



## Objectives

Upon completion of this module you will be able to:

- assess whether research ethics review is required from more than one REB or other authority
- recognize the need to better understand the research setting (e.g., ethical and cultural norms, economic status, politics)
- select the appropriate model of **multi-jurisdictional** review for different research settings

The term “multi-jurisdictional” as used in this module and TCPS 2 refers to research that may require review by multiple authorities (e.g., REBs, school boards, community review bodies). It does not apply to multi-site research that receives review from a single institution or authority.

TCPS 2  
8.1





## Introduction

Two sociology researchers from two different Canadian research institutions are collaborating on a study of graffiti content by urban and suburban youth in Canadian cities.

A Canadian and South American medical engineering research team is exploring the accessibility of 3D printing technologies and training opportunities in Bolivia in collaboration with local researchers.

A team of Canadian researchers from several institutions has been assembled by a funder to investigate access to online education by high school students in sub-Saharan African countries.

All of these examples can be considered multi-jurisdictional research. Each of these projects would require REB review by the researchers' institutions. Some of these projects would also require review by local, regional or national authorities.

In this module, we will examine the ethical issues that arise for researchers and REB members in multi-jurisdictional research and explore practical solutions.

See three perspectives on multi-jurisdictional research ethics review on the following pages.



### Research the Ethics Environment

Hello, my name is **Mary Kasule**.

As a Research Ethics Committee Administrator for a busy Research Ethics Committee (REC) in Botswana, Africa, I have dealt with many researchers who are not prepared for the ethics review requirements in our country. As a Senior Research Officer on a project called MARC (Mapping Research Ethics Review Capacity in Africa), I have learned that the RECs in Africa are diverse in their regulatory mechanisms and their capacity (i.e. skills, resources and efficiency). For multi-jurisdictional research, this can cause a great deal of administrative complexity.



Though some countries are advocating for harmonization of the review process and accreditation of RECs, there is currently little or no mechanism for reciprocal or centralized review in Africa.

The chart below shows a typical research ethics review process for multi-site studies in low or middle income countries. It is important for researchers to understand that this process can take as long as 16 months and can involve four or more ethics review authorities:



Another reason that some researchers have difficulty getting their project approved is that they have not taken the time to understand the cultural norms of places where they wish to conduct the research. This is key to developing appropriate recruitment and consent practices and to obtaining the support of the local communities.

See three perspectives on multi-jurisdictional research ethics review on the following pages.



## Multi-Jurisdictional Research Ethics Review

## Panel on Research Ethics

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### The Coastal CURA project

Hello, my name is **Dr. Tony Charles**.

For 6 years, I led the Coastal CURA (Community University Research Alliance) research project as the Principal Investigator. As part of the Coastal CURA, we formed partnerships with First Nations communities and fishery-related organizations that built knowledge and capacity across the Maritimes, to support community involvement in managing our coasts and oceans. Students and faculty from Saint Mary's University, the University of New Brunswick, and Dalhousie University were involved in different stages and at different times.



To promote collaborative and democratic processes in governance, we were sure to give careful attention to having equal representation from community and academic partners. A Council facilitated governance included all co-investigators, reflected all the CURA partners, and included core collaborators and students. In addition, a management committee was responsible to the Council, carrying out the business of the CURA between Council meetings. The management committee consisted of two university representatives, two community representatives and one student representative.

Given our commitment to participatory research, we delegated ethics review to each participating organization. Participating native communities, for example, usually did their own internal ethics review before a project went forward to the participating university REB. Fishing organizations also passed their proposed research through their management boards before the project was taken to the university REB.

As research funding for students and individual projects was largely distributed to participating universities to administer, it made sense to assign each project to one of the participating universities and to make one or two of the participating faculty members responsible for ethics review.

In our estimation, any other approach would have been extremely cumbersome for the Coastal CURA administrator and me. The guidance of the CURA Council and the management committee allowed for oversight of all projects and for assistance to particular students and faculty involved in ethics review.

See three perspectives on multi-jurisdictional research ethics review on the following pages.



## Multi-Jurisdictional Research Ethics Review

## Panel on Research Ethics

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### Promotion of Sexual Health Services for Students in the Maritimes

Hello, my name is **Dr. Jo-Ann MacDonald**.

As a researcher at the University of Prince Edward Island, I've been involved in a lot of research projects as a principal investigator and as a site investigator. When participating in a project as a site investigator, I've learned that it is important to have good communication with the principal investigator in order to plan the application for local REB review.



A few years ago, I was asked to be a site investigator for the '[Sexual Health Services and Sexual Health Promotion Among Undergraduate Students in the Maritimes](#)' project. This project involved investigators from eight different research Institutions led by a team at Dalhousie University. It was a multi-phase, three-year effort to identify how university sexual health services could better address the needs of students.

For the first phase of the project, I surveyed undergraduate students at my institution about their knowledge of sexual health issues, what kind of sexual health services they needed, whether they were able to get these services at their university and how the university could better promote these services. The principal investigators designed the online survey to protect participant privacy. For example, the survey did not ask for any information that could be used to identify a participant. Their home REB approved the study and they sent the letter of approval to all of the site investigators to include in our applications for local REB approval.

