

KING'S RESEARCH ETHICS REVIEW COMMITTEE TERMS OF REFERENCE

(Revised April 2022)

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Summary

Sections 1-4: Governance Structure, Scope, and Jurisdiction of King's RERC

These sections outline the governance structure, scope, and jurisdiction of King's Research Ethics Review Committee (RERC) as outlined in the 2018 edition of Canada's federal compliance government governing the responsible conduct of research involving humans issued by Canada's Panel on Research Ethics: <u>Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2018)</u>.

Sections 5-9: RERC Commitments

These sections outline the RERC's commitments to Academic Freedom; principles of equity, diversity, inclusion, and decolonization (EDID); confidentiality; managing conflicts of interest; and availability for consultation. The commitments complement and enhance the guidance provided in TCPS2-2018.

Section 10: Human Ethics Training Commitments and Requirements

This section outlines the human ethics and responsible conduct of research training commitments and requirements for both 1) members of the RERC and 2) members of the King's community conducting human research that requires RERC review, approval, and oversight. The primary aim of this training is to ensure that research conducted at King's is conducted in an ethical, respectful, and safe manner meeting the professional standards established by academics working at Canadian post-secondary institutions. The secondary aim is to avoid unnecessary delays in RERC review and approval that can sometimes result from a lack of understanding by RERC members or those applying to the RERC about the human ethics requirements relevant to the studies proposed.

Section 11: Summary of RERC Duties

This section summarizes the core duties of the RERC and, in particular, outlines some of the processes the RERC commits to follow in carrying out its duties and serving the King's community.

Section 12: Navigating Expressions of Research Ethics Concerns or Complaints

This section outlines the process that the RERC will follow should concerns or complaints related to human research ethics be brough to its attention. It clarifies that the RERC will follow the procedures outlined in the appropriate collective agreements at King's such as the "Guide to the Proper Conduct of Research at King's University College" (as appended to the KUCFA Collective Agreement in effect at the time of the complaint) or the *King's Student Code of Conduct*. It clarifies how the RERC's processes will respect existing mechanisms of due-process and avoid unnecessary duplication of policies and procedures while still meeting its own unique responsibilities to ensure ethical and safe conduct of research while such processes are carried out.

A Note on the Inclusion of Text from TCPS2-2018

Previous versions of the Terms of Reference merely made mention to TCPS2 and only sometimes indicated specific sections that were relevant to the terms being presented. While this practice lends itself to a shorter and more succinct document, a significant drawback is that it forces the reader to independently navigate TCPS2-2018 to provide important context and/or language that can be important for conducting ethical research and/or preparing applications for RERC review, approval, and oversight.

This version of the Terms of Reference departs from this practice and instead made a concerted effort to reproduce (with appropriate citation) important passages from TCPS2-2018 within this document itself. This prevents the reader from having to switch between documents and so will hopefully also make it easier to clarify governance, policy, and process questions when they arise.

A Note on Policy vs. Procedure

This document primarily refers to policy governing the structure, decisions, and procedures of the RERC. It does not aim to provide an exhaustive account of the RERC's procedures. A comprehensive and complete account of those procedures will be provided and regularly maintained as a Standard Operating Procedures (SOP) document to be published on King's RERC website.



1 Preamble:

Canadian federal research funding is distributed through three separate funding agencies known collectively as "the Tri-Agencies": Social Sciences and Humanities Research Council (SSHRC), Natural Science and Engineering Research Council (NSERC), and the Canadian Institutes for Health Research (CIHR). To be eligible to receive Tri-Agency funding, Canadian institutions, such as King's, must abide by the requirements mandated by the Tri-Agencies' "Panel on Research Ethics". The Panel on Research Ethics produces the national guidelines for human research ethics with the most recent guideline entitled <u>Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2018)</u>. Occasionally, the Panel on Research Ethics also publishes authoritative <u>Interpretations</u> of TCPS2.

TCPS2-2018 requires institutions to establish an independent body to review, approve, and oversee all human research included within the scope of TCPS2-2018. TCPS2-2018 states the following:

The highest body within an institution shall: establish the REB [research ethics board] or REBs; define an appropriate reporting relationship with the REBs; and ensure the REBs are provided with necessary and sufficient ongoing financial and administrative resources to fulfill their duties. REBs are independent in their decision making and are accountable to the highest body that established them for the process of research ethics review. (TCPS2-2018, Article 6.2)

In accordance with the requirements of TCPS2-2018, King's has established the Research Ethics Review Committee (RERC) to act as King's independent decision-making body responsible for the review, approval, and oversight of all research activities within its jurisdiction as defined in TCPS2-2018 (jurisdiction is described below). While independent in its decision making, King's RERC is accountable (through its Chair) to King's Faculty Council for the execution of its duties under TCPS2-2018 and the efficiency and effectiveness of its operations.

Operationally, King's RERC will be supported through the Academic Dean's Office. Through King's budgetary process, the Office of the President, in consultation with the Chair of the RERC, will ensure that the RERC is provided adequate funds and resourcing to carry out its duties as defined in TCPS2-2018. Funding and resourcing will be proportionate to the data-informed forecasted demand for RERC review and oversight. Data related to RERC demand and service-response is to be provided by the RERC Chair to the Office of the President annually.

