TCPS 2022

Interpretations

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TCPS Interpretations

The Panel is pleased to share a growing collection of its responses to written requests for interpretation of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS).

Interpretations have been updated to reflect the changes in TCPS (2022), where applicable.

Interpretation Categories

Other categories will be added as the collection grows.

- Conflicts of Interest (2)
- Consent (10)
- Fairness and Equity (4)
- Governance (9)
- Multi-Jurisdictional Research (4)
- Privacy and Confidentiality (4)
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- Research Involving First Nations, Inuit, and Métis Peoples of Canada (FNIM) (1)
- Roles and Responsibilities (3)
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The Panel's Role in Interpreting TCPS

Through its interpretation service, the Panel seeks to support the needs of participants, researchers, and Research Ethics Boards (REBs) in the effective use and understanding of TCPS. Answering these questions also helps the Panel to identify issues, gaps, and ambiguities in TCPS that may warrant clarification or amendment. Posting these interpretations on its website is one way for the Panel to respond to the evolving needs of the research community. It is also in keeping with the Panel's mandate to develop a publicly accessible bank of interpretations.

Authority and Application of Interpretations

The Panel considers institutional REBs—with their expertise, delegated authority, and awareness of their particular institutional requirements—as the primary source of guidance for research ethics questions in their community. The Panel is not an appeal body for TCPS-related decisions made by institutional REBs, and it does not provide legal advice or opinions. Interpretations provided are based on TCPS. In their application by REBs, they may be modified to take into consideration the research under review as well as applicable policies, laws, and regulations.

The Panel's interpretations of TCPS are provided as advisory opinions for guidance. The objective of these interpretations is not necessarily to produce identical decisions across REBs, but rather to ensure that researchers and REBs take into account the same considerations as they design and evaluate research involving humans. As with TCPS itself, responses to interpretation questions may also evolve. Changes introduced to subsequent versions of TCPS may result in revisions to interpretations. In case of discrepancy between the interpretations and TCPS, text in TCPS shall prevail. We welcome your input.

Responding to Interpretation Requests

Interpretation questions vary in their level of complexity. Many requests for interpretations are answered directly by the Secretariat on Responsible Conduct of Research (Secretariat). Where the requests raise novel or complex issues, the Secretariat refers questions to the Panel. For some issues, the Panel may require input from other sources or a broader consultation.

Submitting Requests for Interpretations

If you do not find the answer to your question through your REBs or in this collection, you can **request an interpretation**. Simply send an e-mail to the Secretariat on Responsible Conduct of Research at secretariat@srcr-scrr.gc.ca. Put "*Request for Interpretation*" and the focus of your question (e.g., consent, recruitment, identifying information) in the subject line. Please provide your contact information to help us respond to your question. A policy analyst should be in touch with you within 48 hours.

Conflicts of Interest

1. Does TCPS provide guidance about thresholds for financial conflicts of interest?

TCPS does not advocate setting thresholds to determine financial conflicts of interest. The salient factor to consider in assessing financial conflicts of interest is the degree to which the interests conflict, not the monetary value involved. TCPS also does not advocate limiting interpersonal conflicts of interest by closeness of familial relationship, as the conflicts of interest may occur with any degree of familial relationship, friendship, or partnership. Articles 7.3 and 7.4 require the disclosure and management of all real, perceived and potential conflicts of interest by REB members and researchers. It is desirable for institutions to address financial conflicts of interest in their policies in accordance with guidance in Article 7.1.

2. Do REB members and researchers have to disclose real, potential or perceived conflicts of interest posed by their investments in mutual funds?

Articles 7.3 and 7.4 state that REB members and researchers must disclose any real, potential or perceived conflicts of interest. In the case of mutual funds, much depends on the amount of control the individual has over these investments. In the case of a self-directed mutual fund (or any other type of self-directed investment), the investor has first-hand knowledge of the products and companies he/she is investing in. It would be the investor's responsibility to identify any risk of real, potential or perceived conflicts of interest posed by any investment to any research project he/she is involved in, either as a researcher, or as an REB member. Investments that are not self-directed, and of which the investor has no direct knowledge, do not require detailed conflicts of interest disclosure.

Consent

1. Does TCPS specify an age of consent for children?

TCPS does not specify an age of consent for children. Seeking consent from children is not based on their age, but on whether they have the capacity to understand the significance of the research and the implications of the risk and benefits to themselves – as defined in TCPS Chapter 3, Section C. Factors to consider in making the decision to seek consent from children as participants include, but are not limited to, the nature of the research, the research setting, the level of risk the research may pose to participants, provincial legislation and other applicable legal and regulatory requirements related to legal age of consent, and the characteristics of the intended research participants - who may differ in many aspects including their capacity to make their own decisions. As no two research studies or research participants are identical, the decision to seek consent from children instead of an authorized third party should be considered on a case-by-case basis. In practice, the researcher plays a key role, sometimes in association with the parents, in determining whether the child is able to consent.

Children who lack capacity to consent may still be able to express their wishes in a meaningful way (assent or dissent), even if such expression may not be sufficient to fulfill the requirements for consent. Researchers must respect the decision of children who are capable of verbally or physically assenting to, or dissenting from, participation in research, even if the authorized third party has consented on their behalf (see Article 3.10).

2. How do researchers manage the consent process for post-secondary student participants who have not reached the age of majority?

TCPS does not rely on the concept of "age of majority" to determine whether people have the necessary capacity to consent to research. In the case of post-secondary students recruited as research participants, the relevant criterion is not their age, but rather whether these students have the capacity to consent on their own behalf in the context of the particular study (see Article 3.10). In their application for REB review and approval, researchers should point out the issue of consent, the age group of the prospective participants, and their plans

to address the issue in light of the capacity of students to understand the particular research project. Do they understand the consequences of their participation in research, i.e., their ability to assess the risks and potential research benefits of research. This will guide the REB's decision on the consent process necessary for this research. Researchers and REBs must also be guided by applicable legal and regulatory requirements with respect to consent and capacity within their jurisdiction as well as institutional policy.

3. Is the awarding of bonus credits to post-secondary students for their participation in research consistent with the guidance regarding consent in TCPS?

In some institutions, post-secondary students (mostly in first year psychology courses) participate in research to receive bonus credits over and above their normal grade in an academic course. In other institutions, students' participation in research is part of the curriculum and the participation is reflected in the grade earned in the course. In both cases, to ensure that participation in research is voluntary and to minimize the risk of undue influence (Article 3.1), students should be given an alternative means of earning an equivalent participation credit. For example, instead of participating in a survey, students could submit a short, written assignment about the uses of surveys or survey techniques. To maximize freedom of choice, the effort and time expended for the research and the offered alternative, as well as the potential rewards, should be comparable.

4. Is penalizing post-secondary students for failing to fulfill all conditions of research participation for course credit consistent with TCPS?

Penalizing post-secondary students, who participate in research for course credit but who later decide to withdraw from participation in research, by refusing to award them the promised incentive, is a form of coercion (Application of Article 3.1). This is contrary to the principles of TCPS. The imposition of penalties runs directly contrary to a participant's right to withdraw from participation in research at any time (Article 3.1(b)) without suffering any disadvantage or reprisal. If the incentive for participation is a lump-sum reward (Application of Article 3.1(b)), student participants, like all participants, are entitled to the full amount of the reward for their participation even if they choose to withdraw at any point in time. If a schedule of incentives is used,

student participants shall be awarded the incentive earned in proportion to the extent of their participation. For example, a student who completes only one part of a three-part participation commitment in a research study is awarded course credits for one part only. As part of the consent process, researchers should provide participants the necessary information for making an informed decision to participate in research (Article 3.2), including an explanation of the responsibilities of participants, and assurances regarding their rights and freedom to withdraw at any time without prejudice to pre-existing entitlements.

5. In research involving partial disclosure or deception, on what basis can REBs justify no debriefing for participants?

The response to this interpretation has been superseded by new articles in TCPS. See Articles 3.7A and 3.7B for guidance on this topic.

6. Are all models of incentives for recruitment and participation in research ethically acceptable?

TCPS acknowledges the use of incentives as a legitimate way of encouraging participation in research, but neither discourages nor encourages their use. Incentives are an important consideration in assessing voluntariness to consent to participate in research. They should not be so large or attractive as to encourage reckless disregard of risks, or result in undue inducement (see Application of Article 3.1).

Incentives for participation in research may be monetary or may take other forms, for example lotteries, or bonus credits to students. TCPS does not provide guidance on the ethical acceptability of specific incentive models. The onus is on the researcher to justify to the REB the use of a particular incentive model and the level of incentives in the research. It is the REB that makes the final determination on the appropriateness of the use of the proposed incentive from an ethics perspective, taking into consideration the context of the research, the economic circumstances of the pool of prospective participants, their age and capacity, and the customs and practices of the community (see Article 9.15). In their conduct of research and ethics review, researchers and REBs, respectively, should take into consideration TCPS guidance as well as other applicable policies, rules and regulations (see Chapter 1, Research Ethics and Law).

7. Can incentives be offered as a recruitment strategy and paid regardless of whether individuals choose to become involved in the study?

TCPS acknowledges the use of incentives as a legitimate way of encouraging participation in research, but neither discourages nor encourages the use of incentives (see Application of Article 3.1). Ordinarily, incentives are given to participants after they have consented to participate in a study. It is, however, possible to provide incentives in advance of the decision to participate for recruitment purposes if the REB approves this incentive plan. For example, gift cards may be offered to a group with an invitation to participate in an online survey. In this scenario, the researcher is hoping that some portion of individuals who received the gift card will participate in the study but the payment is not dependent on participation. Individuals receive the payment regardless of whether they choose to participate in the study. The REB review should consider whether the incentive is appropriate to the participant population and whether those who do choose to participate are engaged in a study that meets all other criteria to be deemed ethically acceptable. See Consent #6 for guidance on models of incentives for recruitment and participation in research.

The financial obligations of submitting evidence of incentive distribution noted in Privacy and Confidentiality #1 apply regardless of the timing of the incentives. In situations such as the one described here where the researcher cannot be sure which individuals will become participants, and/or collects no identifying information from them (including initials on receipts), the researcher must still comply with any financial reporting requirements that apply (e.g., receipts for purchase of incentives, REB approval of incentive plan, attestation by researcher and any others involved in incentive distribution.)

8. Is it ethically acceptable to require prospective participants to consent to making their de-identified data available for future, unspecified research, as a condition of participation?

It is a relatively common practice for researchers to require prospective participants to consent to making their de-identified data available to people outside the research team (e.g., a clinical trial sponsor, an auditor) for the purposes of verification and quality control. This is considered an ethically acceptable practice.

However, on occasion, REBs are asked to permit researchers to make it a mandatory condition of participation in a study that the prospective participant consent to making their de-identified personal data available for use in future unspecified research. An example would be requiring the provision of de-identified participant data to a clinical trial sponsor for placement in the sponsor's research data repositories and use in accordance with the sponsor's data governance policies. This request to allow mandatory consent for unspecified future uses is based on the premise that there will be no future possibility to inform participants of how their data would be used.

The principle of Concern for Welfare as it relates to the welfare of society is often mentioned when advocating for the re-use of de-identified data for the purposes of future unspecified research. TCPS acknowledges (Chapter 5, Section D) the benefits of re-using de-identified data which includes:

> *avoidance of duplication in primary collection and the associated reduction of burdens on participants; corroboration or criticism of the conclusions of the original project; comparison of change in a research sample over time; application of new tests of hypotheses that were not available at the time of original data collection...*

However, when considering the potential benefit of making de-identified data available for future research, it is important to remember that "the welfare of a group should not be given priority over the welfare of individuals" (Chapter 1, Section B).

Key ethics issues to consider include the following:

a. *Risk of coercion*

   There is a risk of coercion when requiring prospective participants to consent to the sharing of their de-identified data for future unspecified research as a condition of participation in the study. This risk may be increased when, for example, in clinical trials, the experimental therapy has the potential to be of significant benefit to the participant. In such cases, the prospect of possible access to the trial may lead the prospective participant to agree to share their de-identified data when they otherwise would not have done so.

b. *Inclusion/Exclusion and the core principle of Justice*

Excluding individuals from a research study that could benefit them, solely on the basis that they refuse additional consent to storage of their data for future use, would contravene the core principle of Justice. The principle of Justice holds that individuals, groups or communities should not be unfairly excluded from the potential benefits of research participation, and that the criteria for inclusion in research must be relevant to answering the research question (Chapter 4).