When I apply for local REB review as a site investigator, I include a cover letter to explain that the project is being led by investigators from another institution and that their REB has reviewed and approved the project. I include the letter of approval and clearly describe what aspects of the project I propose to carry out. If the letter of approval is not immediately available, I let my REB know that the project is under review and that I will send the letter of approval when it becomes available.

In a multi-phase or multi-year project, there are usually amendments to the study that require ethics review from all of the institutions involved. Each time a change to the design was needed, the principal investigators let all of the site investigators know they had submitted an amendment and sent us their letter of approval when it became available. This allowed me to submit amendments to my own REB without delay. Thanks to excellent coordination by the principal investigator's team, my attention to details and deadlines, and my REB's sensible approach to reviewing amendments, this project went smoothly and provided each institution with information to help improve and promote sexual health services.

See three perspectives on multi-jurisdictional research ethics review on the following pages.



## Multi-Jurisdictional Research: When is more than one ethics review required?

TCPS 2 requires **eligible institutions** in Canada to ensure that any research conducted under their auspices or within their jurisdiction is ethically acceptable. This is the case, regardless of whether the research itself is funded or unfunded. Canadian researchers conducting research outside of their REB's jurisdiction – or collaborating with researchers from other institutions or countries – must be aware of any other ethics guidance that may apply.

View each of the three considerations on the following pages to assess whether more than one ethics review is required:

- Institutional Affiliation
- Involvement of Institutional Resources
- Jurisdiction of Other Authorities

Eligible institutions are Canadian institutions that have signed an [agreement](#) allowing them to administer federal research funding from [CIHR](#), [NSERC](#) and/or [SSHRC](#)



TCPS 2  
8.A

## Multi-Jurisdictional Research: When is more than one ethics review required?

### Consider: Institutional Affiliation

Researchers require ethics review from the REB of their institution, regardless of where the research will be conducted. Other researchers who are co-investigators or collaborators must follow the research ethics policies of their own institutions.

For example, if a student was conducting an on-the-street survey of environmental attitudes held by students, the local public, or passers-by anywhere in the world – they would need REB review from their home institution.

Collaborators from institutions with research ethics boards would need REB approvals, while collaborators from institutions or organizations without an ethics review requirement may have other requirements to fulfill.



TCPS 2  
8.A

## Multi-Jurisdictional Research: When is more than one ethics review required?

### Consider: Involvement of Institutional Resources

An institution's REB must review proposals by researchers not affiliated with their institution if the project:

- Requires the resources of the institution for participant recruitment or data collection (e.g., access to mailing lists, email addresses, classrooms, collaboration of staff) or
- Involves members of the institution on the research team

Members of an institution can participate in research that has not been reviewed and approved by its REB, if recruitment or data collection do not involve the assistance of the institution (e.g., the researchers advertise in local media or access publicly available information such as faculty email addresses; or students respond to a recruitment poster and are interviewed off-campus).



TCPS 2  
8.A

## Multi-Jurisdictional Research: When is more than one ethics review required?

### Consider: Jurisdiction of Other Authorities

TCPS 2 directs researchers to be aware of, and respect, any additional legislation, guidance, or regulations that might apply to their research. For example, anyone wishing to conduct health research in the province of Newfoundland and Labrador must seek ethics review and approval from the provincial health authority even if no local researchers or institutions are involved.

In most African countries, researchers must apply to the national ethics committee for research ethics review and get permission from [all sites](#) involved in the data collection. If research is being conducted in a region where there are no local, regional or national research ethics review bodies, then review and approval from the researchers' home institutions is sufficient. The REB at the home institution should, however, ensure that the research is respectful of local customs and cultures.



TCPS 2  
8.A



## Models of Research Ethics Review

When a project requires ethics review from multiple institutions and/or authorities, there are several ways to manage these reviews. TCPS 2 describes three models of multi-jurisdictional review. Note that these models are examples only. Institutions may choose to use other models for multi-jurisdictional review that suit their needs.

Explore the advantages and challenges of each model on the following pages.

- Independent Review
- Reciprocal Review
- Delegated Review (external, specialized, centralized)



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## Models of Research Ethics Review

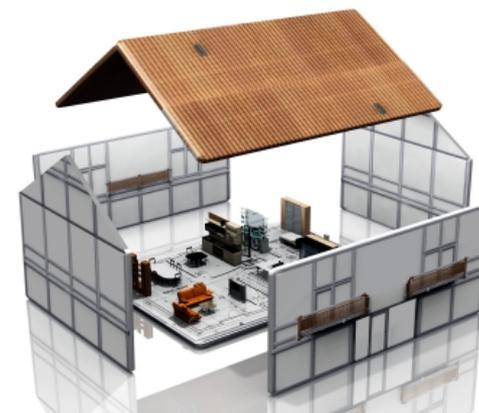
### INDEPENDENT REVIEW BY MORE THAN ONE ETHICS AUTHORITY

**Process:** Submit ethics application to each REB or authority in accordance with its policies.

**Advantages:** Local values, issues and policies are taken into consideration.

**Challenges:** Multiple reviews may extend the timeline of the project. Ethics reviews may differ based on local values, issues and/or policies.