The fundamental obligations of the RERC are:

- 1. To ensure the protection of the dignity, wellbeing, and rights of human research participants in all research activities carried out by people affiliated with King's (faculty, staff, or students) or carried out using King's' resources.
- 2. To help members of King's conduct research activities in accordance with the Guidelines set in the <u>Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans TCPS2 (2018)</u> through constructive collegial feedback and through proactive educational initiatives.

The committee aims to carry out these fundamental obligations in a collegial and participatory way.

TCPS2-2018 provides a synopsis for the core obligations of any research ethics review committee, the tensions that the RERC will sometimes have to navigate with the help of the ethical principles outlined in TCPS2-2018, and the collegial and participatory approach required to navigate such issues. It states:

The importance of research and the need to ensure the ethical conduct of research requires both researchers and REB members to navigate a sometimes difficult course between the two main goals of providing the necessary protection of participants and serving the legitimate requirements of research. The three core principles that express the value of human dignity [Respect for Persons, Concern for Welfare, and Justice] provide the compass for that journey. Their application will help ensure that a balance between these two goals is maintained. Applying the core principles will also maintain free, informed and ongoing consent throughout the research process and lead to sharing the benefits of the research. These results will help to build and maintain the trust of participants and the public in the research process. (TCPS2-2018, Chapter 1B, Article 1.1).



2 RERC Jurisdiction:

2.1 Jurisdiction:

According to TCPS2-2018, an institution's independent research ethics board's authority and accountability (i.e., its "jurisdiction") extend *only* to research activities carried out by people formally affiliated with that institution ("faculty, staff or students") and/or using the institution's resources "regardless of where the research is conducted". (TCPS2-2018, Article 6.1)

2.2 Multi-Jurisdictional Review

TCPS2-2018 Chapter 8 outlines guidelines for cases where research activities are being conducted by people affiliated with various institutions and/or using resources from multiple institutions. Under TCSP2-2018 each institution's REB maintains its independence, and each is accountable for independently ensuring the appropriate approval and oversight of the research activities for which its affiliated people and/or resources are involved. REB's can (and should) communicate and coordinate their independent reviews; however, no REB is bound by the decisions of another REB.

TCPS2-2018 Chapter 8 allows for multiple REB's to enter formal arrangements of Delegated or Reciprocal ethics review. Under such agreements, REB's can accept the decisions of a partnered REB without conducting its own review. At this time, such formal agreements are rare in Canada. In the absence of such formal agreements, each institution's REB must conduct its own review and approval for any activities involving people affiliated with the institution and/or the institution's resources.

Western University is a legally distinct institution from King's with its own independent research ethics boards. There is currently no formal agreement in place for Delegated or Reciprocal ethics review between King's, Western, or any of Western's other affiliates, and so projects involving people from these various institutions must be submitted to each institution's REB for separate review, approval, and oversight.

Western does have a formal agreement in place with Lawson Health Research Institute (LHRI) which allows Western's Medical REB to also act as LHRI's REB. Therefore, projects that also involve people affiliated with LHRI will need to submit to Western's medical REB following the joint procedures laid out by LHRI and Western.

3 RERC Scope: Activities requiring research ethics review, approval, and oversight

The scope of activities requiring review, approval, and oversight of an independent research ethics board are defined as follows in TCPS2-2018 Article 2.1:

Article 2.1: The following requires ethics review and approval by an REB before the research commences. Research involving:

- a. living human participants;
- b. 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.

TCPS2-2018 defines "research" as follows:

For the purposes of this Policy, "research" is defined as an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation. The term "disciplined inquiry" refers to an inquiry that is conducted with the expectation that the method, results and conclusions will be able to withstand the scrutiny of the relevant research community. For example, a study seeking to explore the narratives of teens coping with mental illness would be evaluated by the established standards of studies employing similar methods, technologies and/or theoretical frameworks. (TCPS2-2018, Article 2.1)

All research activities involving living human participants or human biological materials must be submitted for review, approval, and oversight by an independent research ethics board having jurisdiction over the activities **except for** research the solely employs activities under the following exceptional categories (TCPS2-2018, Articles 2.2-2.6):



3.1 Category A: Research Exempt from Research Ethics Board Review (Articles 2.2-2.4)

The following research activities, considered in isolation from any other associated activities, are deemed exempt from RERC review:

1. Research activities relying exclusively* on information:

- a. "publicly available through a mechanism set out by legislation or regulation and that is protected by law (ex. information gathered through Freedom of Information requests, data provided through Statistics Canada, records released by Libraries and Archives Canada); or
- b. in the public domain and the individuals to whom the information refers have no reasonable expectation of privacy." (TCPS2-2018, Article 2.2)

2. Research activities exclusively* "involving the observation of people in public places where:

- a. "it does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups;
- b. individuals or groups targeted for observation have no reasonable expectation of privacy; and
- any dissemination of research results does not allow identification of specific individuals." (TCPS2-2018, Article 2.3)

All other activities falling under TCPS2's definition of "research" and conducted by people affiliated with King's and/or using King's' resources are subject to review, approval, and oversight by King's RERC.

*As soon as any other non-exempted research activities are included in the research activities, the research project as a whole will require RERC review, approval, and oversight.

3.2 Category B: Non-Research Activities Employing Methods and Techniques Similar to those Used in Research

TCPS2-2018 identifies two kinds of activities that is does not consider "research" under its definition, even though such activities may use methods and techniques similar to those used in research.

