, research conducted in Indigenous communities or minority groups, genuine N-S dialogue may have a spill over and ultimately contribute to revising the N-research ethics paradigm in ways that address these issues.

8.3 Recommendations for Improving N-S Research Team – Funder Relationship

1. *It is recommended that funders support research that will contribute to the moral foundations for N-S research collaboration being recognized as belonging to the new paradigm for N-S research. Further, funders should support research that will contribute to the development of this new paradigm.*

Rationale: N-funders and N-S research teams engaged in research in S countries explicitly recognize that an obligation to conduct research addressing S-country needs is the moral foundation of N-S research collaboration. The dominant bioethics paradigm does not have the means to justify this obligation or provide an account of the ethical research practice to implement it. Our empirical data indicates Teasdale-Corti N-S research teams have encountered obstacles to conducting research that expose the need for N-S applied ethics dialogues about the following:

- i. Determining what the needs of the S are.
- ii. What research projects can best address S-needs
- iii. How N-S research teams can implement N-S population health research in morally appropriate ways.
- iv. Addressing S-concerns about N-imposing N's understanding.
- v. N's values (moral, economic and political) and N's way.
- vi. Power imbalances.
- vii. Reciprocal respect

By providing the financial support that is necessary for genuine N-S philosophical dialogue to address these questions, funders will be supporting research that will contribute to developing the new paradigm for N-S research ethics that is urgently needed.

2. *Funders should be included in the N-S ethical research training that is being recommended for researchers and EB members.*

Because ethical research decision-making begins with determining the research that will be funded, and funders engage in this decision-making and moral decision-making and throughout the entire N-S research project, we believe funders, like researchers and EB members, have a moral obligation to become knowledgeable about research ethics. Given the significance of funder decision-making, it is as important that funders' moral decisions about what research to support, where to support it, and who should do it are grounded in the values of the new N-S research ethics paradigm as it is important that N-S teams ground their decisions in these values. The ongoing relationship between funders and N-S research teams makes it extremely important that they share, as much as possible, the same understanding of ethical research decision-making and practice.

By participating in N-S training sessions with researchers and EB members, funders will gain a fuller understanding of how N-funders can intentionally or unintentionally impose the N-dominant paradigm on N-S research teams. Funders will have the opportunity to contribute their understanding of the moral foundations of N-S research collaboration and assist in the development of the new paradigm. Participation in N-S training sessions will also enable funders to become more aware of the obstacles that others, especially researchers, perceive their accountability requirements place in the way of ethical research practice.

Trust needs to displace distrust in both circles in the relationship. We are confident that when N-S researchers perceive funders as being as concerned about ethical research practice as they are, and see that funders are on the same page with them when they engage in applied ethics dialogue, this knowledge should contribute to establishing a trusting collaborative relationship between researchers and funders. And, when funders perceive researchers as being as concerned about ethical research practice as they are, and see that researchers are on the same page with them when they engage in applied ethics dialogue, this knowledge should contribute to establishing a trusting collaborative relationship between funders and researchers.

It is as impossible to eliminate the power differential between funders and researchers as it is between N-S financial resources. Nonetheless, when N-S researchers and N-funders engage in applied ethics dialogue about research ethics, it is probable that they will begin to perceive each other as belonging to a N-S team in which both contribute their capacities to gather population health knowledge and develop S-research capacity with the goal of promoting human well-being in S and N countries. We think the process generating this consensus about the aims and moral foundation of N-S population health research collaboration can be relationship-building. Furthermore, this N-S researcher- N-funder consensus, when brought into the N-S applied ethics dialogue about research team-funder ethical conflicts, should facilitate resolving these conflicts.

8.4 Recommendations for Researchers

1. *Researchers should be involved in all aspects of revising N-S research ethics policies*

Rationale: Researchers, and particularly Principle Investigators, are at the centre of the NER model. N-S researchers are not a homogenous group, and for many the current N hegemony and the institutional emphasis on filling in forms with standard text to meet EB requirements are completely satisfactory. In fact, changing the dominant role of N researchers could be threatening. It can be predicted that not all researchers will be interested in rethinking the role of EBs, and that many will be concerned that the end product would not, in fact, be a welcome paradigm shift but instead the worst of both worlds: requirements for uninspired new ‘training’ or ‘mentoring’ by professionals with little to no actual international field research experience, and EB systems that in practice are no more flexible – and worse, potentially more time consuming – than before they were rethought.