Article 4.1 of TCPS notes that "Taking into account the scope and objectives of their research, researchers should be inclusive in selecting participants." The principle of Justice (Chapter 1) notes that participation in research "*...should be based on inclusion criteria that are justified by the research question. Inequity is created when particular groups fail to receive fair benefits of research or when groups, or their data or their biological materials, are excluded from research arbitrarily or for reasons unrelated to the research question.*"

For this reason, when researchers seek participants' consent, they are strongly encouraged to separate the consent to participate in a specific research project from the consent to make their data available for future unspecified research. In practice, this would mean a) providing information relevant to both their participation in research and making their de-identified study data available for future unspecified uses, and b) providing an option to consent to each separately, either through separate consent forms or separate sections on the same form (See Article 3.13). Exceptions to this requirement may be considered by REBs on a case-by-case basis and at their discretion. The onus is on the researcher to justify that mandatory consent for future unspecified research use of the data and/or human biological materials is required, and that participant autonomy and privacy, as well as the Policy's core principle of Justice are not impacted by this exception (see Consent #10, sub-question B).

In seeking the consent of participants or their authorized third party, researchers must adhere to the core principle of Respect for Persons - that individuals who participate in research should do so voluntarily, based on as full an understanding as possible of the research, its risks, and potential benefits (See Article 1.1, and Chapter 3).

For research involving distinct communities, researchers may be required to adhere to community data management principles, where they exist, or the consent process may include additional requirements to maintain respectful relationships and engagement between researchers and participants. Researchers and REBs can draw on relevant guidance in Chapter 9 of TCPS.

9. What does the requirement for REBs to review the creation of a repository mean in practice?

Article 3.13 outlines the requirements for broad consent for the storage of data and human biological materials for future unspecified research as it relates to repositories. The TCPS defines a repository as "A data repository or biobank with a known governance framework that 'must ensure safe storage, preservation and curation of the data' and human biological materials" (see TCPS Glossary). The REB's assessment of the consent form should be based on TCPS and include an ethics review to ensure that the applicable elements outlined in Article 3.13 are addressed.

The Application of Article 3.13 states that the "creation of a repository requires REB review and is subject to continuing research ethics review, in accordance with a proportionate approach to research ethics review (Article 6.14)." The REB is responsible for reviewing the ethical acceptability (see Article 6.3) of the repository's plans for ensuring that the data and/or human biological materials will be obtained, stored and shared, in a manner that is consistent with TCPS, as outlined in the consent form. Therefore, the REB is only responsible for reviewing the ethical aspects, as outlined in the consent form of the repository, as they pertain to the TCPS (e.g., consent, privacy and confidentiality, and future research that will make use of the repositories).

The creation of a repository is not considered "research" as defined by the Policy. However, it is appropriate for the REB to review the ethical aspects of the repository's consent form to ensure the data and human biological materials stored in the repository are fit for use in future research projects, which will later undergo REB review in accordance with the TCPS. The REB shall determine the appropriate submission requirements and process for the review of broad consent forms.

For the purpose of the TCPS, the term "governance" is intended to mean "Appropriate mechanisms and procedures […] to ensure that subsequent use of

the data and human biological materials is in accordance with the original terms of participant consent" (Application of Article 3.13). The appropriate governance structure and management of a repository will vary depending on its size and usage. The broader policy and procedures necessary for the creation of a repository and, when relevant, ongoing review or accreditation, are outside both the scope of the TCPS and the responsibility of the REB.

10. How does Article 3.13 apply in specific contexts?

The purpose of the new guidance around broad consent is to formally introduce the concept and the elements it includes into the TCPS. It does not impact the application of already existing guidance on topics such as privacy and confidentiality.

A. Is there a threshold between simply possessing one's own research data and the creation of a research data repository?

The term biobank, as defined in the TCPS (see Chapter 12, Section D), ranges from small collections held by an individual to large collections held by institutions. The definitions of research data repository and biobank are intended to mirror one another. Therefore, similar to a biobank, research data repositories can have a wide range of possible characteristics, but the key characteristic is the intent to share data for specific or unspecified future research purposes. Repositories must have a known governance framework to ensure safe and responsible storage, preservation, and curation of data and/or human biological materials.

While different disciplines may have their own definitions for research data repositories, the intent in the TCPS is to capture both the platform and the data archived/deposited therein. Therefore, the general principles outlined in Article 3.13 apply to all disciplines.

Researchers who collect and store data and/or human biological materials for the sole purpose of using them in the context of a specific research project would not be considered to have created a repository, as per the TCPS.

In general, data and/or human biological materials should be de-

identified (coded or anonymized) prior to depositing in a repository and sharing for future research purposes. If this is not possible (e.g., where a repository may intentionally hold onto identifiable data, such as medical record numbers), additional steps should be taken to protect participants from identification ahead of sharing the data and/or human biological materials for future research purposes.

B. How does a researcher manage consent when a participant only consents to participate in specific research, but not to the storage of their data and/or human biological materials in a repository?

The guidance found in Article 3.13, and more specifically the requirement to seek separate consent for a) the specific research project and b) the storage of data and/or human biological materials for future unspecified research aligns with Consent #8. In practice, this means providing an option to consent to each separately, either through separate consent forms or separate sections on the same form. An iterative or phased consent process may be adopted (i.e., documented ongoing discussion with participants) where the research design would permit such an approach.

Participant consent to participate in a specific research project entails the inclusion of their data and/or human biological materials in the analysis. However, if the participant does not consent to the storage of their data and/or human biological materials for future unspecified research, their data and/or human biological materials would not be placed in a repository for this purpose.

In the rare situation where a participant may decline to consent to the storage of their data and/or human biological materials for future unspecified research, the participant should generally not be excluded from participating in the specific research project on that basis (Consent #8). Exceptions to this may be considered by REBs on a case-by-case basis and at their discretion. The onus is on the researcher to justify that mandatory consent for future unspecified research use of the data and/or human biological materials is required, and that participant autonomy and privacy, as well as the Policy's core principle of Justice are not impacted by this exception.

C. Does Article 3.13 apply in the context of open repositories and data sharing with journals for publication or for purposes of verification and error detection (e.g., peer review)?

Article 3.13 applies to the storage and future unspecified use of data and human biological materials. Therefore, it does not specifically apply in the context of archiving data at the completion of a research project, depositing data in a shared/open repository or when sharing datasets in the context of journal publications for purposes of reproducibility/transparency, verification or error detection. These contexts do not necessarily imply that a new research project will be conducted using the shared data (i.e., not a situation of secondary use).

There is a distinction to be made between the storage of data (e.g., archiving) following the completion of a research project and the storage of data for future unspecified use, and this should be clearly specified in both the consent process and in the materials that are submitted to the REB for ethics review and approval. For example, where a research participant has provided consent to participate in a specific research project, this consent extends to the storage of their data for a period of time following the completion of the project (see REB Review #5), as per the terms of the consent form. This could include securely archiving the data in an institutional repository. However, if the same research participant does not consent to the storage of their data for future unspecified use, their data should not be deposited in a research data repository that serves such a purpose. If seeking consent for the deposit of existing data was not part of the consent process, researchers may need to take additional steps to address such situations (see the *Guidance on Depositing Existing Data in Public Repositories*).

The REB determines whether all elements listed in Article 3.13, or additional elements, are necessary to the consent process of a given research project. See sub-question B for considerations around exceptions to the requirement for participants to provide separate consent to participate in a specific research project and to the storage of their data and/or human biological materials for future unspecified research (either in separate consent forms or separate sections on the same form).

Note that the new guidance on broad consent aligns with the *Tri-Agency*

Research Data Management (RDM) Policy, which states that "the agencies expect researchers to provide appropriate access to the data where ethical, cultural, legal and commercial requirements allow, and in accordance with the FAIR principles and the standards of their disciplines." The *RDM Policy* also "aligns with the CARE Principles for Indigenous Data Governance (Collective benefit, Authority to control, Responsibility, and Ethics), which reflect the crucial role of data in advancing Indigenous innovation and self-determination" (Section 2, Tri-Agency Research Data Management Policy – Frequently Asked Questions).

D. Does the guidance on broad consent apply to long-standing repositories or repositories that already exist?

The guidance on broad consent applies to newly established repositories; therefore, REBs are not expected to retroactively review the ethical aspects, as outlined in the consent form, of long-standing repositories or repositories that already exist at an institution. However, it may be appropriate for REBs to review the ethical acceptability of an existing repository's consent form to ensure that data and/or human biological materials have been obtained, stored, and shared in a manner that is consistent with TCPS. For example, this could be done during the continuing review of a research project that is using data and/or human biological materials from the existing repository. As with other areas of guidance, TCPS sets out core principles and general guidelines and it is up to each institution to establish its own policies or procedures that implement those guidelines in a manner that is suited to its own context.

Fairness and Equity

1. Can a researcher justify conducting research in a specific language(s) only?

It is "the focus, objective, nature of research and context in which the research is conducted [that] inform the inclusion and exclusion criteria for a specific research project" (Application of Article 4.1). If the research is focused on a community or group that communicates in a specific language, it would be justifiable to have the research conducted and material provided in that specific language only. However, if the objective of the research is, for example, to gather the views of a cross-section of parents of hockey players in a bilingual community, then the research material and resources (including consent information and other communications addressed to participants) should be available in both languages. Making this decision is based on the extent that the inclusion of the linguistic groups is germane to answering the research question and guided by the principle of Respect for Persons in TCPS. Researchers must provide information in a language that participants can understand to be able to make an informed decision to participate in a research project in accordance with Articles 3.2 and 3.3 of TCPS.

In general, researchers should do exploratory work before conducting the research to understand the make-up of the community they wish to involve in their research. They should also inform the REB of "their strategies to familiarize themselves with the relevant norms and cultural practices (Application of Article 8.3). Though this article deals with research conducted in other countries, it applies equally to any community or participant population in any jurisdiction. It is equally important that in their reviews, REBs should have the relevant expertise and knowledge for a competent review of research material in those languages (see Article 6.5).

2. If research material will be offered to participants in more than one language, how do researchers and REBs decide what research material should be made available in those language(s)?

Deciding upon the language(s) in which research material should be made available must be determined on a case-by-case basis, based on the context of

the research and the extent to which the inclusion of all linguistic groups is germane to answering the research question. This determination should be guided by the principle of Respect for Persons in TCPS. Researchers should provide all information necessary in the language that participants understand to allow them to make informed decisions regarding their participation in research. This means making recruitment, consent and other material, if any, available in the relevant language(s). If the research has a more involved process requiring participant feedback and discussion and/or if the topic is sensitive it may also be necessary to provide translators. As stated in the Application of Article 4.1 of TCPS, where a language barrier exists between the prospective participant and the researcher, various measures, for example an intermediary, may be used to ensure effective communication in recruitment and consent discussions.

The onus is on researchers to provide a rationale regarding their plans for the provision of material or resources in any language(s) – based on the research question. The onus is also on the researcher to satisfy the REB that the proposed research material in other language(s) is accurate, appropriate and understandable for potential participants. The researcher may do so, for example, by having the material translated by a certified translator, or by having the material presented by a translator to the REB, or by attestation of a member of the participant community or by the researcher. The REB may also solicit input from an ad hoc member with the ability to understand and review the proposed material in the other language (see Article 6.5). It is then the REB's responsibility to assess the ethical acceptability of these plans on a case-by-case basis.

3. Within the context of TCPS, what are the ethical implications where research participants are funders of the research?

TCPS applies to all research within the jurisdiction or under the auspices of any institution eligible to administer funding from any of the federal research Agencies (CIHR, NSERC, and SSHRC) regardless of the source of funding. TCPS makes reference to "funding" in general. It acknowledges that the source of funding may raise ethics issues. These include issues of conflicts of interest at the institutional level, as well as at the level of researchers. TCPS advises that "researchers should not benefit financially from … sponsors" and that "REBs shall consider the potential for conflicts of interest in clinical trials because it has been

empirically established as a risk of some sponsored research and can undermine the ethical conduct of research" (Application of Article 11.10).

TCPS does not specifically address situations when participants fund the research. In the absence of specific guidance, researchers and REBs should be guided by the Policy's three core principles: Justice, Concern for Welfare, and Respect for Persons (Chapter 1, Section B).