**Strategies:** Researchers work with REBs to coordinate reviews and open the lines of communication.



TCPS 2  
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## Models of Research Ethics Review

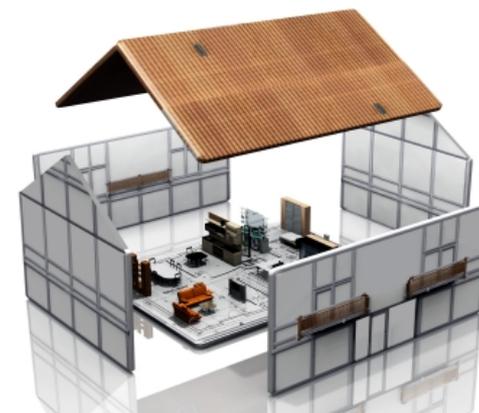
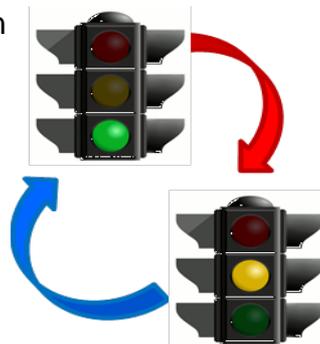
### RECIPROCAL REVIEW

**Process:** The principal researchers' home institution enters into an agreement with one or more institutions to accept each other's REB reviews.

**Advantages:** Streamlined review process on a case-by-case basis by fewer REBs

**Challenges:** In the absence of existing reciprocal agreements between institutions, time will be required to establish these agreements between willing partners.

**Strategy:** Partner REB(s) provide the REB of record with all necessary information for consideration of local interests for each research site. The REB of record provides a copy of the review and the decision to the partner REB(s).



TCPS 2  
8.1

## Models of Research Ethics Review

### DELEGATED REVIEW (SPECIALIZED, EXTERNAL, CENTRALIZED)

**Process:** Submit ethics application to one REB or authority that can act for all of the jurisdictions involved.

**Advantages:** Streamlined review process.

**Challenges:** Local values, issues and needs may not receive enough attention. Centralized REBs are rare and may be focused on only one type of research.

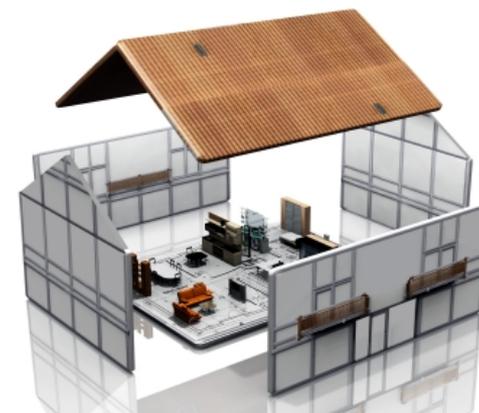
**Strategy:** Clear agreements are necessary between jurisdictions to define roles and responsibilities and to protect local interests.



**Specialized:** the review body typically deals with a particular type of research (e.g., the [Ontario Cancer Research Ethics Board](#)).

**External:** the review body is not affiliated with the researchers' home institution (e.g., an independent review board recognized by the institution).

**Centralized:** the review body is the central review authority for one or more types of research (e.g., the [Health Research Ethics Authority](#) - NL)



TCPS 2  
8.1

## Selecting the Appropriate Review Model

To avoid unanticipated research delays, researchers need to assess the extent of research ethics review their project will need early in the design stage and discuss options with their REBs. REB staff should be able to inform researchers about their institution's policies regarding the models of ethics review that are possible. See the next page for a cautionary tale.

In some cases, independent review from the institutions of the investigator(s) may be the only option. In other cases, institutions may have established reciprocal agreements with other institutions or may be willing to accept the review of a centralized review body. The principal investigator's REB is responsible for deciding which review model is the most appropriate.



TCPS 2  
8.2

## Multi-Jurisdictional Research Ethics Review

## Panel on Research Ethics

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### Lessons learned from a Canada-Caribbean Research Project

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.



One of the funded research projects took place in the Caribbean. The goals of the study were to evaluate the exposures of Caribbean mothers to several environmental contaminants. The team consisted of Canadian and Caribbean researchers. The project ran into difficulty at the research ethics review stage for the following reasons:

1. The research team was unaware during the design stage that the project would need ethics review from each of the 15 English-speaking islands where they proposed to conduct the research, in addition to the reviews needed from the institutions of the research team.
2. The institutions of the research team did not have any existing agreements to permit reciprocal review.
3. There was disagreement between the various research ethics authorities on the ethical acceptability of some elements of the study.
4. Some Caribbean ethics bodies perceived a power imbalance between their authority and that of the Canadian ethics boards (whose approvals controlled the release of funds).
5. The researchers perceived a power imbalance between themselves and the Caribbean ethics bodies (whose approvals controlled access to the participant population).
6. On some of the islands there was no established research ethics review authority. Rather than accept the review of another authority, efforts were made to create new local research ethics authorities.