1. Assessments of Organizational Performance Used Exclusively for Internal Organizational Management (Article 2.5)

a. "Article 2.5 refers to assessments of the performance of an organization or its employees or students, within the mandate of the organization, or according to the terms and conditions of employment or training. Those activities are normally administered in the ordinary course of the operation of an organization where participation is required, for example, as a condition of employment in the case of staff performance reviews, or an evaluation in the course of academic or professional training. Other examples include student course evaluations, or data collection for internal or external organizational reports. Such activities do not normally follow the consent procedures outlined in this Policy. If data are collected for the purposes of such activities but later proposed for research purposes, it 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. Refer to Section D of Chapter 5 for guidance concerning secondary use of identifiable information for research purposes." (TCPS2-2018, Article 2.5)

2. Creative Activities (Article 2.6)

- a. Activities restricted solely to the "creative practice" are not considered research and so are not subject to RERC review (though they may be covered by other professional codes in the cultural sector. TCPS2-2018 defines "creative practice" as "a process through which an artist makes or interprets a work or works of art. It may also include a study of the process of how a work of art is generated" (TCPS2-2018, Article 2.6)
- b. NOTE: "research that employs creative practice to obtain responses from participants that will be analyzed to answer a research question is subject to REB review." (TCPS2-2018, Article 2.6, italics added)

As is the case above, as soon as any other non-exempted research activities are included in the research activities being conducted by people affiliated with King's and/or using King's' resources, the research project as a whole will require RERC review, approval, and oversight.

The Chair of the RERC will make the final determination as to whether or not certain research activities require RERC review, approval, and oversight. Where questions arise as to whether RERC approval is required, the burden of proof will be on the researcher(s) to show that the proposed activities are exempt as outlined under TCPS-2018, Articles 2.2-2.6.

Where researchers are unsure as to whether RERC review, approval, and oversight is required, they are encouraged to seek the RERC Chair's collegial opinion.



3.3 Scholarly Review

In accordance with TCPS2-2018, Article 2.7, King's RERC will limit its consideration of methods and design solely to ethical implications.

Article 2.7

As part of research ethics review, the REB shall review the ethical implications of the methods and design of the research. (TCPS2-2018, Article 2.7)

It is important to note, however, that *a lack of minimally acceptable scholarly quality can have ethical implications*. A core consideration of ethical review, as outlined in TCPS2-2018, is consideration of the reasonable balance of potential harms and benefits to both researchers and participants. If there is reason to believe that the proposed study designs or methods would not meet the minimal standards of scholarly peer-review in the relevant disciplines, then the project may be unlikely to achieve any scholarly benefits. In such cases, there is strong reason to believe that the potential benefits of the study are unlikely to outweigh the potential harms identified. As such, RERC members may raise legitimate ethical concerns about the minimally acceptable scholarly quality of the proposed study in the context of consideration of the balance of proposed harms and benefits.

However, in its deliberations and decisions the RERC must limit itself to the threshold of 'minimally acceptable scholarly quality'. Once the RERC establishes that the minimal quality threshold is met, it should refrain from suggestions about how to improve the rigor/quality of design or methods proposed (except perhaps as friendly/collegial suggestions provided as supplements to the official RERC decision/feedback).

The RERC will not conduct scholarly peer-review of studies submitted for review to the RERC. However, at its discretion, the RERC can request that a proposed study provide evidence of passing such review (according to the relevant standard practices of scholarly review for the proposed study) before granting its final approval.

4 Composition of RERC

4.1 TCPS2-2018 Minimum Requirements

TCPS2-2018 outlines specific requirements for the composition of any research ethics board (Article 6.4): at minimum, research ethics boards must have "at least five members, including both men and women," **each acting as a representative of one of three required categories**:

Category 1: Research Discipline Experts (at least 2 members: broad representation across disciplines should be represented)

Category 2: Ethics Expert (at least 1 member)

Category 3: Community Member (at least 1 member not affiliated with King's whose primary role is to reflect the perspective of the participant, and so prior experience as a research participant is an asset)

TCSP2-2018 (Article 6.4) also identifies an additional category that is *optional* for non-medical REBs.

Category 4: Legal Expert (cannot be institution's legal counsel)

According to TCPS2-2018, **each committee member should only formally represent one membership category**. However, this does not prevent members from contributing to the review of applications from more than one perspective (i.e., members are *not* restricted from providing input from multiple perspectives).



4.2 Voting-Membership Positions Comprising King's RERC

King's RERC will consist of a minimum of 9 voting members, each officially representing one of the following categories:

5 Research Discipline Experts:

To ensure comprehensive disciplinary expertise, King's Research Ethics Review Committee (RERC) distributes disciplinary representation as follows:

- 1 from the Department of Psychology
- 1 from School of Social Work
- 1 representing Arts & Humanities academic units
- 2 representing Social Science academic units (other than Psychology and Social Work)
- 1 Ethics Expert
- 2 Community Members (not currently affiliated with King's)
- 1 Legal Expert (not King's legal counsel)
- *1 Student Member (selected by the student members of Faculty Council)
- *1 King's College Community Member (staff or professional officer)

*Non-mandated representatives: Kings has opted to include certain non-mandated representatives on the RERC to foster broader participation and input into the research ethics review process.