Funders of research may be a group of participants (e.g., individuals with a common condition) who provide all or part of the funding of a research project as sponsors through a charitable organization, or based on their individual efforts to seek donations. In those cases, eligibility for participation in the study is likely not tied to payment, and not all funders are or become participants in the research. This model does not seem to raise new ethical issues beyond what is already addressed in TCPS in relation to funding.

A more direct form of participants' funding research is when a researcher makes payment a condition of participation in the research. This funding model raises ethical issues with respect to inclusion and exclusion criteria. It raises new ethical issues or exacerbates existing risks, and presents key challenges to the obligation to treat people fairly and equitably – an obligation that stems from the core **principle of Justice**. The principle of Justice holds that particular individuals, groups or communities should not be unfairly excluded from the potential benefits of research participation, and that the criteria for inclusion in research must be relevant to answering the research question (Chapter 4). **Exclusion from research solely on the basis of inability or refusal to contribute financially to the research contravenes the principle of Justice**. Limiting access to research to those able to pay may lead to preferential treatment. It may influence eligibility for participation in a study by introducing biases in recruitment and selection. Researchers may feel pressured to include participants who want to pay to participate, but who are ineligible to participate based on the inclusion and exclusion criteria of the research. This may possibly result in skewing the results of research and constraining its scientific validity.

Paying to participate in research may also result in undue pressure on participants to harness their fundraising ability, and risk unnecessary psychological and financial pressures. **Concern for Welfare**, another core principle of TCPS, requires researchers and REBs to protect the participants'

welfare including impacts on individuals' mental and spiritual health as well as economic and social circumstances (Chapter 1, Section B).

The core **principle of Respect for Persons** implies that individuals who participate in research should do so voluntarily, based on as full an understanding as possible of the research, its risks, and potential benefits (Chapter 3). Considering these issues is of particular importance in the pay-to-participate funding model. This model may raise unrealistic expectations in that prospective participants will incur direct benefits from the research having paid for it, may exaggerate benefits of the research, or may increase the risk that the research will be confused/conflated with treatment (therapeutic misconception – Article 11.6). It may undermine voluntariness to consent by presenting an undue inducement to continue in a study rather than withdraw, as withdrawal may be perceived by a participant as a loss of their investment. This would undermine the core principle of Respect for Persons, by diminishing the voluntariness of ongoing consent.

In their review of pay-to-participate research, REBs have an ethical obligation to take into account the additional risks that may be introduced by this funding model in light of the issues discussed above. As with all ethics review, the level of scrutiny shall be proportionate to the level of risk posed to participants (Article 2.9). This scrutiny may include greater initial review, more extensive continuing ethics review, and/or more frequent reporting to the REB and monitoring (Application of Article 6.14). Also, "[i]n addition to the principles and guidelines in this Policy, researchers are responsible for ascertaining and complying with all applicable legal and regulatory requirements" (Chapter 1, Research Ethics and Law).

4. What should REBs consider when reviewing research that involves the use of crowdsourcing to recruit participants?

In the context of research, crowdsourcing is a use of online services to host opportunities for a large pool of individuals to participate in research. It includes utilizing online data collection services such as Amazon Mechanical Turk, and Survey Monkey Audience amongst others. TCPS does not discuss the merits of different strategies for research recruitment because appropriateness depends considerably on context. In the absence of specific guidance, the use and review of crowdsourcing as a participant recruitment tool in research should be guided by the core principles of the Policy: Justice, Respect for Persons, and

Concern for Welfare (Article 1.1).

Following the principle of Justice, researchers and REBs should be concerned with the fair and equitable inclusion and exclusion criteria of using crowdsourcing to recruit participants in a research project. The research question should guide the recruitment process and the tools used to recruit groups/individuals targeted by the research. Researchers should satisfy their REB that using a specific participant pool is germane to answering the research question (Article 4.1). For example, if the research targets a specific socio-economic group, and the crowdsourcing pool is known for such socio-economic circumstances, this would justify the use of this recruitment tool. Mere convenience is not sufficient justification for inclusion/exclusion.

Researchers should provide relevant information on their proposed crowdsourcing recruitment method to their REBs to consider in the review of the ethical acceptability of their research. For example, for some crowdsourcing applications, incentives provided to participants may vary according to circumstances, and the researcher would not know the exact level of incentives offered to the individual participants. If relevant, researchers should explain and justify this to their REBs.

Governance

1. Which institutional body should establish the REB(s)?

TCPS requires that the highest governing body of the institution establish the REB (or REBs), define an appropriate reporting relationship with the REB (or REBs), and ensure that REBs have the necessary financial and administrative resources to fulfil their duties. TCPS does not specify which body within an institution meets this description, as the governance structures of institutions vary. However, in the application to Article 6.2, TCPS provides a range of possibilities as to who could fill this role, with a focus on the one that holds the highest administrative rather than academic responsibility. Institutions determine the highest governing body based on their individual governance structures and taking into consideration whether other responsibilities of those bodies may conflict with the responsibility for establishing an REB.

2. What is the rationale for not permitting external legal counsel from serving on an REB of an institution for which the counsel provides service?

The rationale for excluding external legal counsel from serving on a REB of the institution, regardless of the type of legal advice they provide to the institution, is the same rationale for excluding in-house legal counsel from serving on the REB. There is a danger that the lawyer's role as a legal adviser and as an REB member will become confused. The external legal counsel, even if retained by the institution only on a case-by-case basis is not immune from the pressures of being identified too closely with the institution's interests – whether its financial interest in having research go forward or its interest in protecting itself from potential liability. This presents a potential source of conflicts of interest that may undermine the independence and credibility of the REB.

For a REB to function optimally, it is important that its members, including the member knowledgeable in law, understand the role of the REB as described in Article 6.3, as well as the specific role of the member knowledgeable in law "to alert REBs to legal issues and their implications (e.g. privacy issues), not to provide formal legal opinions or serve as legal counsel for the REB" (Application of Article 6.4).

3. Can an external legal counsel, who is not currently providing legal services for the institution, serve on that institution's REB?

While not ideal, it is possible for an external legal counsel to serve as the member knowledgeable in law on the REB when he/she is no longer providing legal services for the institution. (See application of Article 6.4 for a description of the role of the member knowledgeable in law). In making a decision to appoint a former external legal counsel to the REB, the institution should take into account the following considerations:

- The amount of time lapsed since the external legal counsel last provided legal services for the institution.
- Whether other alternatives are available to the REB for obtaining the same knowledge/expertise.
- Whether the legal firm to which the external legal counsel is affiliated has an active business relation with the institution (that is, whether other lawyers from that counsel's firm are providing legal services to the institution).
- Whether the external legal counsel has an interest in getting future business from that institution.

It is prudent to keep a written record of steps taken to reach the decision to appoint this member.

4. Where an individual working under the auspices of an institution is involved in research solely as a service provider to researchers in other institutions, should the REB of that institution review the research?

The individual in question would not be required to submit the research for REB review within their institution so long as

- the individual is not a member of the research team,
- they do not benefit from authorship on publications, and
- their contribution is limited in nature to a service that does not in and of itself constitute research involving humans as defined in TCPS (see Application of Article 2.1).

If the service provider meets the above criteria, or falls within an exception set out in their institution's policy, it would be sufficient for the individual to get

confirmation from the principal investigator (PI) that this research has been reviewed by the PI's institutional REB so long as it is compliant with TCPS. Alternatively, the individual can make the provision of his/her services conditional on receiving evidence of an REB review and approval in accordance with TCPS.

5. Should institutions make REB minutes publicly available?

There is no general requirement in TCPS regarding public accessibility of REB minutes. What TCPS advises in the application of Article 6.17 is that files, minutes and other relevant documentation must be accessible to the authorized representatives of the institution, researchers, sponsors and funders under certain circumstances "when necessary to assist internal and external audits, or research monitoring, and to facilitate reconsideration or appeals." (Application of Article 6.17)

While not specific to public sharing of minutes, it should be noted that guidance in TCPS encourages institutions' transparency to demonstrate their accountability while maintaining researchers' confidentiality (see Application of Article 6.1).

6. In the case of a strike at an institution that disables the REB's ability to conduct ethics reviews, must all research stop?

Institutions are encouraged to take measures to ensure that delays do not impact the welfare of participants, in particular by increasing risks or adding new risks. Institutions should try to anticipate the impact and the demands of a strike on the functioning of the REB. Institutions are encouraged to develop mechanisms to permit the continuity of research ethics review and initiate them in case of a strike that involves the REB.

Institutions may consider developing agreements with other institutions to assume responsibility for its research ethics review in the event of a strike. In developing their procedures, institutions may consider following relevant guidance in Chapter 6, Section D of the Policy on research ethics review during publicly declared emergencies. While a strike is not a publicly declared emergency, it raises similar challenges for research ethics review in that it has a temporary impact on the normal procedures of an REB.

7. If a researcher transfers their research from one institution (where the REB initially approved an ongoing research project) to a second institution, is the researcher required to seek REB review at the second institution?

As the research involving humans is ongoing, REB review is required at the second institution, unless the institutions have authorized an alternative review model as outlined in the Application of Article 8.1. Each institution is responsible for reviewing the ethical acceptability of research involving humans conducted within their jurisdiction or under their auspices (Article 6.1). When a researcher transfers their research from one institution to another, they in effect transfer the research from the auspices of one institution to the other.

To facilitate the review, the researcher may provide the REB at the second institution with contact information for the REB at the first institution. The REB at the second institution may request documentation to facilitate and inform its review of the ethical acceptability of the research; for example, a copy of the consent documentation, evidence of ethics approval from the first institution, or a copy of the original research proposal. Alternatively in the case of minimal risk research, the REB of the second institution may accept the review of the first institution (Application of Article 8.1). The level of REB review should be guided by the proportionate approach to research ethics review (Article 6.12).

8. Do course-based research activities intended for pedagogical purposes fall within the jurisdiction of the REB?

Course-based research activities intended primarily for pedagogical purposes fall within the jurisdiction of the REB (Application of Article 2.1 and Article 6.12). Such research activities are assigned to students for the purpose of teaching them how to conduct research in a structured educational context. This includes, for example, asking students to conduct interviews to collect data to be used in a course assignment, or to practice interviewing techniques. Participants in the activities may be exposed to risks (normally minimal risk) as a result of their participation, and may not distinguish these activities from others that meet the definition of research in TCPS (Application of Article 2.1).

In keeping with a proportionate approach to research ethics review, course-based research activities of minimal risk are generally eligible for delegated review. Course-based research activities of minimal risk are unique in that TCPS allows them to be reviewed by delegates of the REB at the department, faculty or equivalent level, if authorized by the institution (Application of Article 6.12). Typically, the course instructor, as the contact person for the REB, submits an application for ethics review describing the course-based research activities, how the data will be managed, and whether the data will be used for any purpose beyond the course assignment. This would eliminate the requirement for each student or student group to submit individual applications for ethics review.

An REB that implements a delegated review process for course-based research activities "shall require that the actions and decisions of the delegated reviewer(s) be well documented and formally reported to the full REB… Accountability requires that, regardless of the review strategy, the REB continues to be responsible for the ethics of all research involving humans within its jurisdiction" (Application of Article 6.12).

Where course-based research activities pose more than minimal risk to those involved in the activities, or if the activities are later used for the purpose of research (e.g., as part of a researcher's own research program), they shall be submitted for review under the secondary use provisions following the regular institutional REB process (Article 6.12). Student theses or other equivalent research projects involving humans typically meet the TCPS definition of research (Application of Article 2.1). See also REB Review #1. They are not considered course-based activities even if they are associated with a course number. They should be reviewed by the REB following a proportionate approach.

9. According to the TCPS, what makes a REB independent?

The TCPS states that "REBs are independent in their decision making and are accountable to the highest body that established them for the process of research ethics review" (Article 6.2). Independence of an REB means independence in its ability to review and make decisions on the ethical acceptability of research without undue influence or interference. Institutions must ensure that the governance and necessary supports are in

place to ensure that REB independence is established and maintained. Operationally, "the highest body within an institution shall establish the REB or REBs, define an appropriate reporting relationship with the REBs" [see Article 6.2; also see Governance #1 for guidance on which institutional body should establish the REB]. The highest body of the institution must also secure necessary financial and administrative resources for the effective and continuous operation of the REB without interfering with, or influencing its independence in its decision-making on the ethical acceptability of research. To maintain the independence of the REB in its ethics review and decision-making, 'institutional senior administrators' must not serve on the REB nor should they interfere with the REB deliberations and decisions (Article 6.4). Their intervention or their presence in a room where the REB is making decisions can influence the decision-making process, and undermine the independence of the REB in fulfilling its role.