2. *Researchers should become engaged in, and promote, inter- and trans-disciplinary research*

Rationale: Developing and participating in inter- and trans-disciplinary ‘team-based’ research projects requires an investment in new skills and values. It challenges existing ways of thinking and requires thoughtful engagement with other methodological approaches, and in some cases, alternative worldviews. Research framed by systems- and complexity-based thinking challenges existing discipline-based hierarchies. Navigating such differences is not always easy, yet the new knowledge that is generated and the humility and sense of reciprocity that can be generated makes this form of research practice a vital one for training a new breed of reflective practitioner. The researcher characteristics encouraged by systems and complexity based thinking are intellectual and moral virtues that support ethical research practice on the part of N-S research teams.

3. *N-S research teams should reflect on what ‘team’ means in the context of their global population health research partnership.*

Rationale: The tension between the individual and the collective is relevant to both population health research and population health research teams. The roles and responsibilities of the team in navigating its dynamic set of relationships, the way in which inter-team conflicts can be identified and addressed and the role of non-academic support staff in the process are all important to consider. Difficult inter-team relationships can foster dysfunctional research environments for a multitude of participants and collaborators. Better mechanisms to encourage team members to challenge decisions and speak out against ethics violations are needed, lest passively accepting the status quo become entrenched as the more socially accepted behaviour.

4. *N-S researchers should be more forthcoming about the benefits of this research to the N and the S.*

Rationale: N-S research is sometime framed as being more beneficial to one side than the other, or even neo-colonial. Most N and S researchers work both internationally and domestically and the lessons learned from N-S collaborations benefit both sides – the collaborative experience is invaluable for both. This message needs clearer articulation in global population health research outputs.

8.5 Final Recommendations

1. *N-S researchers and N-funders should work collaboratively with both N and S research ethics policy-making agencies to redesign ethics review process for N-S research collaborations.*

Rationale: The history of the development of research ethics review explains clearly why research ethics review became a legal requirement and why the ethics review process takes the form of a legal process rather than applied ethics dialogue. Our empirical data and our analysis support transforming ethical review of N-S research proposals from the legal-like process it is now into a N-S applied ethics dialogue.

Since we have established that the dominant bioethics paradigm is inappropriate for N-S research collaborations, we conclude that it is necessary to remove ethics review of N-S proposals from ethics review processes grounded in this dominant paradigm. Until the new paradigm for N-S research ethics is developed, only a N-S applied ethics dialogue approach to ethics review for N-S research protocols seems appropriate. Otherwise, the numerous disagreements and ethical dilemmas experienced by N-S research teams in their relationship with N and S EBs will continue unabated.

2. *N-S philosophers specializing in practical ethics and politics should be invited to be part of research ethics research and training.*

Rationale: In light of the need for N-S dialogue about moral theory and applied ethics, we believe that it is necessary that philosophers contribute to the discussion of N-S research ethics and the development of the new research ethics paradigm. Currently, researchers from the social and natural sciences and lawyers dominate research ethics policy discussion and formulation. All these areas of expertise contribute to the full discussion of research ethics that is necessary in order to develop a morally appropriate new N-S research ethics paradigm. However, given the role knowledge of moral theory, moral values and applied ethics dialogue must play in the formulation of the new paradigm, the full discussion required to construct the it will be impossible unless N-S philosophers are active participants in it.

3. *N-governments, N-research policy makers, N-funders and N-universities should assume the collective responsibility for hosting and conducting International Research Ethics Workshops.*

Rationale: We believe that it is in the interest of N-governments, N-research policy makers, N-funders and N-universities who are committed to supporting N-S research collaboration to assume responsibility for the cost of making N-S research practice ethical. Each of these institutions and agencies expects and requires N-S research teams to engage in ethical research practice. Since there is a lot that is yet unknown about what constitutes N-S ethical research practice, and much in the dominant bioethics research paradigm and current system of ethics review are morally problematic in the context of N-S research collaborations, it is important that N-S research collaborations be supported to gather the required knowledge and resolve documented problems. N-S research teams do not have the financial resources to support the International Research Ethics Workshops we are recommending. Hence, we are calling upon agencies and institutions which oversee research practice to sponsor these N-S workshops. At these gatherings, N-S research ethics policy makers, N-S EB members, N-S researchers and N-funders will engage in a N-S applied ethics dialogue that supports knowledge gathering, relationship building between each of the circles in the network of relationships, and the development of the new N-S paradigm for research ethics.

4. *N-S EBs should revise their aims and review processes for N-S protocol review.*

Rationale: In practice, it often appears that the motivation for ethics review is not the lofty ideal of participant protection and support for researchers that research ethics policy statements and EBs would have one believe are the only objectives of ethics review. Historically, ethics review became necessary when N-governments, because of some researchers' mistreatment of study participants, made ethics review a necessary condition for securing research funding.