The Chair and Vice-Chair of the RERC can each officially represent one (but no more than one) of the mandatory member categories (a research discipline expert or ethics expert). In practice, this means that in addition to the Chair and Vice-Chair, there will be 7 other voting members.

As outlined in TCPS2-2018, Article 6.4 "To ensure the independence of REB [research ethics board] decision making, institutional senior administrators shall not serve on the REB." As such, any person serving King's in a Vice-President, President, or equivalent role cannot be a member of King's RERC while they hold that position.

The term for each new RERC member commences on July 1 of each year. The length of term for all RERC's members is 3 years as approved by Faculty Council, except for the two student representatives, where the term is 1 year and except for the Chair and Vice-Chair (terms outlined below).

4.3 RERC Executive: Chair and Vice-Chair of RERC

4.3.1 Term

The RERC will have a Chair and Vice-Chair, each serving a 2-year term. At the end of the Vice-Chair's two-year term, they will automatically become the Chair of the committee for a two-year term, unless a decision has been agreed in advance that the Chair will continue (see below). This structure will ensure stability across the committee each year and will ensure that Chairs have an opportunity (as Vice-Chair) to learn the workings of the committee and the requirements of TCPS2-2018 before taking on full responsibility for the RERC.

The RERC is free to nominate former Chairs Vice-Chairs to serve again if they choose to do so (i.e., there is no statutory limitation on how many terms any individual can serve as either Vice-Chair or Chair); however, the RERC is encouraged to nominate people who have not served as Chair or Vice-Chair in the past in order to foster diversity of experience and leadership.

If a scenario arises where the current Vice-Chair is unwilling or unable to take on the role of Chair at the end of their two-year term, the current Chair will be provided the option to remain as Chair for two additional years. If the current Chair is unwilling or unable to stay on for two more years, candidate for a new Chair and a New Vice-Chair will be presented by RERC to Faculty Council for confirmation using the process described for nomination/confirmation just outlined.

In cases where the Chair resigns before the end of their two-year term, the Vice-Chair will automatically assume the role of Chair as of the Chair's resignation date. The VPAD will then appoint a new Vice-Chair in consultation with the current RERC membership according to the process outlined in 12.3.2.



4.3.2 Selection Process

Six months before the end of the current Vice-Chair's term, the RERC will nominate a new Vice-Chair and present the nomination to Faculty Council for formal confirmation. The nominee does not have to be a member of the RERC at the time of nomination (however they must meet all eligibility requirements outlined below, which includes previous service to the RERC).

If Faculty Council confirms the Vice-Chair nomination, the nominee will assume the role of Vice-Chair on the next July 1st. (If the Vice-Chair role is vacant at the time of nomination, Faculty Council can appoint the nominee as Vice-Chair effectively immediately; However, the two-year term will not formally begin until July 1st).

If Faculty Council does not confirm the RERC's selection, the RERC will present an alternative candidate to Faculty Council. If Faculty Council is unable to confirm a new Vice-Chair for the RERC after a second nomination, the new Vice-Chair will be named by the Vice-President & Academic Dean.

4.3.3 Qualifications

Vice-Chair of RERC:

• Required:

- Past experience as principal/lead investigator on at least three completed research projects that required human research ethics approval.
- Served at least 3 full years (1 term) on King's RERC (or a comparable research ethics board/committee at another academic institution).
- Completed all research ethics training mandated by the Canadian Tri-Agencies.
- Has never been found guilty of an offense against academic integrity by a duly recognized academic institution through a duly recognized academic integrity investigation process.

Advantageous:

- Completed some form advanced/supplementary research ethics training beyond the online training provided by the Tri-Agencies (if available) through King's, Western, or any other institution eligible to hold government-issued research funding.
- Completed training in how to identify, prevent, and mitigate bias (implicit or explicit).
- Evidence of scholarly output in the last 7 years.

Chair of RERC:

- Served at least one two-year term as Vice-Chair of King's RERC.
 - Exception: In cases where no one with this experience is available, the nominated Chair must meet all of the requirements outlined for the Vice-Chair.

4.3.4 Removal of Chair or Vice-Chair

To maintain the independence of the RERC, a Chair or Vice-Chair can only be removed from their positions during their term under any of the following circumstances:

- a) The Chair or Vice-Chair is no longer employed by King's University College as a full-time faculty member in good standing.
- b) The Chair or Vice-Chair is found to have committed an offence against academic integrity through the formal process outlined in the Collective Agreement between KUCFA and King's University College.
- c) A super-majority (2/3) of the RERC membership votes to remove the Chair or Vice-Chair. The VPAD must be informed immediately of any successful motion to remove a Chair or Vice-Chair (unsuccessful motions do not need to be communicated outside of the RERC).

4.4 Non-Voting Members

4.4.1 RERC Administrative Assistant (Mandatory)

Under TCPS2-2018, King's is institutionally obligated to provide the RERC "necessary and sufficient ongoing financial and administrative resources to fulfill their [the RERC's] duties" (Article 6.2). As such, King's (via the Academic Dean's Office) will assign the RERC an administrative assistant on at least a part-time basis to provide administrative support to the

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RERC Chair, Vice-Chair, Administrative Officer, and RERC as a whole. The level of administrative support to be provided to the RERC by the ADO will be determined annually based on trends of submissions and requests processed by the RERC (the review should be conducted in accordance with the annual budget process/schedule).