While the REB should be independent in its decision-making on the ethical acceptability of research, this does not mean that it is independent from the institution. The REB is created by the institution, draws its authority and resources from the institution, and is accountable for the integrity of its processes to the institution. Operationally, the institution "should establish a mechanism to coordinate the operations of all its REBs, and clarify their relationship…with other relevant bodies or authorities" (Application of Article 6.3). While research ethics administration staff are dedicated to supporting the functions of the REB, they are also accountable to the institution on administrative and operational matters.

To balance the independence of the REB in its decision-making with its accountability to the institution, TCPS states that "Institutions shall have in place written procedures for the appointment, renewal and removal of REB members, including Chairs" (Application of Article 6.2). Ideally, such procedures should be developed in consultation with those affected by, or involved in, its implementation. In addition, TCPS encourages effective communication processes to be established between REBs and relevant officers of their institutions. In managing this communication, "REBs and senior administrators should consider other venues [other than REB meetings] to discuss policy issues, general issues arising from the REB's activities, or training and education needs, to the benefit of the overall operation and mandate of the REB" (Application of Article 7.3).

Multi-Jurisdictional Research

1. If a researcher obtains REB approval at their own institution to gather data from participants who are members of other institutions, is it necessary to have the research reviewed by REBs of the institutions that employ the participating members?

The issue to consider is whether the research is being conducted within the jurisdiction or under the auspices of the other institutions in addition to the researcher's own institution. The determining factors include (1) the extent and nature of the other institutions' involvement, and (2) whether it is necessary for the researcher to collaborate with the other institutions in order to carry out the research.

If the researcher is seeking the collaboration of staff from other institutions and/or using the resources of those institutions (e.g., bulletin boards, email lists, meeting rooms, equipment) to recruit members of the institution or for the purposes of data collection, then the research would be under the auspices of these other institutions. The research would require ethics review by the REB(s) of the other institutions in addition to the researcher's REB (see Article 8.3). The level of REB review may be adjusted in accordance with a proportionate approach to research ethics review (see Article 6.12).

However, if recruitment and/or data collection involving an institution's members as prospective participants is done through other means that do not involve the resources of the institution, the research would not fall under its auspices and would not be subject to review by its REB(s). For example, if names and emails of faculty or department heads are publicly available on websites or through some disciplinary association and the researcher uses this information to recruit them as participants, then REB review at the researcher's institution would suffice. Similarly, if the researcher approaches members of the institution in a public space outside the institution for recruitment and/or data collection (e.g., on-the-street survey), the researcher would only need approval from his/her home REB.

Note that research that involves members of the institution for the purposes of critical inquiry does not require the permission of the institution (Article 3.6).

If the research falls under the jurisdiction or within the auspices of more than one

institution, then researchers should consult the REB(s) and/or research ethics offices at the institutions in question to determine the requirements for research ethics review.

2. Three researchers conduct separate but related research that has been approved by their respective REBs. When their separate data collection is complete, they share their results and publish a paper together. Is this considered multi-jurisdictional research requiring REB review based on guidance in TCPS?

If the three researchers are intending to collaborate from the start, the research project should be characterized from the beginning as multi-jurisdictional research with procedures set out for safeguarding participant privacy in the context of data sharing/linking/management (Article 5.7), and following guidance in Article 8.3. If the three researchers initially conduct separate research projects and collaboration is only discussed at the results and dissemination stage, the researchers are introducing a change to their approved research (Article 6.16). The researchers should consult their REBs to determine whether the change to the way the research data/results/findings are shared, pooled, stored or disseminated is a change to what the participants agreed to in their initial consent, the ethical implications of that change and what impact it has on the level of risk to participants. The REBs should also decide whether the research would be considered multi-jurisdictional research.

In making this determination, REBs should take into consideration: what information is being shared, in what form (e.g., raw, aggregate, coded, anonymized) for what purpose, whether data linkage is involved, whether the sharing of results has ethical implications and/or introduces risks for participants, whether participants have been or should be informed about the sharing of their data, and depending on the identifiability of the information being shared, whether follow-up consent may or may not be necessary. If the change to the research is substantive, researchers must submit it to their REBs who "shall decide on the ethical acceptability of those changes to the research in accordance with a proportionate approach to research ethics review" (Article 6.16).

3. In multi-jurisdictional research, if a researcher is involved in collecting data relevant to a small component of the overall research project, should that researcher's REB review the entire project or only that

component?

In multi-jurisdictional research, in the absence of an official agreement between institutions or an approved model for single or streamlined review of multijurisdictional research (Application of Article 8.1), each institution's REB is responsible for reviewing the entirety of the research. By reviewing the research in its entirety, the REB will have sufficient details to fully assess the risks to participants and the potential benefits of the research. This will enable the REB to fully understand the ethical implications of the research, and to make an informed judgement on its ethical acceptability. (Article 6.1).

4. If a health care professional at an institution makes a patient aware of research being conducted at another institution, is REB review required at the health care professional's institution?

REB review is not required at the health care professional's institution so long as:

- the health care professional is not on the research team; and
- any participation in the research is initiated by the patient.

In making the patient aware of the research project, the health care professional's actions are analogous to those of a service provider (Governance #4). The health care professional can, on the advisement of the patient, communicate directly or share patient information with the research team. This may be the case, for example, to facilitate the assessment of the patient eligibility to participate in the research.

Privacy and Confidentiality

1. In seeking reimbursement for expenses related to incentives offered to research participants, how can researchers meet their financial obligations of submitting evidence of incentive distribution without compromising participants' confidentiality?

Researchers have an ethical duty of confidentiality to participants which includes safeguarding their information (Article 5.1). Researchers must also satisfy their institutional financial reporting requirements for the use of funds to pay for incentives to participants. To satisfy both obligations, researchers may submit a coded list of participants who received incentives. This would offer a degree of privacy protection for participants while providing an acceptable audit trail for the use of funds. The code (e.g., a sealed envelope containing participant initials or signatures, and dates and amounts of incentive distribution) can be made available upon request to third-party auditors. An acceptable audit trail should also include the researcher's application to the REB, detailing the incentive plan (amount of incentive, number of participants, method of distribution), the REB's letter approving the ethical acceptability of the research, receipts for purchase of non-monetary incentives, an attestation by the researcher (and/or anyone else involved in the distribution of incentives) as to the number of participants who received incentives (including dates and circumstances), and, where appropriate, the aforementioned coded list. This is consistent with guidance in TCPS that requires relevant documentation of REB records to be accessible for legitimate reasons including "when necessary to assist internal and external audits" (see Article 6.17).

Participants' identifying information, signed receipts and other forms of proof of receipt of incentives that have the potential to identify them as participants must be safeguarded by researchers in a location separate from participants' data, or where required by the institution, equally protected by staff with responsibility for safeguarding financial information (see Article 5.4).

In the event that the institution requires researchers to provide documentation that includes identifiable information about individual participants, this should be reflected in the consent process so that prospective participants can be informed about who has access to their identifying information (see Article 3.2).

Further details related to financial administration can be found in the *Tri-Agency Guide on Financial Administration*.

2. What is the nature and extent of institutions' responsibilities under Article 5.1 to "support their researchers in maintaining promises of confidentiality" where complying with legal obligations would conflict with those promises?

Key elements of this interpretation have been integrated into TCPS Application of Article 5.1

For the purposes of clarity, the main question has been broken down into five components:

A. What are the responsibilities of researchers, REBs and institutions with respect to privacy and confidentiality?

Researchers, REBs and institutions share the responsibility for protecting participant confidentiality. Researchers' responsibilities include safeguarding participant information and anticipating any reasonably foreseeable disclosure requirements. Researchers shall "avoid being put in a position of becoming informants for authorities or leaders of organizations." See Article 5.1 and Article 5.2.

REBs' responsibilities include reviewing the ethical acceptability of the research protocol, including any privacy and confidentiality commitments. See Article 5.3 and Article 6.1.

Institutions are responsible for creating and maintaining a supportive research environment, establishing appropriate institutional security safeguards, training researchers and REBs regarding best privacy practices and implementing policies, procedures or guidelines that guide and support researchers and REBs in protecting participant confidentiality. See Article 5.1, Article 5.4, Article 6.2, Article 6.7 and the Agreement on the Administration of Agency Grants and Awards by Research Institutions.

B. Why are institutions required to support researchers?

The researcher conducts research under the auspices of the institution. The REB is appointed by the institution as its vehicle for reviewing research projects to ensure their ethical acceptability. In granting its approval for a study, the REB triggers the responsibility of the institution to support researchers in their commitment to protect participant confidentiality (see Article 6.1 and Article 6.2). Use of an alternative model of REB review (e.g., delegating review to an external REB) does not relieve the institution of this responsibility. Institutions that have adopted alternative review models remain responsible for the ethical acceptability and ethical conduct of research undertaken within their jurisdictions or under their auspices (Article 8.1).

C. What are the institution's responsibilities when there is a conflict between ethics and legal obligations?

In some circumstances, a third party may seek to compel disclosure of participant information obtained in confidence in a research context, through the force of law (e.g., by subpoena or search warrant). The section on Research Ethics and Law in Chapter 1 of TCPS advises that researchers "should…if necessary, seek independent legal advice to help resolve any conflicts between law and ethics, and guide an appropriate course of action." Article 5.1 requires institutions to "support their researchers in maintaining promises of confidentiality." When read together it becomes clear that institutional support includes providing the means for researchers to obtain independent legal advice where such advice is required. For the purposes of this Policy, "legal advice" includes all legal services that a researcher in this situation may require, including representation. In situations where there is an attempt to compel disclosure of confidential participant information by legal means, institutional support consists of providing researchers with financial and other support to obtain the independent legal advice which permits the researcher to make an informed decision as to whether to disclose or to resist disclosure of confidential participant information. If resisting disclosure is warranted, institutional support includes the independent legal advice, which makes that resistance possible, or ensuring that such support is provided.

D. Why is it important for the researcher to obtain independent legal advice?

When researchers face situations where their ethical duty of participant confidentiality and legal obligation to disclose confidential participant information cannot be reconciled, the purpose of independent legal advice is to advise them on the personal consequences of a possible decision to respect ethical principles rather than legal obligations. Such legal advice should be independent of any advice to the institution.

E. How can the institution fulfill its responsibilities?

In situations where there is an attempt by legal means to compel disclosure of confidential participant information, TCPS requires institutions to provide researchers with financial and other support to obtain independent legal advice or to ensure that such support is provided.

As with other areas of guidance, TCPS sets out general guidelines and each institution establishes policies or procedures that implement those guidelines in a manner that is suited to its own individual needs and resources. Institutions should consider whether research being conducted under its auspices or within its jurisdiction is likely to put researchers in a position where they may experience tension between the ethical duty to maintain participant confidentiality and the legal obligation of disclosure of confidential participant information. Where that likelihood exists, the institution should establish policies, procedures or guidelines that explain how it will fulfill its responsibilities to support its researchers. They should include an explanation of the nature and the scope of the support, a mechanism to determine the level of support in individual cases, the source of funding (e.g., dedicated fund, insurance, agreement with professional association) and any other relevant criteria. The institution should establish such policies, procedures or guidelines in collaboration with its researchers.

Summary

Article 5.1 states: "Institutions shall support their researchers in maintaining promises of confidentiality." When there is a conflict between researchers' ethical duty of participant confidentiality and a legal obligation of disclosure of confidential participant information, institutions must provide financial and other support for researchers to obtain independent legal advice or ensure that such

support is provided. Institutions should establish policies, procedure or guidelines that explain how they will provide that support.

3. Is it ethically acceptable to conduct research on an anonymous basis if it may foreseeably trigger legal reporting obligations?

It is ethically acceptable to conduct research that may foreseeably trigger legal reporting obligations on an anonymous basis if it is the only way that participants will consider participating in the research and provide honest responses. If it allows identification of participants, it is unlikely that research could be conducted effectively on such matters as sexual abuse, violence, reportable infectious diseases, and other topics that may foreseeably trigger legal reporting obligations. Important knowledge and insights from research would consequently be foregone.