The delays caused by these difficulties had a substantial negative impact on the research team. At times, they felt overwhelmed by the back and forth between the established REBs and the newly forming ethics authorities, and despaired that the project might never begin. It was 13 months before they could begin their data collection. The lessons learned from these challenges are to thoroughly assess the ethics environment when planning a multi-jurisdictional study and to be aware of local norms, issues, policies and infrastructure.



TCPS 2  
8.2

## Considerations in Selecting a Review Model

Article 8.2 states that “In choosing the appropriate research ethics review model, the researcher and the REB should pay attention to the research context, and the characteristics of the populations targeted by the research.”

When there is more than one model of research ethics review available, the following factors should be considered:

- Research discipline and review expertise
- Project scope and appropriate review
- Participant and community characteristics
- Potential review conflicts
- Conflicts of interest and undue influence
- Standard of care, services and operations



TCPS 2  
8.2

## Considerations in Selecting a Review Model

### Research discipline and review expertise

Do the Canadian REBs of the researchers have, among their members, the appropriate discipline-specific expertise to review the proposal? A TCPS 2-compliant REB that finds itself without the necessary expertise to conduct a review should bring in ad hoc advisors.



TCPS 2  
6.5

When this is not sufficient, the institution can delegate the review to an ethics review board with the relevant expertise. Other guidance regarding expertise may apply in other jurisdictions.

TCPS 2  
8.1



TCPS 2  
8.2

- Research discipline and review expertise
- Project scope and appropriate review
- Participant and community characteristics
- Potential review conflicts
- Conflicts of interest and undue influence
- Standard of care, services and operations

## Considerations in Selecting a Review Model

### Project scope and appropriate review

It is up to the principal researcher to find out how many potential REBs or other authorities could be involved in the review of a project. Researchers can discuss with their REB and other ethics authorities whether duplication of review is necessary or appropriate.



For example, if the risks and benefits to participants do not differ by the region in which the research is conducted, is review necessary in each location? Is it possible to seek agreement from the relevant authorities to engage in a collaborative review process (e.g., representatives from each authority for one review)?



TCPS 2  
8.2

- Research discipline and review expertise
- **Project scope and appropriate review**
- Participant and community characteristics
- Potential review conflicts
- Conflicts of interest and undue influence
- Standard of care, services and operations

## Considerations in Selecting a Review Model

### Participant and community characteristics

What is the cultural context of the research site(s) with regard to the ethics approval and conduct of research? Are there particular characteristics of the population in one or more research sites that require local review?



Are any of the prospective participants in vulnerable circumstances? What review model would be in their best interests given the potential risks and benefits of participation?

TCPS 2  
4.7



TCPS 2  
8.2

- Research discipline and review expertise
- Project scope and appropriate review
- **Participant and community characteristics**
- Potential review conflicts
- Conflicts of interest and undue influence
- Standard of care, services and operations

## Considerations in Selecting a Review Model

### Potential review conflicts

Any time research requires the approval of more than one research ethics authority, there is potential for disagreement. It is in the researcher's best interest to investigate the policies of the different review bodies in search of differences that could affect the design, review and approval of the project.

REBs can help researchers come up with ways to resolve potential review conflicts and may also be able to facilitate a collaborative review process and/or a review dispute resolution mechanism.



TCPS 2  
8.4



TCPS 2  
8.2

- Research discipline and review expertise
- Project scope and appropriate review
- Participant and community characteristics
- **Potential review conflicts**
- Conflicts of interest and undue influence
- Standard of care, services and operations

## Considerations in Selecting a Review Model

### Conflicts of interest and undue influence

The choice of review model can be affected by real, potential or perceived conflicts of interest. For example, if a community or an institution has a financial partnership with a project funder, their ethics authority may be perceived to have a conflict of interest affecting their ability to provide an unbiased review.

TCPS 2  
Ch. 7



REBs of institutions that control the release of project funds for a multi-jurisdictional project may also be perceived as having undue influence over other authorities involved in the ethics review process – particularly when there is a power imbalance between institutions (see *Lessons Learned* on page 15).



TCPS 2  
8.2

- Research discipline and review expertise
- Project scope and appropriate review
- Participant and community characteristics
- Potential review conflicts
- **Conflicts of interest and undue influence**
- Standard of care, services and operations

## Considerations in Selecting a Review Model

### Standard of care, services and operations

Local review of multi-jurisdictional research can be affected by the ability of participating institutions or communities to provide access to services for researchers and for participants.

There may also be differences in the standard of care (in the case of biomedical studies) or the ability to provide research ethics review among research sites.

These differences should be identified early in the research design process so that researchers can work with the ethics authorities involved to find solutions.