The RERC Administrative Assistant is not a member of the RERC and should not serve as a member of the RERC while also acting as Administrative Assistant. In order to carry out their administrative duties, the Administrative Assistant will attend all RERC meetings as a non-voting observer.

Responsibilities of the Administrative Assistant may include (but are not limited to): coordination of meetings; taking minutes; document preparation, processing, and filing; maintaining the RERC email inbox (ethics@kings.uwo.ca); technological support; etc.

4.4.2 RERC Administrative Officer (Optional)

TCPS2-2018 states that: "Where research ethics administration staff have the requisite experience, expertise and knowledge comparable to what is expected of REB members, institutions may appoint them (based on the written policies and procedures of the institution) to serve as non-voting members on the REB" (Article 6.4). As such, where qualified individuals exist (as described in the quote above), King's RERC can appoint one person employed by King's as the RERC Administrative Officer.

The Administrative Officer will be a non-voting member of the RERC with rights to attend all RERC meetings in an advisory role. The Administrative Officer will directly support the Chair and Vice-Chair in carrying out their administrative responsibilities, including (but not limited to): providing initial assessments of risk to determine the appropriate level of review (full vs. delegated review); providing expert advice on the application of TCPS2-2018 to particular situations; keeping the RERC up-to-date on revised/updated human research ethics guidance from the Tri-Agencies (or other relevant bodies); and the regular review/revision of the RERC's Standard Operating Procedures (SOPs).

4.5 Quorum:

The requirements for quorum are outlined in TCPS2-2018, Article 6.9 as follows (bolding added for emphasis):

Institutions shall establish quorum rules for REBs that meet the minimum requirements of membership representation outlined in Article 6.4. When there is less than full attendance, decisions requiring full review should be adopted only when the members in attendance at that meeting have the specific expertise, relevant competence, and knowledge necessary to provide an adequate research ethics review of the proposals under consideration. ... Ad hoc advisors, observers, research ethics administration staff and others attending REB meetings should not be counted in the quorum for an REB. Nor should they be allowed to vote on REB decisions (Article 6.5). Decisions without a quorum are not valid or binding.

King's RERC will establish quorum whenever:

- a) there at least 5 voting-members present; and,
- b) where the members present officially represent <u>each of the 3 mandatory membership categories</u> required by TCPS2-2018 for non-medical research ethics boards:
 - At least 3 Research Discipline Experts (having expertise in the discipline(s) with submissions under consideration).
 - At least 1 Ethics Expert
 - At least 1 Community Member

(Note: each member can only officially represent one membership category.)



5 Commitment to Academic Freedom

The RERC is committed to principles of academic freedom, in particular as they are outlined in the Collective Agreement between the King's University College Faculty Association (KUCFA) and King's University College. As such, the RERC is committed to approving all research that meets the ethical standards outlined in TCPS2-2018, even if the subject matter is otherwise deemed controversial or offensive to particular RERC members.

6 Commitment to Equity, Diversity, Inclusion, and Decolonization (EDID)

King's RERC is fully committed to integrating principles of equity, diversity, inclusion, and decolonization (EDID) in relation to its composition, processes, and reviews. The RERC is committed to ensuring that such EDID considerations (and others) contained in TCPS2-2018 are core considerations in its review of submissions and the feedback provided to researchers. Acknowledging that considerations of EDID are grounded in fundamental principles of ethics and justice, the RERC is also committed to ensuring that EDID training is mandatory for both researchers seeking review and approval from the RERC and for all RERC members.

6.1 EDID in TCPS2-2018

Considerations of EDID are contained in various parts of TCPS2-2018. In particular, considerations relevant to EDID are rooted in TCPS2's core ethical principles, especially the principle of Justice:

Justice refers to the obligation to treat people fairly and equitably. Fairness entails treating all people with equal respect and concern. Equity requires distributing the benefits and burdens of research participation in such a way that no segment of the population is unduly burdened by the harms of research or denied the benefits of the knowledge generated from it. Treating people fairly and equitably does not always mean treating people in the same way. Differences in treatment or distribution are justified when failures to take differences into account may result in the creation or reinforcement of inequities. (TCPS2-2018, Article 1.1).

When considering equity, TCPS2-2018 asks researchers and REB members to keep in mind how "limited access to social goods, such as rights, opportunities and power" may give rise to important differences in the kinds of experiences and burdens borne by participants situated within varying intersecting identities and circumstances. (TCSP2-2018, Article 1.1). TCPS2-2018 also requires researchers and REB reviewers to carefully consider who is included and excluded from participation in the study (both through inclusion criteria and strategies for recruitment) and to ensure that particular groups are not "excluded from research arbitrarily or for reasons unrelated to the research question" (Article 1.1). Chapter 4, "Fairness and Equity in Research Participation" provides detailed guidance on issues related to equity, diversity, and inclusion in the design of studies, selection of appropriate methodologies, and recruiting of participants.