TCPS acknowledges that researchers may face situations where they experience a tension between the requirements of the law and the guidance of the ethical principles of TCPS. The Policy advises that "in such situations, researchers should strive to comply with the law in the application of ethical principles" (see Chapter 1, Section C, Research Ethics and Law). While the research should not be designed to avoid an obligation to report, neither should it necessarily be structured in such a way as to make the researcher an investigator on behalf of the authorities. As TCPS states "Researchers shall avoid being put in a position of becoming informants for authorities or leaders of organizations." (Application of Article 5.2)

An ethical balance must be struck between, on the one hand, the goals of protecting privacy and obtaining honest responses and, on the other hand, concern that some of the participants may be in need of protection or that they may present a threat to themselves or to others. An appropriate ethical balance could be achieved for example by giving participants the option to identify themselves to researchers. Participants may be informed that they are not required to identify themselves for the purpose of research, but they may do so if they wish. It should be made clear to participants that if they include their identifying information in the consent process, and the data collected reveal they are being abused or analyses reveal a reportable infectious disease for example, that researchers must, by law, share this information with the responsible authorities. If participants are experiencing abuse, neglect or

otherwise want to reach out for help, this option allows them to do so.

As part of the consent process, researchers should also consider providing information about services available to participants who are experiencing harm, are harming others, or are at imminent risk of harming others. Participants could be informed about services available to provide counselling and assistance in abusive situations. If participants choose not to identify themselves, information about those services would give participants an alternate way to seek assistance.

4. What is the difference between 'anonymous' and 'non-identifiable' information as defined in TCPS?

'Anonymous information' and 'non-identifiable information' have different definitions for the purposes of TCPS. Anonymous information is "information [that] never had identifiers associated with it … and the risk of identification of individuals is low or very low" (Chapter 5, Section A). TCPS defines information as non-identifiable "if it does not identify an individual, for all practical purposes, when used alone or combined with other available information … The assessment of whether information is identifiable is made in the context of a specific research project" (Chapter 5, Section A).

An important distinction between the two definitions is that 'anonymous' is a type of information that does not change relative to a specific research project, while the assessment of whether information is 'non-identifiable' may differ depending on the context of a specific research project. For example, the secondary use of coded information may identify individuals in research projects where the researcher has access to the key that links the participants' codes with their names. However, the same coded information may be assessed as non-identifiable in research projects where the researcher does not have access to the key.

In general, research that relies exclusively on secondary use of anonymous information is exempt from REB review (Article 2.4). Research that relies exclusively on secondary use of non-identifiable information generally requires REB review. However, consent is not required for this type of research (Article 5.5B).

REB Review

1. Can the delegated review process applicable to minimal risk course-based research also apply to minimal risk undergraduate and graduate thesis research?

To fall within the delegated review of minimal risk course-based research activities (described in the Application of Article 6.12) , the intent of the activity should be primarily to provide students with exposure to their field of study (e.g., interviewing techniques), as part of their skill development. If such activities are used for the purposes of research they should be reviewed according to the regular institutional REB procedures. Theses involving human participants typically meet the TCPS definition of research requiring REB review and should be reviewed by the REB following a proportionate approach outlined in Article 6.12. Regardless of the review strategy, the REB continues to be responsible for the ethical acceptability of research involving humans within its jurisdiction.

2. When does REB-approved research no longer require ongoing REB review?

TCPS does not make a determination regarding the stage at which REB review and approval would no longer be required. The reason for not making this determination is that research projects, disciplines, or methods of study vary, and the duration of the involvement of humans as research participants also varies. For the purposes of REB involvement, the end of the project involving human participants may be defined as the point after which there is no further contact between the researcher and participants, taking into account the risk of the research to participants. The end-point for REB involvement might come, for example, at the end of data collection when the researcher has no intent of further contact with participants or after data analysis. In some cases, researchers report back to participants, or to the community or group from whom they collected data. In these cases, contact with participants would only end after data analysis, interpretation of findings, and dissemination. REB involvement would likely end at this point. These are only illustrative examples, and are not intended to be an exhaustive list of scenarios.

Institutional ethics policies should include provisions that assist REBs, researchers and the institution to determine when continuing research ethics review is no

longer required. Such provisions should take into consideration the different types of research designs (short-term project, longitudinal research, research with reporting back requirements, etc.). They should also consider issues such as the extent of any remaining risk to participants, the nature of the plans (if any) for future interaction with participants; the status of any commitments or agreements made to participants, for example, with respect to reporting findings; and/or the relative likelihood of future unanticipated events, material incidental findings, or information.

3. How should the REB proceed if a researcher does not submit an annual report and continues to conduct research in the absence of a renewal of REB approval?

The researcher's failure to submit an annual status report means that the researcher would not be in compliance with TCPS requirements regarding continuing ethics review (Article 6.14). At the time of its initial review of research, an REB determines the frequency of continuing ethics review (Article 6.14) and communicates it to the researcher. While an institution may put in place a system for notifying its researchers that their ethics approval is about to expire, it is the researcher's responsibility to maintain ethics approval for his/her study throughout the life of the project.

If the researcher has been notified that ethics approval for a study will expire by a certain date and fails to submit a report by the specified date, the REB has the authority to terminate its approval of the ethical acceptability of the research (Article 6.3). The REB should notify the institution of its decision to terminate its approval. It is up to the institution to determine how it will proceed to ensure the non-compliant research is either brought into compliance or is stopped. REBs should also confer with the institution's designated point of contact for matters pertaining to the responsible conduct of research to discuss whether the situation needs to be addressed in accordance with the institution's policies on responsible conduct of research (see Roles and Responsibilities #3).

4. How should the REB proceed if there are substantive changes to ongoing research and the researcher does not seek ethics approval for those changes?

If the change to research is a necessary reaction to an unanticipated event

Article 6.15 would apply. If the change is a result of a researcher's planned deviation from the original study Article 6.16 would apply. In either case, the nature of the change from the approved research will determine when the researcher should have informed the REB or sought reed research ethics approval. In both cases, if earlier notification was required and the date of the unanticipated issue report or the request for change has passed, the researcher would be conducting research not in compliance with TCPS. The REB may formally notify the researcher and the institution that its approval for the research is suspended or revoked and may investigate whether the level of risk to participants was altered or increased as a result of the unreported change. It is up to the institution to act to ensure that the non-compliant research does not proceed. The REB should also confer with the institution's designated point of contact for matters pertaining to the responsible conduct of research to jointly determine how to proceed (see Roles and Responsibilities #3).

5. What is the appropriate duration for data retention in TCPS?

TCPS does not specify the required length of time for retention of research data. Data retention periods vary depending on the research discipline, research purpose and kind of data involved. TCPS underscores the importance of data retention as a matter to be considered by REBs in their review of studies that collect identifiable personal information about research participants (see application to Article 5.3) In TCPS, a number of factors are relevant to defining periods of data retention. Researchers' plans for preserving or destroying participants' data should be appropriate to the field of research in light of its best practices and professional, ethical and legal norms. Relevant tri-Agency policies should also be respected. For example, under Division 5 of the Health Canada Food and Drug Regulations which pertains to clinical trials of drugs, sponsors are required to maintain records for a period of 25 years. As another example, in the Tri-Agency Open Access Policy on Publications (2015) CIHR requires grant recipients to retain original data sets arising from CIHR-funded research for a minimum of five years after the end of the grant.

6. When does the following become eligible for delegated review: "annual renewals of more than minimal risk research where the research will no longer involve interventions to current participants, renewal does not involve the recruitment of participants, and the remaining research activities are limited to data analysis."

The response to this interpretation has been superseded by a text in TCPS. See Application of Article 6.12 for guidance on this topic.

7. Can TCPS be interpreted broadly to allow annual ethics review of more than minimal risk research by delegated review so long as there has been little or no change in the study and no increase in the risks?

Key elements of this interpretation have been integrated into TCPS Application of Article 6.12

Delegated review is acceptable for annual renewal of research involving more than minimal risk so long as:

1. there have been little or no changes to the research, with no increase in risk to or other ethical implications for the participants since the most recent review by the full REB, and
2. the REB Chair remains responsible for determining if the delegated review process is appropriate.

While the Panel on Research Ethics recognizes that the Application of Article 6.12 states explicitly that delegated review should only be used for minimal risk research, the Panel has considered other guidance in TCPS in arriving at the above interpretation. This includes whether full board annual review is necessary for the protection of participants (Concern for Welfare, Respect for Persons and Justice) if there have been no substantive changes to the study and no increase in risks or other ethical implications since the most recent review by the full REB. It is also based on the notion of proportionality in ethics review, that "is intended to direct the most intensive scrutiny, time and resources, and correspondingly, the most protection, to the most ethically challenging research" as outlined in the Application of Article 2.9. Where no change in risk has occurred since the most recent full REB review, the same level of scrutiny is no longer needed.

The REB Chair is responsible for making a determination of the level of research ethics review (full board or delegated review) as outlined in the Application of Article 6.12: "It is the REB, based on its established procedures and through its Chair, that decides on the level of review for each research proposal." Article 6.14 is also relevant: "At the time of the initial review, the REB has the authority to determine the term of approval and the level at which continuing ethics review

occurs in accordance with a proportionate approach to research ethics review."

REBs should respect other relevant guidelines/policies (such as the International Conference on Harmonization Good Clinical Practices - ICH-GCP) that may require a full REB review of the annual renewal of specific types of research.

8. Can ethics review be delegated for research involving only a small number of participants?

The decision of whether to delegate research ethics review is a function of the level of risk, not the number or the source of prospective participants. When it is determined that research poses minimal risk to participants, an REB may authorize a delegated research ethics review in accordance with its institution's policies and written procedures (Article 6.12).

9. Does research involving ancient human skeletal remains require REB review?

Research involving ancient human skeletal remains is research involving humans and falls within the scope of TCPS. As stated in TCPS, REB review is required for "research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living **and deceased** individuals" (Article 2.1 (b)) [*emphasis added*].

REB review is not required if the research involving ancient human skeletal remains "relies exclusively on secondary use of anonymous information, or anonymous biological materials" and "so long as the process of data linkage or recording or dissemination of results does not generate identifiable information" of a community or group (Article 2.4). Where there is a reasonable prospect that the data linkage will generate identifiable information, REB review is required.

10. What key ethics issues should the REB consider in the review of self-study research?

The REB must assess the ethical acceptability of self-study by considering its foreseeable risks, its potential benefits, and the ethical implications of the

research. The researcher may be the sole participant, e.g., a researcher writing a self-study of his/her experience camping alone in the woods. REBs should assess the level of risk that the researcher is willing to assume to himself/herself.

Some self-studies may also involve others with whom the researcher interacts or studies. The level of involvement of others in the research determines whether they are also research participants as defined in the Policy (Application of Article 2.1). If the REB determines that others are involved as research participants, the REB must assess how the researcher plans to manage the consent process. In general, researchers must seek participants' consent to participate in the self-study. In some exceptional circumstances, the researcher may request an alteration to consent requirements if s/he satisfies the REB that the provisions of Article 3.7A are met. In general, if the material on which self-study is based (e.g., journal entries, recollections) was not originally intended for research, but is later proposed for research purposes, then the consent of the individual(s) and/or communities involved, if any, must be sought.

Out of concern for welfare, regardless of whether or not they meet the definition of research participants, others mentioned in the self-study have a right to privacy protections. Individuals and/or groups mentioned in the study may not be aware that their interactions with the researcher would be included in a research project. The REB should assess whether the dissemination of the research could lead to the identification of individuals and/or communities, and may pose additional risks to participants' and non-participants' privacy and confidentiality. This assessment should also consider the research context, and the level and relevance of privacy protections to others mentioned in the self-study. For example, participants, or other individuals implicated in the research, who seek or expect public acknowledgement of their contributions may not have the same expectations or needs for privacy protections.

As with any research that poses risks of identification, the researcher and the REB should work together to minimize and/or manage these risks to individuals and communities who are mentioned in the self-study research (e.g., remove identifiable information, disguise names and identities). See also Scope #13.

11. What should a REB consider when reviewing a research study involving the secondary use of non-identifiable information?