TCPS 2  
8.3



TCPS 2  
8.2

- Research discipline and review expertise
- Project scope and appropriate review
- Participant and community characteristics
- Potential review conflicts
- Conflicts of interest and undue influence
- **Standard of care, services and operations**

## Research Without Borders

When Canadian researchers plan to conduct research outside the jurisdiction of their home institution, an important part of the plan is understanding the local research ethics environment. There are some situations in which **no local research ethics review is necessary** (see next page) but for many projects, researchers will have to navigate local laws, policies and guidelines concerning the ethical conduct of research involving humans. For initial and continuing ethics review, researchers must demonstrate to their REBs that the requirements of TCPS 2 and the requirements of each research site are fulfilled.

For example, to conduct research in any of Canada's three Northern territories, researchers must apply for a [research license](#). Several organizations, such as Inuit Tapiriit Kanatami (ITK), provide helpful [guides for both researchers and REBs](#).

In some parts of the world, there may be no established infrastructure for research ethics review (e.g., no local policy, no REB). Researchers should consult with their REBs to determine how to ensure that the interests of participants at these sites are safeguarded. See pages 25 and 26 to explore two different solutions to this issue:

- Alternativas y Capacidades (*Alternatives and Capabilities*)
- The New Zealand Ethics Committee



TCPS 2  
8.3

TCPS 2  
8.4

## Research without Borders

### When no local research ethics review is necessary

Under TCPS 2, the following circumstances may allow a research project that has been approved by the researcher's home REB to be conducted in an area outside of the REB's jurisdiction – without any local ethics review:

- There are no other legal or regional laws, policies or guidance documents that apply to the research.
- Recruitment of participants does not involve the assistance of an institution or organization with a research ethics authority.
- The research team does not include collaborators who are affiliated with other institutions or organizations that have a research ethics authority.

For example, a study of the attitudes of street youth to policing authorities in Vancouver, conducted by a researcher from Manitoba, would not require ethics review from any local REBs because no local researchers are involved and no local institutions are involved in participant recruitment or data collection.

- Alternativas y Capacidades (*Alternatives and Capabilities*)
- The New Zealand Ethics Committee

TCPS 2  
8.3TCPS 2  
8.4

## Alternativas y Capacidades (*Alternatives and Capabilities*) – Creating an ethics environment

A civil society organization called Alternativas y Capacidades was funded by the Canadian International Development Research Centre (IDRC) to study the role and influence of civil society organizations (CSOs) on the development of more equitable public policies for the health of indigenous women in Mexico. Most of the research teams included indigenous women who were very familiar with the issues.

IDRC has adopted TCPS 2 as its research ethics policy. Alternativas y Capacidades did not have an internal research ethics board, but was required by IDRC to make every effort to obtain formal ethics approval from a research ethics authority in the country of study, or to find another way to get local ethics review. The researchers approached a number of institutions seeking ethics review; however, these institutions were already too busy meeting the demands for ethics review from their own researchers.

As an alternative to traditional ethics review, Alternativas y Capacidades formed an Advisory Committee from representatives of the various CSOs, academic institutions and indigenous women leaders who were stakeholders in the research project. This group reviewed and approved the research plan before any data were collected. They ensured that the research plan reflected the real needs of those being studied in an ethical, context-specific and respectful manner.



TCPS 2  
8.3

TCPS 2  
8.4

## Diverse approaches to research ethics review in New Zealand

In New Zealand, there is an established research ethics review infrastructure for health research. There are also institutional research ethics committees that review proposals from their own researchers. But, until 2008, there were no ethics review options for social science research projects from professional, community and government researchers. That’s when a group of social science researchers who also served as health and disability ethics committee chairs decided to found a non-profit organization (New Zealand Ethics Limited) and form the New Zealand Ethics Committee (NZEC) – a non-profit research ethics review service.

The organization offers research ethics review services of social science research. Their goals are to safeguard the rights, health and well-being of research participants, and to foster dialogue between researchers and ethics committees in New Zealand.



TCPS 2  
8.3

TCPS 2  
8.4

## Identifying Challenges – Planning Solutions

Apply what you have learned so far. Read the case studies on the following pages. See if you can spot the ethical issues in each one. This is an exercise you can do on your own or with a group.

Make sure you have access to TCPS 2 – in hard copy or [online](#). Then see if you can find the guidance in TCPS 2 that would apply. What changes would you make to each study plan to make it consistent with the core principles of TCPS 2?

- The effect of climate change on Inuit resource management strategies
- Social Cohesion: The key to overcoming violence and inequality?
- A Comparison of Three Malaria Treatments in Columbia



## Identifying Challenges – Planning Solutions

### The Effect of Climate Change on Inuit Resource Management Strategies

#### Background

A multi-disciplinary team of researchers from Big Lake University plans to collaborate with an Inuit community in Canada's Arctic in an exploration of the effects of climate change on individual and group well-being. One of the researchers is from this community and has assured the other members of his team that he will have no difficulty recruiting his friends and family to participate and that they, in turn, will help to recruit other members of the community.

#### Research Question

Have the changes to the community's environment (weather patterns, availability of traditional foods) that are attributed to climate change had any effects on the physical, mental and emotional health of community members?