TCPS2-2018 also includes an entire chapter dedicated to "Research Involving the First Nations, Inuit and Métis Peoples of Canada" (TCPS2-2018, Chapter 9). While not sufficient on its own to ensure responsible Indigenous Research, this chapter does provide researchers and RERC reviewers a foundation upon which to think about the extent to which research with potential relevance to Indigenous Peoples has appropriately engaged Indigenous communities and/or Indigenous researchers in a way the ensures the research will be respectful, reciprocal, responsible, and relevant. This chapter is noteworthy insofar as it challenges researchers and RERC members to think beyond the paradigm of "individual autonomy" that saturates the rest of TCPS2-2018, and instead think about autonomy, consent, and well-being in the context of participation and community. The participatory approach and the emphasis on community engagement (vs. the mere engagement of individuals) outlined in Chapter 9 can be applied to interactions with many other communities in addition to Indigenous communities. As such, the RERC recognizes that Chapter 9 not only informs the RERC's consideration of ethical implications related to decolonization, but also EDID more broadly.

6.2 Limitations and Possibilities of TCPS2-2018

The RERC also acknowledges that there are legitimate grounds for criticizing TCPS2-2018 from considerations of EDID. TCPS2-2018 is not perfect, nor should it be assumed to be comprehensive on its own. There are a number of scholarly peer-review articles outlining concerns with TCPS2-2018 (and other standards of research ethics) available for consideration. While TCPS2-2018 represents a necessary minimum standard, in many ways researchers need to go beyond the minimal requirements outlined in TCPS2-2018 to more fully ensure studies meet the ethical imperatives of EDID. Many disciplines, organizations, and funders are publishing discipline specific EDID guidelines and directives and researchers are strongly encouraged to consult such resources and build in such best practices into their own research projects.

The RERC also acknowledges that while it is bound to adhere to the guidance outlined in TCPS2-2018 in order to receive federal Tri-Agency funding, it is also the case that TCSP2-2018 does not represent the totality of ethical and moral frameworks adopted by people in good-faith through years of experience and reflection at both the individual and communal



level. TCPS2-2018 arises from a specific Anglo-American, secular, academic tradition (recognized for lacking sufficient diversity within its ranks) and is framed in the concepts and structures of that tradition. The RERC accepts that there are many communities and cultures that have developed their own ethical frameworks according to their own concepts, symbols, and ceremonies and respects these traditions. Therefore, the RERC will make every effort to recognize the diversity of ethical frameworks used by various communities to express ethical ideas and will do the work to translate such frameworks alongside TCPS2-2018 for the purpose of assessing the ethical implications of the proposed research project.

The RERC also acknowledges that it is part of the network of power relationships inherent in research activities. While research ethics committees play a legitimate role in ensuring that appropriate measures are in place to prevent power-asymmetries between researchers and participants from producing harm through research activities, research ethics committees must also ensure that they are aware of the power-asymmetries that exist between the committee and researchers and/or the committee and participants when assessing applications and providing feedback.

6.3 Research Ethics Implications of Sections 318-320 of the Criminal Code of Canada (Criminal Offenses Related to "Hate Propaganda")

It should be noted that some acts of hate (such as "advocating genocide", "public incitement to hatred", and "wilful promotion of hatred") are declared harmful and illegal under Canadian laws² and so can be deemed unethical by the RERC under the TCPS2-2018 ethical principles of Respect for Persons, Concern for Welfare, and Justice. Where concerns are raised about the possibility of reasonably foreseen acts hate prohibited under Canadian law arising within the proposed research activities, the RERC will not grant its approval for the research activities unless, and until, it is satisfied the risks of reasonably foreseen acts of hate or violence have been acknowledged and appropriately addressed. The RERC will seek appropriate legal advice and subject-matter expertise to guide their decisions and the advice provided to researchers.

7 Statement of Confidentiality:

King's RERC is committed to transparency of process and procedures. To meet this commitment King's RERC will publish all its Standard Operating Procedures and a list of current and recent RERC members on a publicly accessible website.

To protect the confidential nature of research projects submitted to the RERC for review and consistent with TCPS2-2018's guidelines related to confidentiality and governance, RERC meetings, documents, and web-based discussions are incamera. Members are required to maintain confidentiality and to protect the privacy and identity of the individuals involved, even when charged with consulting outside the committee on an issue.

King's RERC will also publish a publicly accessible list of approved research studies on at least an annual basis, where doing so is consistent with protecting all relevant considerations of privacy, confidentiality, wellbeing, and the integrity of the research project. The list will include the title of the study, the name of the lead researcher associated with King's, a King's RERC approval number, and the originally proposed duration of the study. Researchers will be provided the option on the application form to request that the details of their study not be published as part of this list.

8 Conflict of Interest:

A perceived conflict of interest for any committee member (regarding the applicant or project) will be brought to the attention of the RERC Chair (ex. if the applicant collaborates with a RERC member). A conflict of interest for the Chair will be brought to the attention of the committee as a whole. When a committee member is in a conflict of interest the member will leave the room while the rest of the committee deliberates on the application and makes a decision.

9 Option to Consult:

The RERC Chair will act in a consultative capacity for those Researchers who would like to discuss their research project and its ethical aspects.

The RERC Chair, and the RERC as a whole, will also seek out advice and expertise beyond the RERC membership as appropriate and as required (being sure to maintain all requirements of confidentiality in such consultations).