"Information is non-identifiable if it does not identify an individual, for all practical purposes, when used alone or combined with other available information" (Chapter 5, Section A). Research that relies exclusively on the secondary use of non-identifiable information is subject to REB review in accordance with Article 5.5B. When reviewing research that relies on secondary use of non-identifiable information, an REB must review whether the research respects the terms of consent under which the participants initially provided their data, if this information is available. REBs must also assess the potential for new risks that may not have been foreseeable, and that arise as a result of the secondary use of non-identifiable information in the new research context, particularly "[p]rivacy concerns … when information provided for secondary use in research can be linked to individuals, and when the possibility exists that individuals can be identified in published reports, or through data linkage." (Chapter 5, Section D)

REBs should consider factors that may contribute to new risks in the new research context and that can harm participants – the source of the data – or the group or community to which they belong. The risk of re-identification may be heightened with the rapid technological advances that make it harder to achieve anonymity, or where the research targets information about a distinct population such as a cultural group. The re-identification risk may also increase where the data is about a group with unique conditions such as a rare disease, or with unique characteristics such as a geographical location, or where the data contains sensitive information related to, for example, violence or sexual practices.

REBs should also assess measures that the researchers propose to minimize any new risks associated with the secondary use of non-identifiable information in new research contexts. REBs may require that researchers engage in discussions with people whose perspectives or expertise can help identify the ethical implications of the research, and suggest ways to minimize any associated risks. For example, "[w]here the information can be identified as originating from a specific community or a segment of the Indigenous community at large, seeking culturally informed advice may assist in identifying risks and potential benefits for the source community" (Article 9.21). REBs may determine that community engagement is required in accordance with Articles 9.1 and 9.2 to seek guidance on secondary use of information originating from the Indigenous community, unless the researchers satisfy the REB that secondary use is

consistent with an existing research agreement (see Article 9.20).

REBs should also recognize that secondary use of non-identifiable information may have potential benefits for participants, groups or communities to which they belong. This should be taken into account in the review of the balance of risks and benefits of the research.

See also Scope #17 and Guidance on Depositing Existing Data in Public Repositories.

12. Does TCPS require that researchers submit an amendment to their REB when a change to the composition of the research team occurs during the course of research?

As stated in TCPS, and highlighted in public interpretations (REB Review #2, #3, #4), the role of the REB does not end with the provision of an initial ethics review. Specifically, "research ethics review shall continue throughout the life of the project" (Article 2.8). The life of a project includes "all stages of a research project" (Application of Article 2.8). It does not end with the completion of data collection, but also includes data analysis, as well as result interpretation and dissemination.

Researchers are required to "submit to their REBs in a timely manner requests for substantive changes to their originally approved research" (Article 6.16). Thus, it is the responsibility of the researcher to determine whether a change to the composition of the research team is substantive and should be submitted to the REB for review. Determining whether it constitutes a substantive change depends primarily on a consideration of the information that formed the basis of participants' consent.

TCPS2 does not specifically require that the names of all members of the research team be mentioned in the consent process. According to the Application of Article 3.2, the information generally required for informed consent includes, amongst other things, "the identity of the researcher, the identity of the funder or sponsor, [and] an indication of who will have access to information collected about the identity of participants". This includes informing prospective participants about whether the researcher plans to share research data with individuals outside of the research team, or deposit the data in an

open-access public repository after data collection is complete (*Guidance on Depositing Existing Data in Public Repositories*). Providing this information is important to ensure that consent is informed (Article 3.2) and ongoing (Article 3.3).

Therefore, a key question that researchers should ask themselves when considering whether they shall inform the REB of a change to the composition of their research team is the following:

Considering the specific context of the research and the information provided to participants during the consent process, does this change constitute a departure from what participants consented to in the first place?

To answer this question, researchers may need to refer back to their documentation of the consent process. Most of the time, changing the composition of the research team does not constitute a substantive change to the terms of consent. However, where it does, the researcher must submit an amendment to the REB. This would be the case, for instance, where the information initially provided to participants about who would have access to their data was very specific, and the researcher now wishes to provide such access to more or different people.

Subsequently, where it is determined by the REB that this information is relevant to participants' ongoing consent, the researcher shall work with the REB to determine whether participants must be informed, and if so, which participants to inform, and how to inform them (Articles 6.15 and 11.8).

These requirements still hold even if the REB has previously determined that continuing ethics review is no longer required. Some institutions may have additional administrative requirements regarding changes to approved research. When facing uncertainty in determining whether a change to the composition of the research team may cause participants to reconsider their consent and require an amendment, the researcher should reach out to the REB for guidance.

Research Involving FNIM

1. Can guidance in Chapter 9 for research involving FNIM peoples also apply to other communities?

Chapter 9 on research involving the First Nations, Inuit and Métis (FNIM) peoples of Canada acknowledges the unique status of the Indigenous peoples of Canada as recognized and affirmed in the *Constitution Act, 1982,* and their experience with research historically. While Chapter 9 is designed to guide research involving those communities, its discussion of respectful relationships, collaboration and engagement between researchers and participants may also be an important source of guidance for research involving other distinct communities. The need to respect a community's cultural traditions, customs and codes of practice may extend beyond FNIM communities. REBs and researchers may draw on articles of Chapter 9 that are of relevance to the particular community involved in the research.

Roles and Responsibilities

1. What are the responsibilities of researchers according to TCPS?

Researchers have a responsibility "to ensure that research involving humans meets high scientific and ethical standards that respect and protect the participants" (Chapter 1, Ethics Framework, A. Importance of Research and Research Ethics). This responsibility does not end when a study receives REB approval but continues for the entire lifecycle of the research. For research participants, researchers are the front line representatives of research ethics and have primary responsibility for implementing the core principles of TCPS: Respect for Persons, Concern for Welfare and Justice.

Researchers affiliated with an institution eligible to administer Agency funds are expected to be knowledgeable about TCPS guidance relevant to their research, and to apply this guidance to the design and conduct of their research. Researchers should ensure that all team members under their supervision are trained to conduct ethically acceptable research in accordance with TCPS (Application of Article 6.14). They should also be aware of their professional and other institutional responsibilities, as well as their legal obligations in the conduct of their research.

2. What responsibility does the researcher have in sharing the results of research with research participants?

The TCPS recognizes the importance of sharing the results of the research with participants, and states that "informing participants of the research results is as important as dissemination of results to the research community." (Preamble of Article 4.8). Researchers are strongly encouraged to offer to participants an accessible summary of research results, unless it is impracticable to do so (e.g., when participants or their authorized third party may be deceased, or difficult to track due to insufficient identifiers, cost, or time elapsed). REBs are also strongly encouraged to ask researchers to include in their initial application their plan to share the research results with participants, and to report on its implementation in their final report to the REB.

In general, there are benefits to sharing at least a summary of the research results with participants. Disseminating the results of research may contribute to building participants' and society's trust in research. Sharing a summary of the results also respects participants who volunteered their time, effort, and information to research, and acknowledges their contribution and assumption of risk. There may be a benefit to the participants of knowing a summary of results, even if there is uncertainty that the results may apply to them. For example, sharing a summary of a study that finds that 60% of participants in a trial of radiation for a disease develop another disease or condition is useful for participants to know, so they recognize the value of following up regularly with their physician. A summary of results may also afford the researcher an additional opportunity to inform participants of the potential benefits of the research, and its probable impact on the participants' and others' wellbeing. In doing so, researchers adhere to the core principles of Respect for Persons, and Concern for Welfare.

The format of sharing the results should respect the core principle of Justice in treating participants equitably. The Policy states that the "[R]esults of the research should be made available to them [participants] in a culturally appropriate and meaningful format, such as reports in plain language in addition to technical reports" (Application of Article 4.8). A number of options and formats exist for the researcher to provide copies or access to publications or lay summaries to the participants. For example, the researcher may consider providing the summary results directly back to the participants, indicate a website to which the participants may go to retrieve results, or provide face-to-face results directly or in a group setting. Where possible and appropriate, a permanent record, paper or electronic, is preferred such that participants can reference these reports in the future.

In some contexts, researchers may wish, or may have a duty, to share the individual research results with participants (see incidental findings addressed in Article 3.4). In addition, key guidance on disseminating research results to Indigenous communities can be found in Articles 9.11, 9.17 and 9.22. In some areas of research, such as genetics, the ramifications of research results go beyond the individual participant to involve others with whom the individual shares genetic ancestry. For this type of research, researchers should be guided by the provisions relevant to sharing research results with and beyond participants– see Article 13.2 and other guidance in Chapter 13.

3. What process should institutions and REBs follow when a concern arises with respect to a possible breach of TCPS?

For ease of reading, the response to this question has been broken down into sections.

A. Introduction

Most researchers conduct their research with human participants responsibly and in accordance with the *Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans (TCPS)*.

A failure to respect the guidance in TCPS may constitute a breach of the *Tri-Agency Framework: Responsible Conduct of Research (RCR Framework)*. When a concern arises that a researcher may have breached a provision of TCPS, institutions and their REBs must work together to ensure both due process and consideration of participant welfare.

This interpretation seeks to clarify the distinct, but sometimes overlapping roles of institutions and their REBs, when responding to such concerns.

B. What are the main responsibilities of institutions and REBs when addressing allegations that a researcher may have breached TCPS?

Section 4 of the *RCR Framework* indicates that the Institution is responsible for conducting an inquiry or investigation into allegations of breach of the *RCR Framework*. This includes allegations of breach of TCPS. It is the Institution's designated point of contact for RCR matters ("RCR Contact") or their delegate that takes the lead in coordinating the inquiry and/or investigation.

In the event that the inquiry or investigation confirms that a breach of TCPS has occurred, the Institution is also responsible for: a) ensuring that measures for rectifying or mitigating the breach are carried out, b) imposing a recourse, if warranted, against those who were found to have committed a breach, and c) reporting to the Agencies, through the Secretariat, when Agency funds are involved.

At the same time, Article 6.3 of TCPS gives REBs the authority and

responsibility to approve, reject, propose modifications to, or terminate any research involving humans at the Institution. This responsibility is essential to safeguarding participant welfare.

Good communication between REBs, REB administrators, and RCR contacts is essential in order to ensure that the inquiry and, if necessary, the investigation are carried out smoothly and that research participants are protected throughout.

B.1 REB

The REB's specific responsibilities may vary according to the nature of the allegation. They may include:

- informing the RCR contact of the concern as soon as possible, if the REB is the first to become aware of the concern;
- collaborating with the RCR inquiry/investigation process by:
    - providing any relevant documents to the RCR Contact, or his/her delegate, upon request;
    - responding to questions posed by the RCR contact or his/her delegates; and/or
    - providing advice on matters such as how to interpret TCPS2 and appropriate measures for participant protection.

To avoid the perception of conflict of interest, REB members and Chairs should not sit on investigation committees for allegations relating to research that they or their Board had a role in approving.

If the research is still active, the REB should decide independently, based on the information available to it through communication with the RCR contact, whether to suspend its approval of the research, or allow the research to continue, while the Institution's inquiry or investigation is underway and after it has been completed. The decision will depend on the nature of the allegation and whether the alleged breach has the potential to affect the safety of participants.

B.2 Institution

As part of its responsibility to conduct an inquiry or investigation, the Institution must appoint an individual or committee, depending on circumstances, to gather evidence, interview affected parties, determine the facts of the matter, and make a determination as to whether a breach of TCPS occurred.

If the process confirms that TCPS was breached, the Institution must determine actions to be taken in response. Examples of such actions may include, but are not limited to:

- taking disciplinary action against those who committed the breach;
- ensuring that measures to correct the research record are taken;
- requiring those who committed the breach, and possibly other parties at the Institution, to take further training in research ethics and RCR;
- determining how to manage the data that was collected while the researcher was in breach of TCPS; and/or
- taking measures to minimize or mitigate harm to research participants.

The Institution should work closely with the REB to obtain all evidence relevant to its investigation.

It should provide the REB with any information that the REB may require to fulfil its mandate under Article 6.3 of TCPS.

In addition, the Institution should seek the REB's advice when it makes decisions about matters for which the REB has expertise, for example, measures to mitigate harm to participants.

C. Do REBs have the authority to take actions against a researcher personally?

The REB's authority is with respect to the research itself, not the researcher. While an REB has the authority to suspend or terminate approval of a research project, actions such as requiring a researcher to seek additional training in research ethics, or requiring the researcher to destroy research data, are the Institution's responsibility.

D. Are there any TCPS compliance situations that REBs may address directly, without referring the matter to the Institution's RCR contact for an inquiry or investigation?