#### Proposed Method

The research team will chart changes to the environment of this community using available survey information regarding changes to the air, water, and soil as well as the plant and animal populations. They plan to access health records of the community from the local health authorities and to conduct physical and mental health assessments of current community members. They will also interview individual community members about the effect of climate change on their traditional way of life. They would also like to interview Hamlet Council members about the effect of climate change on their resource management. The team has allotted one month for their data collection.

**What ethical issues do you see in this part of the case study (1 of 3)?**

**Consult [TCPS 2](#) online to see what guidance would apply to these issues.**

**What changes would you make to this part of the case study to make the plan consistent with TCPS 2?**

## Identifying Challenges – Planning Solutions

### The Effect of Climate Change on Inuit Resource Management Strategies

#### Participants (Inclusion/Exclusion Criteria)

All members of the community (male and female adults and children). Full participation would be ideal.

#### Risks

There are no risks to the community members as the measures taken will be no different from routine medical and mental health assessments. The interview will not ask any sensitive questions.

#### Potential Benefits

The members of the community will get health services beyond what they would normally receive. They will have an opportunity to express their observations of the changes to their environment and how these changes have affected their way of life. The findings may benefit the community with respect to informing decision-makers regarding resource management and community support.

#### Recruitment

The member of the research team who is also a member of the community will meet with his friends and family to explain the study, provide them with written descriptions of the research plan and consent forms, and ask them to invite the rest of the community to participate.

**What ethical issues do you see in this part of the case study (2 of 3)?**

**Consult [TCPS 2](#) online to see what guidance would apply to these issues.**

**What changes would you make to this part of the case study to make the plan consistent with TCPS 2?**

## Identifying Challenges – Planning Solutions

### The Effect of Climate Change on Inuit Resource Management Strategies

#### Consent Process

The researchers will follow up with each community member to ensure they received the written materials and give them an opportunity to ask questions. During these visits, the community members will be asked to formally indicate on the consent forms whether or not they will participate in the study.

#### Data Security

The information obtained from old medical records, the new medical and mental health assessments, and the personal interviews will be coded and matched to a code for each community member. The key for the code will be kept by the Principal Investigator in a secure location. The data will be retained for possible follow-up studies.

#### Research Ethics Review Plan

The research team intends to apply for approval of their project from their home institution's REB. They will then send their letter of approval to the Hamlet Council with a request to schedule a community meeting. At the meeting, the researchers will explain their study to everyone who may be interested.

#### Dissemination

Analyses of the data will be included in a conference paper and submitted for publication. The team also plans to present its findings at several conferences.

**What ethical issues do you see in this part of the case study (3 of 3)?**

**Consult [TCPS 2](#) online to see what guidance would apply to these issues.**

**What changes would you make to this part of the case study to make the plan consistent with TCPS 2?**

## Identifying Challenges – Planning Solutions

**The Effect of Climate Change on Inuit Resource Management Strategies**

Ethical Issues	TCPS 2 Guidance
Research Question and Proposed Method	2.7; 9.12; 9.13; 9.15
Participants (Inclusion/Exclusion Criteria)	Chapter 4; Chapter 9
Risks and Benefits	Chapter 2, Section B
Recruitment	3.1; 3.2; 9.1; 9.2; 9.3
Consent Process	Chapter 3; 9.5; 9.6; 9.8
Data Security	5.1; 5.2; 5.3; 5.4; 5.7; 9.16
Research Ethics Review Plan	6.11; Chapter 8; 9.9; 9.10
Dissemination	3.2; 9.17; 9.18

Review the list of relevant articles for each section of the case study. Did you consult the same articles in [TCPS 2?](#)

Discuss how applying this guidance at the research design stage could affect research ethics review.

Were there questions unresolved by the guidance? Refer back to the [core principles](#) to help resolve outstanding issues.



## Identifying Challenges – Planning Solutions

### Social Cohesion: The Key to Overcoming Violence and Inequality?

#### Background

Researchers at the Human Sciences Research Council, South Africa and the State University of Rio de Janeiro, Brazil, plan to collaborate in a study of the impact of strong social cohesion on violence. The research will be conducted in the cities of Cape Town and Rio de Janeiro, which suffer from high levels of inequality and violence. Their study is part of an initiative called Safe and Inclusive Cities, funded by Canada's International Development Research Centre (IDRC) as part of their Social and Economic Policy Program.

#### Research Question

Is social cohesion a critical factor in understanding why violence occurs in some contexts of poverty and inequality and not in others?

#### Method

A series of scripted interviews and focus groups will be conducted in these cities. Participants will be asked about their perspectives on crime, their fear of crime, forms of resilience and resistance to violence they are aware of and may have used, and the impact of violence on their lives.

#### Inclusion and Exclusion Criteria

To address the research question at the community level, the researchers plan to interview a broad cross-section of the community including: boys and girls in secondary school; men and women of all ages; local social workers; non-governmental organisations; community elders and leaders; health care providers; and members of the local police.