¹ Juritzen, Truls I, Herald Grimen, and Kristin Heggen. "Protecting vulnerable research participants: A Foucault-inspired analysis of ethics committees," *Nursing Ethics* 188.5 (2011), 640-650. https://doi-org.proxy1.lib.uwo.ca/10.1177/0969733011403807

² Walker, Julian. "Hate Speech and Freedom of Expression: Legal Boundaries in Canada." *Library of Parliament: Research Publications*. Publication No. 2018-25-E (June 29, 2018). https://lop.parl.ca/sites/PublicWebsite/default/en_CA/ResearchPublications/201825E



10 Required Training:

10.1 RERC Members:

Within 1 month of appointment, and prior to actively participating in the ethics review process, all members on the King's University College Research Ethics Review Committee are required to complete the following training:

- 1) **Research Ethics Training**: the most up-to-date version of the online *TCPS2 Tutorial Course on Research Ethics (Core)* provided by the Tri-Agency's "Panel on Research Ethics".
- Equity, Diversity, Inclusion, and Decolonization (EDID) Training: All RERC members are expected to read/watch the following online resources.
 - a. **SSHRC:** Best Practices in Equity, Diversity and Inclusion in Research (https://www.sshrc-crsh.gc.ca/funding-financement/nfrf-fnfr/edi-eng.aspx)
 - b. **SSHRC:** Guide to Addressing Equity, Diversity and Inclusion Considerations in Partnership Grant Applications (https://www.sshrc-crsh.gc.ca/funding-financement/apply-demande/guides/partnership edi guide-partenariats guide edi-eng.aspx)
 - c. CIHR: Bias in Peer Review Learning Module (https://cihr-irsc.gc.ca/lms/e/bias/)

10.2 People Submitting to RERC

Researchers submitting their study protocols to King's RERC for review, approval, and oversight must complete the following training *prior to* starting any research involving humans and it is *strongly recommended* prior to uploading their first RERC submission. Completing the training *before* submitting a proposal to the RERC will ensure that researchers are familiar with ethical policies, guidelines, and standards the RERC will be using to assess their submission.

- 1) **Research Ethics Training:** the most up-to-date version of the online *TCPS2 Tutorial Course on Research Ethics* (*Core*) provided by the Tri-Agency's "Panel on Research Ethics".
- 2) **Equity, Diversity, Inclusion, and Decolonization (EDID) Training:** All people submitting applications to the RERC are expected to read/watch the following online resources.
 - a. **SSHRC:** Best Practices in Equity, Diversity and Inclusion in Research (https://www.sshrc-crsh.gc.ca/funding-financement/nfrf-fnfr/edi-eng.aspx)
 - b. **SSHRC:** Guide to Addressing Equity, Diversity and Inclusion Considerations in Partnership Grant Applications (https://www.sshrc-crsh.gc.ca/funding-financement/apply-demande/guides/partnership edi guide-partenariats guide edi-eng.aspx)

RERC members and those engaged in research activities at King's are also strongly encouraged to attend professional development opportunities related to research ethics to be offered on a regular basis through King's Research Office in partnership with the RERC.

11 Duties of the Research Ethics Review Committee

- a) A proportionate approach to research ethics review will be used. *TCPS2 (2018) Section 1C and Article 6.12* recognizes two levels of review: 1) full review; and, 2) delegated review of minimal risk research.
 - i. By default, all proposals submitted to the RERC will be initially assigned to full review (i.e., review by the full RERC membership). (TCPS2-2018, Article 6.12)
 - ii. Research proposals judged by the RERC Chair as "minimal risk" will be re-assigned to delegated review. Such proposals, after appropriate delegated review, can be approved by the RERC Chair without review and approval by the full RERC. A delegated review normally involves assigning one or more members of the Research Ethics Review Committee with appropriate expertise/experience to assess the research proposal.
 - iii. TCPS2 (2018) defines "minimal risk" research as:
 - "research in which the probability and magnitude of possible harms implied by participation in the research are no greater than those encountered by participants in those aspects of their everyday life that relate to the research. In their assessment of the acceptable threshold of minimal risk, REBs have special ethical obligations to individuals or groups whose situation or circumstances make them vulnerable in the context of a specific research project, and to those who live with relatively high levels of risk on a daily basis. Their inclusion in research should not exacerbate their vulnerability (Article 4.7)." (Section 2B).
 - iv. The RERC Chair may engage the RERC's administrative team to conduct initial triaging of applications and provide a recommended risk designation to the RERC Chair.