It may be possible for an REB to address certain concerns with TCPS compliance, for example, an overdue annual report. REBs and institutions should discuss these situations on a case-by-case basis before determining how to proceed or, if they occur frequently, establish written policies and procedures to address the most common situations.

E. What information about RCR matters should institutions share with REBs?

Institutions have the responsibility and the discretion to determine what information may be shared about an RCR matter and with whom. The Institution's decision may depend on a number of factors including, but not limited to, provincial legislation, institutional policies, and the provisions of collective agreements.

Scope

1. Does TCPS apply to any organization or individual who plans to carry out research involving humans?

As indicated in the introduction to the Policy, TCPS applies to all research conducted under the auspices of any institution that is eligible to receive and administer research funds from any of the three federal Agencies (the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada). Eligible institutions are those that have entered into the *Agreement on the Administration of Agency Grants and Awards by Research Institutions* with the Agencies.

An eligible institution is responsible for the ethical conduct of research undertaken by its faculty, staff or students, regardless of where the research is conducted. This means that TCPS applies to Agency and non-Agency-funded research, as well as non-funded research, that takes place under the auspices of the eligible institution and its affiliates. Typically, eligible institutions include Canadian universities, colleges and affiliated hospitals.

Other organizations have chosen to adopt the TCPS to guide the ethical conduct of research involving humans that falls within their institutional jurisdictions. For example, some private REBs and other federal government entities such as Health Canada, the National Research Council, and the Department of National Defence have done so. In academic and other settings where TCPS applies, it is often one of several norms that complement applicable legal, institutional, and professional standards.

2. Does program evaluation require REB review?

REB review would be required only if program evaluation falls within the definition of research or serves as a component of a research project. Although program evaluation may share some methods and techniques with those employed in research (such as data collection and data analysis), the intent and objectives of the data collection, as well as the further use of the collected data, may be determining factors for establishing whether it is research and

whether it should be reviewed by an REB. The determination of whether an evaluation study is research and therefore requires REB review should be made on a case-by-case basis, and should be guided by the definition of research in TCPS (see Application to Article 2.1). TCPS exempts from REB review program evaluation activities normally administered in the ordinary course of operation of an organization (see Article 2.5). If the collected data for such activities is later proposed for research purposes, it is considered secondary use of information not originally intended for research, and may require REB review at that time. Where in doubt about the applicability of TCPS or the requirement for REB review of a particular research project, the researcher should consult the REB.

3. Should researchers affiliated exclusively with institutions located outside of Canada be required to obtain REB approval in Canada when conducting research involving human participants in Canada?

TCPS does not require researchers affiliated exclusively with institutions located outside of Canada to undergo REB review in Canada unless at least one of the following is true:

- The research is conducted under the auspices of a Canadian institution eligible to receive and administer research funds from one of the three federal research Agencies (the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada) (see Scope #1);
- The funding comes from, or is administered through, an eligible Canadian institution;
- At least one of the research collaborators is affiliated with an eligible Canadian institution.

However, even in the absence of these conditions, access to research sites and research participants should be determined on a case-by-case basis, considering the local context. Some non-eligible institutions have voluntarily adopted TCPS or require ethics review by a private REB. It is the responsibility of researchers to determine whether access to the research site or its members is subject to research ethics approval from any such body. Moreover, even if not subject to TCPS, researchers conducting research in Canada are subject to applicable laws, regulations, and policies, including but not limited to those

concerning the protection of privacy of participants, confidentiality, and the capacity of participants to consent.

4. How do researchers and REBs judge that a space described in a research proposal is a public place qualifying for exemption from REB review as specified in Article 2.3?

The assessment of whether a space is a public place must be made on a case-by-case basis. The first consideration is whether the space in question is open to the public and intended to serve the public (e.g., stadium, planetarium, beach, museums, parks, or library). The second key consideration is whether the proposed research fulfills the three conditions of the exemption in Article 2.3: a lack of researcher involvement/interaction with the individuals or groups concerned, a lack of any reasonable expectation of privacy, and the impossibility of identifying specific individuals in the dissemination of research results. If all conditions are met, the proposed research involving the observation of people in a public place would be exempt from REB review. If there is any doubt as to whether a particular condition has been satisfied, for example whether the people being observed have a reasonable expectation of privacy, then the proposal should be submitted to the REB for consideration.

5. Should surveys conducted by administrators rather than researchers under the auspices of an eligible institution be submitted for REB review?

It is the intended purpose of the survey that determines the requirement for REB review, not the role of the person administering it. TCPS does not provide for any exemption from REB review based on who conducts the research. If it is determined that the intended purpose of administering the survey is research, then it would require REB review (Article 2.1). If the survey is normally administered as an operational requirement for quality assurance, quality improvement, or for program evaluation purposes, then it would not require REB review (Article 2.5), because the survey would not be considered "research" as defined in this policy. Also refer to Scope #2.

6. What is the meaning of "disciplined inquiry" in the definition of research in TCPS?

This interpretation has been integrated into the TCPS under Application of Article 2.1.

7. Does publishing the results of a quality assurance study in a journal determine whether it is research, and whether it requires REB review?

Publishing or otherwise disseminating the results of an activity is not a factor that determines whether the activity is research or not (Application of Article 2.1). Publishing the results of a quality assurance study or another activity in a relevant journal (e.g., quality assurance and program evaluation journals) may inform other studies, but does not alter that the main purpose for which the study was conducted is for quality assurance/another activity. To qualify as research as defined in TCPS, the study must seek to address a research question that may extend knowledge to other programs. REB review is not required for quality assurance activities on the basis that such studies do not meet the TCPS definition for research when those activities are "used exclusively for assessment, management or improvement purposes" (Article 2.5). Such activities may, however, raise ethical issues that would benefit from careful consideration by an individual, or a body other than the REB, capable of providing some independent guidance e.g., in professional or disciplinary associations. When in doubt about the applicability of TCPS articles to a particular project, researchers shall seek the opinion of the REB for a final determination (see Application of Article 2.1).

8. Is it ethically acceptable to recruit participants for a dual purpose: a quality improvement study and research?

It would be ethically acceptable to recruit participants for the purpose of both quality improvement and research if the relevant guidelines of both activities are respected. Article 2.5 describes activities (e.g., quality improvement, program evaluation, performance reviews) that may use methods and techniques similar to research but are not considered research as defined by TCPS. The same activities, when conducted for the purposes of research, require

REB review prior to recruitment and/or data collection. If the researcher plans to use data collected for both a research and a non-research activity, this must be made clear in the consent process, and other distinguishing elements should be managed – such as the voluntariness of consent (Article 3.1). If individuals are mandated to participate in the non-research activity (as a condition of admission to an educational program, for example), the researcher must provide the prospective participants with the option of either consenting or refusing to allow their data to be used for research purposes.

9. Is it ethically acceptable to use information for the purpose of research if it was originally collected for another purpose?

The use of information originally collected for a purpose other than the current research purposes is considered secondary use of information and is acknowledged in TCPS. Secondary use of information has the potential to avoid duplication of primary data collection and the associated burdens on participants (Chapter 5, Section D). An REB must review the ethical acceptability of the research involving secondary use of information; including issues of privacy (see Articles 5.5A, 5.5B and 5.6). For example, data collected from students by institutions for program evaluation or quality improvement purpose but later proposed for research purposes would be considered "secondary use of information not originally intended for research, and at that time may require REB review in accordance with this Policy" (Application of Article 2.5). Similarly, the requirement for REB review applies to information that may have been collected for a specific research purpose and is later proposed for a new research purpose.

10. Are researchers required to follow guidance in TCPS even if their research is exempt from REB review?

The Introduction to the Policy states: "Researchers are expected, as a condition of funding, to adhere to the TCPS." Further, the Introduction of Chapter 2 describes the purpose of the Policy as follows: "to establish principles to guide the design, ethical conduct and ethics review process of research involving humans". Ethics review is therefore only one component of TCPS guidance. Consequently, researchers affiliated to institutions eligible for Agency funding are responsible for complying with all TCPS guidance relevant to their research, even if their research is exempt from REB review. See also Scope #1.

11. Does public health surveillance require REB review?

Public health surveillance is the systematic collection, analysis, and interpretation of health-related data for the planning, implementation and evaluation of public health practice. The TCPS definition of research is "an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation" (Article 2.1). Although public health surveillance may share some methods and techniques with those employed in research (such as data collection and data analysis), the intent and objectives of the data collection, as well as the further use of the collected data, are determining factors for establishing whether it is research as defined in TCPS. Activity that is conducted in support of a public health program or under the jurisdiction of a public health authority and that does not have research as a primary goal, does not fall within the TCPS definition of research and does not require REB review.

Activities outside the scope of research subject to REB review as defined in this Policy may raise ethical issues that would benefit from careful consideration by an individual or body capable of providing independent guidance. These ethics resources may be based in professional or disciplinary associations.

12. In interviewing staff at an organization for a research project, researchers are collecting both public information and personal opinions from staff members. Does this research require REB review?

Research that relies exclusively on public information that meets the definition and criteria in Article 2.2 (publicly available and protected by law, or in the public domain with no expectation of privacy) does not require REB review. Research that relies only on seeking information that staff normally provide as part of their work duties (e.g., a Parks and Recreation staff member providing lists of parks with hiking trails) does not require REB review, as the staff are not considered participants in research as defined in TCPS (Application of Article 2.1). In this case, the information is the focus of the research, not the views of the staff member.

However, where researchers are collecting public information and asking staff members to provide personal opinions outside the scope of their job roles, their research must be reviewed by an REB. This follows guidance in TCPS that states

that "individuals are considered participants because they are themselves the focus of the research. For example, individuals who are asked for their personal opinions about organizations, or who are observed in their work setting for the purposes of research" (Application of Article 2.1).

13. Does self-study research require REB review?

Self-study done for the purpose of research, as defined in the Policy, and involving human participants falls within the scope of TCPS, and requires REB review (Application of Article 2.1). Self-study typically involves a scholarly reflection on one's own experiences in a particular context. Self-study may involve narratives, reflections and/or analyses of experiences based on the researcher's observations of, interactions with, or information about other individuals or communities. In self-study, at least the researcher is a research participant. See also REB review #10.

14. When does creative practice require REB review?

TCPS defines "research" and "creative practice". Research is defined as "an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation" (Application of Article 2.1). Creative practice is defined as "a process through which an artist makes or interprets a work or works of art" (Application of Article 2.6). When research incorporates creative practice methods, it requires REB review. When creative practice activities incorporate research methods, REB review is not required. When the activity has a dual purpose of research and creative practice, REB review is required.

If an activity is being carried out as a form of expression for an artistic purpose, e.g., a theatrical work or video that involves interviewing people, then it is creative practice even if research methods, such as questionnaires, are being used, and even if a form of knowledge is being generated. This type of activity does not require REB review. If the activity is being done for research purposes then it is considered research, even if creative practice methods are being used.

The distinction between research and creative practice is not always clear, and remains a challenging issue in practice. The final assessment of whether an activity is research is the responsibility of the REB, in collaboration with the

individual proposing the project, and must be made in the context of the specific project under consideration.

15. Does product testing involving humans require REB review?

Product testing requires REB review if it falls within the definition of research, or serves as a component of a research project, and involves humans as participants in the testing of the product. The TCPS defines research as "an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation" (Application of Article 2.1). Human participants are "those individuals whose data, biological materials, or responses to interventions, stimuli or questions by the researcher are relevant to answering the research question(s)" (Application of Article 2.1).

The purpose of the product testing determines whether it falls within the definition of research. For example, a project designed to understand factors affecting the acceptance of a product that employs a repeatable and rigorous method of investigation, and involves human participants in a process or experiment designed to assess those factors, falls within the definition of research involving humans. However, if the sole purpose of the product testing is to assess or improve its quality, such as improving the design of the product to make it more consumer-friendly, then the intent of the activity is for quality assurance/quality improvement. While the product testing in this case may employ similar methods as those used in research, its intent is for a purpose other than research, and therefore it falls outside the scope of TCPS, and does not require REB review (Article 2.5).

Where the product testing activities have a dual purpose – to improve the design of a product, and to answer a research question – the activities fall within the scope of TCPS, and REB review is required. If in doubt about the applicability of TCPS or the requirement for REB review, researchers should consult their REB.

16. Is REB review required for research that relies exclusively on information unauthorized for public release, but available in the public domain?