**What ethical issues do you see in this part of the case study (1 of 3)?**

**Consult [TCPS 2](#) online to see what guidance would apply to these issues.**

**What changes would you make to this part of the case study to make the plan consistent with TCPS 2?**

## Identifying Challenges – Planning Solutions

### Social Cohesion: The Key to Overcoming Violence and Inequality?

#### Community Engagement and Recruitment

As a community engagement strategy, the researchers plan to approach service organizations and the police to formally introduce them to the community so that they can explain the project. The sampling strategy for selecting participants, as well as the instruments, will be developed during this process and after creating detailed community profiles from secondary data sources.

#### Consent Process

Before being interviewed, participants will be informed of the research, in the language most comfortable to them, through a process of informed consent. Participants will be given a choice of receiving the information in writing (with verbal explanation) or verbally. They may choose to indicate their decision in writing on a consent form or by verbally agreeing or refusing to participate. The researcher might be under obligation to report disclosed incidences of child or spousal abuse. If this is the case, the researcher will remind the participant of this obligation during the consent process.

#### Potential Benefits

This study offers no direct benefits to participants. There is potential benefit at the societal level as we anticipate the results will help to inform future social and economic policy initiatives.

**What ethical issues do you see in this part of the case study (2 of 3)?**

**Consult [TCPS 2](#) online to see what guidance would apply to these issues.**

**What changes would you make to this part of the case study to make the plan consistent with TCPS 2?**

## Identifying Challenges – Planning Solutions

### Social Cohesion: The Key to Overcoming Violence and Inequality?

#### Foreseeable Risks

Participants will be informed that the study is designed to elicit people's perceptions and experience of violence. Individuals might recall their experience of traumatic violence and, consequently, suffer some emotional distress. In order to minimize this potential harm, the researchers plan to make arrangements for the appropriate counselling services to be available to any participants who experience distress or who wish to seek counselling during or after the interview.

Participants might also be concerned about the confidentiality of their disclosures of violent episodes. Interaction with community members will be tailored to protect residents, whether this means holding discussions in community halls, having more informal conversations in the streets or in people's homes, or finding other methods that will enable research participants to speak freely with the researchers.

#### Data Management Plan

Records of field notes, transcripts of discussions or interviews will be kept on the lead investigator's computer. In any public reports or journal articles, pseudonyms will be used to identify any participant.

#### Research Ethics Review Plan

The principal researchers will submit an application for ethics review to the research ethics review body at their respective institutions.

**What ethical issues do you see in this part of the case study (3 of 3)?**

**Consult [TCPS 2](#) online to see what guidance would apply to these issues.**

**What changes would you make to this part of the case study to make the plan consistent with TCPS 2?**

## Identifying Challenges – Planning Solutions

Social Cohesion: The Key to Overcoming Violence and Inequality?	
Ethical Issues	TCPS 2 Guidance
Research Question and Proposed Method	2.7; 9.12; 9.13; 9.15
Participants (Inclusion/Exclusion Criteria)	Chapter 4; Chapter 9
Risks and Benefits	Chapter 2, Section B
Community Engagement & Recruitment	3.1; 3.2; 9.1; 9.2; 9.3
Consent Process	Chapter 3; 9.5; 9.6; 9.8; 10.2
Data security	5.1; 5.2; 5.3; 5.4; 5.7; 9.16
Research Ethics Review Plan	6.11; Chapter 8; 9.9; 9.10
Dissemination	3.2; 9.17; 9.18

Review the list of relevant articles for each section of the case study. Did you consult the same articles in [TCPS 2](#)?

Discuss how applying this guidance at the research design stage could affect research ethics review.

Were there questions unresolved by the guidance? Refer back to the [core principles](#) to help resolve outstanding issues.

## Identifying Challenges – Planning Solutions

### A Comparison of Three Malaria Treatments in Columbia

#### Background

A team of epidemiologists wants to run a phase III clinical trial to evaluate the safety and efficacy of three different malaria treatments among populations of small towns along the Pacific coast of Colombia where malaria is endemic. Animal testing indicates that the two experimental treatments should be at least as effective as the standard treatment and may also have fewer side effects on the auditory system. The principal investigator is affiliated with the Health Research Center based in Bogotá, where malaria does not occur. Two of the research team members are affiliated with hospitals that routinely treat patients diagnosed with malaria. They will be the site investigators.

#### Research Questions

Are the two experimental treatments as good, or better than, the standard treatment? Do they have fewer side effects?

#### Proposed Method

Two hospitals in two towns that regularly treat malaria patients will participate in the trial. The site investigators for each hospital will randomly assign patients to experimental treatment A (ExA), or experimental treatment B (ExB), or the standard treatment (Std). All three treatments will be in the form of pills. The efficacy of the treatments will be measured by the number of malaria parasites in the blood of the patients at the end of the three-day treatment as well as seven, 14 and 28 days after treatment. Side effects, such as hearing loss and/or tinnitus (ringing in the ears) will be evaluated by audiometry tests of the patients before treatment and seven days after treatment.