In N-countries, governments created agencies analogous to Canada's Tri-Council for the purposes of creating policies to protect research participants from researchers who would intentionally or unintentionally harm them. At the same time, governments gave universities the responsibility to implement the policies. Unfortunately, giving universities the responsibility for ethics review ensured that research oversight became entangled in a values conflict from the outset. Obviously, universities and researchers who sit on EBs have an interest in researching pursuing knowledge-gathering, (i.e. conducting research). Governments' approach to dealing with bad researchers, which in practice allows researchers (under the watchful eye of lawyers) to determine the ethical requirements that they are to follow and to conduct the ethics review that approves research gives

rise to the same type of concerns that characterize governments' decision to allow any group to police itself.

Our study did not explore whether the conflict of interest inherent in 'self-policing' has contributed to N-S ethical disagreements, conflicts, or challenges. The TCPS policy statement, for example, and EB ethics review practice in Canada pertaining to some Teasdale-Corti research shows that the value of knowledge can result in minimizing participant cost in benefit–burden calculations. However, we believe that Canada's policy statement and EBs need to better understand the special circumstances in which N-S research teams are implementing their research projects, in particular, they should have increased understanding of S-moral theory and moral value differences that may result in conflicts between N-S policy statements or N-S EB requirements and create ethical disagreements and dilemmas for N-S research teams.

5. *There should be on-going relationship-building meetings and dialogue between N-S research teams the N-S EBs.*

Rationale: In general, our empirical data and analysis provide strong support for recommending the means to build a better relationship between N-S research teams and the N-S EBs with which they are in relationships. Data from our on-line surveys supports recommending ongoing researcher-EB communication and relationship building. However, note that the communication required is not the one-on-one communication between N-researcher and N-EB that now sometimes happens in the ethics review of N-S research protocols. The communication that is necessary is a N-S applied ethics dialogue between N-S researchers and N-S EB members.

Comments of N and S researchers and others who took part in our International Research Ethics Workshop support our confidence that practicing our N-S applied ethics methodology can expose shared understandings, generate insights about other perspectives in the network of relationships and help resolve ethical disagreements and conflicts. Hence, we think EBs who facilitate N-S applied ethics dialogue will support better relationships with N-S research teams and generally promote greater understanding of N-S research ethics.

6. *Discussions of research ethics should acknowledge that most Universities' concern about research ethics is an anomaly and thus recommend that they engage in the philosophical discussion with researchers and EBs that is required in order to morally rectify this anomaly.*

Rationale: It became clear in the context of our analysis of the many aspects of research practice that are excluded from ethics review (but which are nonetheless contexts in which decision-making is moral decision-making and actions can be morally appropriate or inappropriate) we became aware of an analogous situation in all the Universities we

interacted with. A University's focus on the *ethics* of research practice can be considered as an anomaly. For the most part, N-universities display an almost total disinterest in ethics. It is curious that in an institution known to have a hierarchical framework, which creates power imbalances and in which there are many ethical decision-making contexts, research is the only activity universities have undertaken to formally address ethics. In other University contexts such as for example the hierarchical relationship between administration, faculty, and staff; contractual hiring; and tenure and promotion processes, there is no discussion of what constitutes ethical practice. Even if unethical practices are prohibited, it is not explicitly from an ethical perspective. Rather, unethical practices are prohibited because of legal rules and various clauses in faculty Collective Agreements. For most faculty, professional ethics primarily means 'Don't have sex with students.'

Typically, faculty actively engaged in research experience their University as an intensely competitive environment. For young faculty in contractual positions or without tenure, the need to survive makes self-interest an important motivator. Little in the university institutional setting discourages faculty from pursuing their self-interest, and the promise of increased academic status, increased decision-making power and influence, and greater financial rewards since successfully 'climbing-the-hierarchical' ladder means that pursuit self-interest is actively encouraged.

Unless an unethical practice violates the collective agreement or a specific legal rule, it is treated as though it has not happened. There is no applied ethics discussion of how persons in the network of relationships in University's complex, hierarchical, institutional structure ought to treat one another given the fundamental moral values and principles that are presumed morally binding by EBs and in ethics review processes. Research is the only context in which faculty are required to think about their decision-making and actions as moral decision-making and morally acceptable or unacceptable actions. University's glaring absence of ethical concern for other faculty relationships can reasonably make faculty (i.e. researchers) question the motivation for imposing it in the context of their research.

Since universities have decided to remain silent about ethics generally, and their concern about research ethics can easily be perceived to rest primarily on their legal obligations rather than genuine moral concern, it is recommended that universities sponsor the philosophical inquiry that will moral justify the ethics only in research anomaly. By doing so, universities would contribute significantly to dispelling the perception of some researchers' that EBs are essentially groups of researchers who volunteer to 'police' other researchers so that the university can fulfill its legal obligations and so that the university will be less likely to be sued by injured research study participants.