TCPS exempts from REB review research that "relies exclusively on information that … is in the public domain and the individuals to whom the information refers

have no reasonable expectation of privacy" (Article 2.2b). Research involving information that has made its way into the public domain, but has not been authorized for public release must be reviewed by an REB, as it does not meet the second condition set out for this exemption. While the released information may now be in the public domain, the individuals who contributed this information may have had a reasonable expectation of privacy when they provided their data.

In their review of the ethical acceptability of research that relies exclusively on information in the public domain but unauthorized for public release, REBs should weigh the potential benefits to society against the foreseeable new risks that the re-use of this information in research may introduce to the involuntary participants. For example, the re-use of this information for the purpose of research may exacerbate the harm caused by the original privacy breach. REBs should make this assessment on a case-by-case basis, taking into account the nature of the information proposed for use in the research, and the circumstances of the individuals who contributed this information.

REBs should not prohibit research simply because the research is unpopular, looked upon with disfavour by a community or organization in Canada or abroad or because the research involves critical assessments of public, political or corporate institutions and associated public figures. There "may be a compelling public interest in this research" (Application of Article 3.6).

17. Is secondary use of de-identified information stored in a research data repository exempt from REB review?

Generally, secondary use of de-identified information stored in research data repositories for future research purposes would not qualify for the exemption from REB review outlined in Articles 2.2 and 2.4.

Applicability of Article 2.2

Article 2.2a specifies two criteria for the exemption from REB review to apply: that the information (i) is "publicly available through a mechanism set out by legislation or regulation", and (ii) "protected by law". De-identified information stored in a research data repository for secondary use would not typically meet the description of "publicly available through a mechanism set out by legislation or regulation". In addition, those responsible for guarding the data may not meet the definition of a "custodian/steward" in the TCPS. The TCPS clarifies that a custodian/steward is "designated in accordance with access to information and privacy legislation who protects privacy and proprietary interests associated with the information" (Application of Article 2.2).

Article 2.2b also specifies that REB review is not required for research that relies exclusively on information that is (i) in the "public domain" and (ii) "individuals to whom information refers have no reasonable expectation of privacy." Both criteria must be clearly met in order for the exemption to apply.

The extent to which a research data repository may be considered to be in the public domain depends on how access to this information is managed. This can range from freely available without any requirement for REB review or for specific permission to use this information (i.e., no barriers at all), or accessible if a person formally requests and is granted access in accordance with established criteria.

With respect to expectations of privacy, it should be noted that even information that is easily accessed by members of the public may be associated with expectations of privacy, particularly if the terms of consent are unclear. When participants provide informed and voluntary consent to sharing their de-identified information in a repository, this generally suggests that participants have been informed of, and understand, the protections that the researcher will put in place to protect their privacy, and have consented to these measures. If the privacy expectations of individuals to whom the information refers are unclear or contested, however, then research relying on their information would require REB review.

Applicability of Article 2.4

The narrow exemption from REB review in Article 2.4 is limited to the exclusive

reliance of the research on secondary use of anonymous information. Anonymous information is defined in the TCPS as, "the information never had identifiers associated with it" (Chapter 5, Section A). Anonymous information is distinct from de-identified information where identifiers existed but were removed. Therefore, the exemption from REB review outlined in Article 2.4 does not apply to the secondary use of de-identified information stored in repositories.

See also REB review #11 and *Guidance on Depositing Existing Data in Public Repositories*.

18. Do the Agencies require eligible institutions to comply with any research ethics norms other than the TCPS?

Institutions eligible to administer funding from any of the three federal research funding Agencies (the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada – the Agencies) are required to comply with the TCPS for all research involving human participants conducted under the institutions' auspices or within their jurisdiction (TCPS Introduction). Failure to comply with the requirements of the TCPS by researchers or their institution may result in a recourse by the Agencies, as set out in the *Tri-Agency Framework: Responsible Conduct of Research* (RCR Framework).

In addition to the requirements of the TCPS, researchers and their institutions may be subject to other research ethics norms. For instance, researchers may be subject to professional standards, or consensus guidelines, such as the *ICH Consensus Guideline for Good Clinical Practice ICH E6(R2)*. Private and public organizations may also voluntarily choose to adopt other standards or complementary research ethics norms beyond the TCPS. For instance, they may require that their REBs comply with the *HRSO standard for Ethical Review and Oversight of Human Research (CAN/HRSO-200.01-2021)*. However, the Agencies do not require eligible institutions to adopt or comply with such other standards or research ethics norms.

The mandate of the Panel on Research Ethics, an interagency advisory body created by the Agencies, is the interpretation, education, and evolution of the TCPS. As a collective body, the Panel does not develop, endorse, or implement

research ethics norms beyond the TCPS. However, individual members of the Panel may be involved in such work independent of their advisory role to the Agencies. When they do so, they do not represent the Panel or the Agencies.

Compliance with other research ethics norms does not diminish the protections provided by the TCPS and cannot serve as a replacement for compliance with the TCPS by eligible institutions. Where the TCPS appears to be silent on a particular issue, or there is uncertainty about the meaning and significance of the content of the TCPS, the research community may seek clarification from the Secretariat on Responsible Conduct of Research.

19. Does all citizen science research require REB review?

Citizen science is a broad approach that can be applied to research within and beyond the scope of TCPS. From their home, their backyards or with academic researchers, members of the public of all ages can engage in citizen science. Citizen science is an umbrella term describing a variety of ways in which members of the public can be involved in research by contributing to a project led by researchers. For researchers, citizen science is a means to access expertise or spaces that would otherwise be challenging or impossible to access. In citizen science, members of the public have a unique role in research—they can be participants, and they can also share responsibilities in the design and conduct of the research. This public interpretation addresses this situation.

According to the TCPS, research requires REB review if 1) it is "an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation"; and 2) it involves "human participants" (Article 2.1). Citizen science therefore requires REB review if it constitutes research involving human participants. Some citizen science projects however, do not fall within those definitions or the scope of the TCPS. An example would be projects where members of the public are called upon to collect data, otherwise inaccessible to researchers, such as reporting the number of birds seen or heard at a chosen location. This may not be considered research involving human participants if members of the public are solely assisting in collecting data that does not pertain to themselves or to other human participants. Other projects, such as those that require members of the public to wear a pedometer to count their steps, are considered research involving human participants since those are

"individuals whose data, biological materials, or responses to interventions, stimuli or questions by the researcher, are relevant to answering the research question(s)" (Article 2.1). Even if a citizen science research project does not fall within the scope of TCPS, researchers are encouraged to follow its core principles—Respect for Persons, Concern for Welfare, and Justice.

For ease of reading, the response to the above question has been sub-divided into sections.

A. How to define citizen science?

In citizen science, members of the public contribute to research out of interest in the topic that the research team is studying. They are part of a research team. While several terms, each with their own definition, are used in the scientific literature to discuss research involving members of the public, the TCPS uses the phrase "collaborative research" as an all-encompassing term that can apply to any research that relies on members of the public having responsibilities in the research. Collaborative research is defined in Article 9.12 as involving "respectful relationships among colleagues, each bringing distinct expertise to a project. Collaboration often involves one of the partners taking primary responsibility for certain aspects of the research, such as addressing sensitive issues in community relations, or scientific analysis and interpretation of data." While this definition is presented in the context of Chapter 9, it is not limited to research with Indigenous communities and can be applied to any research that involves members of the public. Citizen science is one among many types of collaborative research.

B. What is the role of a member of the public in citizen science?

In citizen science, a member of the public can be both a participant and a researcher, and can switch between roles during different stages of the research. Members of the public can be participants when their data, biological materials, or responses to interventions, to stimuli, or to questions asked by a researcher are relevant to answering the research question(s) (Chapter 2). Members of the public can also be researchers by engaging in all, or some, of the following activities: identifying a research question; designing the research; gathering, analyzing, or interpreting data; and/or disseminating research results.

In the context of citizen science, and in this interpretation, the term "partner" is understood as referring to a member of the public who has responsibilities in a research project based on the partnership formed with the researcher. This term promotes collaborative working relationships in research and emphasizes the importance of establishing those relationships through research agreements, whether formal or informal. Partners can contribute to a research team and project in various ways—for example by sharing their expertise or providing access to spaces otherwise challenging or impossible to access. Such involvement deserves some form of acknowledgment from others in the research team. Regardless of the research design, researchers and partners share responsibilities during the life cycle of a research project.

While academic researchers should be aware of their responsibilities under the TCPS, members of the public may not. Thus, it falls to the researcher to ensure that partners recruited from the public are made aware of their responsibilities and are acknowledged for their contributions.

C. What are the potential risks for partners?

Researchers who want to involve partners in their research team must consider the potential risks such individuals incur, so that they can be mitigated throughout the life cycle of their research. This includes considering how a partner may be impacted by combining the roles of participant and partner. The potential risks that could evolve over the course of the research should be considered, addressed and mitigated before initiating a partnership, and discussed throughout the life cycle of the research. Examples of potential risks may include, but are not limited to:

i. Power sharing and decision-making

Based on different backgrounds and experiences, partners and researchers may have expectations about each other's roles and responsibilities throughout the research, and their approaches to power sharing and decision-making may differ. Conflicts may also arise among research team members (which can include partners) if

they have divergent interests about the data collected, stored, analyzed or disseminated. Researchers and partners should aim to have open communication from the outset to limit the risks of establishing an unbalanced partnership. There should be a clear description of decision-making authority.

ii. Intellectual contribution, property, ownership of data, and copyright assignments

A major element that distinguishes partners from participants is the nature of the contribution that partners make to research. Ownership of data collected, recognition of intellectual property of research outputs, and copyright assignments are aspects of research that researchers may need to reflect upon before seeking partners and throughout the life cycle of the project. When recruiting potential partners, clear limits to partner access to these elements should be communicated from the outset of the research project.

iii. Acknowledgment and recognition of partners' contributions and involvement

Partners invest time, energy, and expertise into a citizen science research project. Just like participants, partners are sometimes offered incentives to be involved in research. Recognition of partner contributions could include acknowledgement in publications, to a token of appreciation, to co-authorship, to financial remuneration. Expectations should be communicated to potential partners at the time of recruitment.

iv. Conflicts of interest, data access, and confidentiality

Real, perceived, or potential conflicts of interest (Chapter 7) and confidentiality issues (Chapter 5) may arise when partners have competing interests about the data they have collected or analyzed. Partners may be biased due to their role or position in their everyday life. Researchers should have open communications with partners to discuss these interests and ways in which they can be managed. In addition to research team members having to consider and disclose their own conflicts of interest, research teams should remember that partners may also have conflicts of interest, even if these are not

financial in nature (see TCPS Glossary).

By involving multiple partners in research, researchers are potentially exposing the data collected to a large number of individuals, therefore increasing the potential risks of privacy and confidentiality breaches. Moreover, privacy laws and regulations can affect how data should be handled. Early in the research process, research teams should identify who can access the data, as well as if, when, and in what format data will be made available to partners and team members. The responsibilities of data stewards, data producers and data analysts may be separated between different individuals for a citizen science research project; partners may be called upon to collect, handle or analyze data. Institutions also have an interest in safeguarding data (Article 5.4). Researchers may need to take into consideration how these responsibilities interact when involving partners.

D. How can a research agreement help define partnerships?

One way to address the potential risks mentioned in section C above would be for researchers and partners to enter into an understanding through a research agreement. While research agreements are strongly encouraged for research involving Indigenous communities, they could also be used for citizen science research project with non-Indigenous participants and partners, in other contexts. "Research agreements serve as a primary means of clarifying and confirming mutual expectations" (Article 9.11). They serve as a tool for all parties involved in research and help define roles and responsibilities for both parties, as well as mechanisms to address issues that may arise.

Research agreements, which may take various forms, can be a useful tool to define the extent of a partnership between researchers and partners. While research agreements can be legally binding, they are also a tool to clearly define expectations, roles, and responsibilities and facilitate communications to resolve issues that may arise over the course of the research. Entering into a research agreement would serve as an opportunity to articulate ways to mitigate potential risks, such as the decision-making process, or how contributions will be recognized. Proactive communication between researchers and partners at the time

of recruitment into the research project is an important means of setting expectations before any contributions are made.

That being said, research agreements may not always be necessary. The level of scrutiny applied to a citizen science research project should follow a proportionate approach to research ethics review, as per TCPS, taking into consideration the foreseeable risks, the potential benefits, and the ethical implications of the research in question.