**What ethical issues do you see in this part of the case study (1 of 4)?**

**Consult [TCPS 2](#) online to see what guidance would apply to these issues.**

**What changes would you make to this part of the case study to make the plan consistent with TCPS 2?**

## Identifying Challenges – Planning Solutions

### A Comparison of Three Malaria Treatments in Columbia

#### Participants (Inclusion/Exclusion Criteria)

Patients older than 12 years of age and diagnosed with malaria who have agreed to be in hospital for three days of treatment. Patients with severe malaria (more than 100,000 parasites/ml), a current ear infection or hearing impairment (abnormal audiogram) will be excluded.

#### Risks

The experimental treatments may not have fewer severe side effects than the standard treatment. For any treatment of malaria, there is the possibility that the treatment will fail. In each case of treatment failure, a rescue treatment (normally injections of quinine or other approved treatment) will be administered.

#### Potential Benefits

If one of the treatments is better than the others, the participants assigned to that treatment will experience the direct benefit of receiving more effective or less toxic treatment for malaria. The more effective or less toxic treatment will be given to the participants assigned to the other treatments as soon as possible and may be considered the new standard of care for malaria.

**What ethical issues do you see in this part of the case study (2 of 4)?**

**Consult [TCPS 2](#) online to see what guidance would apply to these issues.**

**What changes would you make to this part of the case study to make the plan consistent with TCPS 2?**

## Identifying Challenges – Planning Solutions

### A Comparison of Three Malaria Treatments in Columbia

#### Recruitment

Patients who meet the inclusion/exclusion criteria will be identified by hospital nurses. The nurses administering care to these patients will ask them if they wish to be entered into the study. The patients will be asked to make a decision quickly to avoid any delay in treatment.

#### Consent Process

Upon indicating an interest in entering the study, each patient will be given a consent form explaining the purpose of the study to read and sign. When the consent form is signed, blood tests, an audiogram, and a physical exam will be performed. If the patient is under 18 years of age, a parent or legal guardian will be asked to sign the consent on their behalf.

#### Data Security

Investigators will include data from patients' medical history to take into account underlying health conditions. These data will be entered into a database of electronic medical records. Data will be coded to match with the health outcome measures of participants' malaria treatments. The key to the code will be kept by the principal investigator in a secure location. All site investigators and support staff will have access to these records. Copies of the records will be sent by email to members of an independent data management committee.

**What ethical issues do you see in this part of the case study (3 of 4)?**

**Consult [TCPS 2](#) online to see what guidance would apply to these issues.**

**What changes would you make to this part of the case study to make the plan consistent with TCPS 2?**

## Identifying Challenges – Planning Solutions

### A Comparison of Three Malaria Treatments in Columbia

#### Stopping Rules

If interim results of the ongoing study show a difference in the efficacy of the treatments and/or the number and severity of side effects, the independent data management committee may advise that the trial be stopped so that all patients will receive the best possible treatment.

#### Research Ethics Review Plan

The Principal Investigator will submit the research ethics proposal to the Ethics Committee of the Health Research Centre in Bogotá, where she is a physician/researcher. Because the two hospitals where the research will take place do not have a research ethics review body, a committee will be formed with representatives from the two hospitals to review the proposal after it is approved by the Health Research Centre. This committee will have the option of accepting the decision of the Health Research Centre.

#### Dissemination

Analyses of the data will be included in a conference paper and submitted for publication.

**What ethical issues do you see in this part of the case study (4 of 4)?**

**Consult [TCPS 2](#) online to see what guidance would apply to these issues.**

**What changes would you make to this part of the case study to make the plan consistent with TCPS 2?**

## Identifying Challenges – Planning Solutions

A Comparison of Three Malaria Treatments in Columbia	
Ethical Issues	TCPS 2 Guidance
Research Question and Proposed Method	2.7; 11.1
Participants (Inclusion/Exclusion Criteria)	Chapter 4
Risks and Benefits	Chapter 2, Section B; 11.4; 11.5; 11.6
Recruitment	3.1; 3.2; 9.1; 9.2; 9.3
Consent Process	Chapter 3; 11.5; 11.6
Data Security	5.1; 5.2; 5.3; 5.4; 5.7
Research Ethics Review Plan	6.11; Chapter 8
Stopping Rules	11.4; 11.7; 11.8
Dissemination	3.2; 11.3; 11.12

Review the list of relevant articles for each section of the case study. Did you consult the same articles in [TCPS 2](#)?

Discuss how applying this guidance at the research design stage could affect research ethics review.

Were there questions unresolved by the guidance? Refer back to the [core principles](#) to help resolve outstanding issues.

## Summary

- Research that requires review from more than one research ethics authority is considered to be multi-jurisdictional research.
- TCPS 2 describes three models of multi-jurisdictional REB review:
  - independent review;
  - reciprocal review; and/or
  - delegated review (specialized, external, centralized).There are other possible models of multi-jurisdictional review.
- It is up to researchers to investigate and understand the research ethics environment wherever they wish to conduct research – to ensure that all of the required research ethics reviews and approvals are obtained, and to be aware of, and respect, all local laws and customs relevant to their research.



### Additional resources:

-  [PRE List: Ethics guidance outside of Canada](#)
-  [PRE List: Multi-national research ethics organizations](#)

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