- v. The RERC Chair will, report all projects approved under delegated review to the RERC as a whole at each meeting of the RERC.
- vi. Delegated reviewers can either:
 - 1) Recommend that the RERC Chair approve the research project.
 - 2) Refer projects they cannot recommend for approval to the Full RERC outlining the concerns they have with the project. Only the full RERC can decline to approve a project on ethical grounds.
- b) To review research projects falling under its defined jurisdiction and scope for compliance with *TCPS2* prior to the research being done, at least annually thereafter for multi-year projects, and upon the completion of the project (TCPS2-2018, Chapter 6).
- c) As outlined in TCPS2 (2018) research projects conducted by students affiliated with King's are defined as research activities under the RERC's scope and so must be reviewed through the RERC (Article 6.12). The review of minimal-risk course-based research activities conducted for pedagogical purposes may qualify for special delegated review by non-RERC members as outlined in TCPS2(2018) Article 6.12. A consultative, collegial, and participatory process for special delegated review of minimal risk course-based research activities for pedagogical purposes will be developed by the RERC in consultation with Academic Unit Heads and published in an appropriate section of King's website (ex. under the RERC section of the King's webpage).
- d) To ensure that up-to-date versions of the TCPS2 Tri-Council Policy Statement be made available on the King's University College website. Current instructions for submission shall be made available on the King's University College web site. Included on this website will be resources required to conduct all required training.
- e) To meet as a committee at regular intervals (at least thrice annually) to review submissions. Meeting dates will be posted publicly on the appropriate section of the King's website (webpage for the Research Ethics Review Committee). The dates by which submissions must be provided to be considered at each sitting of the RERC will be included in the publicly posted meeting schedule.
- f) Under TCPS2(2018) the jurisdiction of King's RERC only extends to research being conducted by King's faculty, staff, or students and/or that involves King's resources (regardless of where the research is being conducted) (Art. 6.1) As such, the Committee shall only consider submissions from faculty, staff, or students affiliated with King's.
- g) Failure to comply with research ethics guidelines is considered a breach of research integrity. Such failures by faculty members shall be addressed by the Academic Dean which may (if appropriate) involve following the process outlined for "Misconduct in Research" as outlined in the KUCFA collective agreement. Such failures by students shall be addressed according to the Code of Student Conduct. Failures by staff will be addressed by the Academic Dean and in accordance with existing HR policies and/or collective agreements.

12 Expressions of Research Ethics Concerns or Complaints

As the body ultimately responsible for research ethics oversight for human research activities conducted by people formally affiliated with King's (ex., faculty, staff, professional officers, students, etc.), the RERC maintains the right to officially receive any concerns or complaints related to research ethics from any member of King's or any member of the public. The RERC will ensure that a user-friendly process for filing complaints is published on King's website in a prominent and easy to find location of the "Research" portion of King's website.

Violations of TCPS2-2018 are considered violations of academic integrity and as such are subject to all relevant procedures and potential penalties in place to address failures of academic integrity at King's. Upon receipt of a complaint, the RERC Chair will immediately initiate the Research Integrity Procedure outlined in the *Guide to the Proper Conduct of Research at King's University College (as appended to the KUCFA Collective Agreement in effect at the time of the complaint).* If students are implicated in the complaint (ex. student-led research or student RA's working on a research project), the RERC Chair will also initiate appropriate procedures as outlined in *King's Student Code of Conduct.* If staff members or professional officers are implicated, the RERC Chair will also initiate appropriate procedures related to employee conduct and discipline as set out in King's HR policies and any relevant agreements or memoranda in place with the affected employee groups.

Regardless of the research integrity and conduct procedures in effect at the time, King's RERC Chair retains the authority established under TCPS2-2018 to temporarily suspend research activities for the purpose of protecting research participants from possible harm. Any mandated suspension of research activities will follow the RERC review and approval procedures in place at the time the risks are brought to the Chair's attention. Such decisions (in accordance with the proportional approach underlying TCPS2-2018) must always weigh the risk of harms of suspending a study against the risk of harms in allowing the study to continue. Where the risk of suspending a study can be reasonably expected to cause more harm than allowing the study to continue, the Chair may choose to allow the study to



continue (with the option of requiring certain modifications aimed at reducing the risk of further harm). Such suspensions of studies are independent of the Research Integrity Procedure insofar as that procedure aims at establishing whether the investigator violated norms of research integrity and the RERC Chair's primary aim in suspending a study is to protect participants from unnecessary or disproportionate harm. (It is possible that participants could face unnecessary or disproportionate harm even if the investigator is not guilty of violations of academic integrity. Even in cases where investigators are cleared of any accusation of academic offense, the RERC Chair may still require the investigator to adapt the study protocol to reduce/mitigate any credible harms identified in the complaint.)

13 Revision History

RERC Terms of Reference

Approved Revisions to the RERC Terms of Reference:

- April 13, 2022 (v2022.04.04 approved by Faculty Council)
- April 8, 2015 (Approved by Faculty Council: April 6, 2016)
- December 10, 2014
- October 3, 2014
- August 30, 2013

RERC Terms of Reference Originally Approved: September 2009.

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2

Prior Versions of TCSP2-2018 (no longer in effect) referred to in previous versions of King's RERC Terms of Reference:

- TCPS2-2014: https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_initiatives.html
- TCPS2-2010: https://publications.gc.ca/collections/collection_2011/ger-pre/MR21-18-2010-eng.pdf
- TCPS2-1998 (with 2000, 2002, 2005 amendments): https://publications.gc.ca/collections/collection 2009/irsc-cihr/MR21-18-2005E.pdf

Anticipated Revisions to TCPS2-2018: https://ethics.gc.ca/eng/consultations 2021.html

- The Panel of Research Ethics conducted consultations on possible changes to TCSP2-2018. The proposed changes were presented according to four major themes:
 - 1) the review of multi-jurisdictional research;
 - 2) broad consent in research:
 - 3) the review of research involving cell lines; and
 - 4) research involving totipotent stem cells.
- The consultation process ended in October 2021 with revisions anticipated to be published in 2022/2023.
- Revisions under the first theme (multi-jurisdictional research) may impact King's terms of reference. As such, the
 terms of reference will be reviewed based on any revisions to TCPS2-2018 and revisions to the terms of reference
 will be put forward at that time, if necessary.