7. *Ethics research training should be focused on the notion of moral agency rather than on following rules.*

Rationale: Presently, as noted above, researchers are encouraged to think that they have satisfied their moral obligations as ethical researchers by following the rules that are created for them by governments, research policy generating agencies, and EBs. Philosophers and some scholars who have contributed to the literature on research ethics support the view that an action that is morally appropriate in some contexts may be morally appropriate in another context. Our empirical data supports this conclusion in that both S and N researchers and members of EBs were in agreement that N-research requirements might be morally inappropriate in S-contexts.

If in the context of N-S research practice it is necessary to be more flexible about rules/requirements, it follows that the N-S applied ethics dialogue will need to be embedded in N-S research practice. If in N-S research ethics there is a switch from rule following to moral decision-making, it is necessary that ethics training for N-S researchers focus on the notion of moral agency. The notion of moral agency can be applied to the act of decision-making as well as to any action researchers or others take in order to implement research projects. A moral agent reflectively acts on moral principles rather than blindly obeys a list of rules. Also, the notion of a moral agent identifies persons having responsibility to determine what is the right thing to do as well as the responsibility to do the right thing.

8. *N-S research ethics training should promote epistemic humility.*

Rationale: N-S research collaborations are necessarily multidisciplinary. This recognizes the research project and the knowledge gathering it undertakes require the participation of many, not only one academic discipline. However, the dominant epistemology in N-countries does not accord equal epistemological respect to all academic disciplines or all methodologies. Since epistemic conceit can lead to actions that disrespect others, for example, a researcher disvalues the discipline or methodologies of another team member, ethics literacy needs to include training that encourages epistemic humility. Hence, research ethics training must either include or accompany epistemological training that enables students to understand the epistemic value of quantitative and qualitative research and how every discipline contributes to knowledge gathering.

9. *A revised account of ethics review that is consistent with a holistic understanding of ethical research practice should be undertaken.*

Rationale: It is recognized that ethical decisions are made throughout the entire research process—from the decision about what to study to the dissemination of study results—which give rise to important implications for understanding ethics review. In the new N-S research ethics paradigm, ethics review is embedded in the whole of research practice. Hence, researchers have an obligation to make ethics review an *ongoing* component of research decision-making and implementation. In the

context of this new paradigm, ethics review is primarily the responsibility of researchers and must primarily be engaged by researchers and funders. This has implications for ethics training of researchers, funders, and EB members. Moreover, it has implications for how the new paradigm articulates the role of EBs in ethics review.

In the new N-S research ethics paradigm, EBs have a very narrow mandate for ethics review. They play a relatively small part and a secondary role in the large ethics review process that needs to be undertaken. Since we think researchers and funders are the moral agents who have the larger share of responsibility for ethics review in the new paradigm, we do not recommend EB responsibility be extended to encompass the whole of research practice. We do, however, recommend that EB members be trained to understand and make their decisions based on how their component of ethics review fits into the much larger whole, that is, the many components of ethics review that are the responsibility of researchers and funders. Hence, we recommend joint N-S applied ethics training for everyone involved in research decision-making and implementation and responsible for the ethics review process.

10. N-S research ethics training should include N-S research teams' obligations to communities.

Rationale: N-S research collaborations by their very nature are engaged in community research. The notion of researchers in relationships with communities rather than individual study participants is not part of the dominant bioethics research time. Hence, researchers, EBs, and funders all need N-S research ethics training that examines N obligations to communities when N agencies are supporting community research. Researchers, EB members, and funders are all necessary participants in this N-S applied ethics dialogue since each group has moral obligations related to this type of research. Hence, it is recommended that N-S research ethics training be based upon a N-S applied ethics dialogue that aims to develop an account of researchers', EB members', and funders' moral responsibilities to communities in community research. This N-S applied ethics dialogue needs to examine community involvement in the research process from study design to owning and disseminating study results. In addition to resolving the conflict between the dominant bioethics paradigm and S-understanding of justice, and mediating the disagreement between researchers and communities, this dialogue can contribute to a fuller understanding of participatory and capacity building approaches to N-S research.

11. N-S Research ethics training should encompass the whole range of ethical relationships utilizing and applying the Network of Ethical Relationships model.

Rationale: Ethical issues and challenges in N-S research practice arise outside the researcher-participant relationship. We have documented

ethical challenges arising in the researcher – EB and researcher – funder relationships and we believe that attending to these ethical challenges and determining ethical obligations in these relationships will increase understanding of respectful human interaction and thereby result in more

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Appendices

- A.1 Literature Review
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