

Research Activities Exempt from CFREB Review

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The University of Calgary complies with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS), a joint policy of Canada's three federal research agencies (CIHR, NSERC, and SSHRC). The TCPS can be found online at:

www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

All research (funded or unfunded) must receive ethics review unless the research activities qualify for one of the exemptions described below. The TCPS provides the guidelines that the CFREB uses to determine if certain activities are exempt from ethics review.

What is the TCPS definition of “Research”?

The TCPS defines “research” 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.

Note that choice of methodology and/or intent or ability to publish findings are not factors that determine whether an activity is research requiring ethics review. (TCPS Article 2.1)

If your study involves “interactions” with people (e.g., conducting interviews; administering surveys or questionnaires via the internet or in person; measuring responses on tasks, recording observations of behavior in a laboratory), and your study meets the TCPS definition of “research”, then it will likely require ethics review.

Research Activities Exempt from CFREB Review

1. The TCPS indicates that research-related activities that involve interactions with people may not require REB review if the individuals are merely facilitating access to information and are not the focus of the research:

In some cases, research may involve interaction with individuals who are not themselves the focus of the research in order to obtain information. For example, one may collect information from authorized personnel to release information or data in the ordinary course of their employment about organizations, policies, procedures, professional practices, or statistical reports. Such individuals are not considered participants for the purposes of this Policy. This is distinct from situations where 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, are considered participants.
(TCPS Article 2.1)

2. CFREB review is not required for the initial exploratory phase of a research project, which may involve contact with individuals or communities intended to establish research partnerships or to inform the design of a research proposal. These activities include conversations that researchers may have with prospective participants as part of the development of the design of their research. These preliminary conversations may include negotiations concerning the terms on which a researcher may engage with a particular community or group (TCPS Article 3.5). Note that this exemption does not apply to pilot testing of data collection procedures.
3. Research that relies exclusively on information that is publicly available, or made accessible through legislation or regulation, does not require CFREB review when:
 - a. the information is legally accessible to the public and appropriately protected by law; or
 - b. the information is publicly accessible and there is no reasonable expectation of privacy.

Publicly available information is any existing stored documentary material, records, or publications, which may or may not include identifiable information. Article 2.2 of the TCPS provides several examples:

For example, identifiable information may be disseminated in the public domain through print or electronic publications; film, audio, or digital recordings; press accounts; official publications of private or public institutions; artistic installations, exhibitions, or literary events freely open to the public; or publications accessible in public libraries. Research that is non-intrusive, and does not involve direct interaction between the researcher and individuals through the Internet, also does not require REB review. Cyber-material such as documents, records, performances, online archival materials, or published third party interviews to which the public is given uncontrolled access on the Internet for which there is no expectation of privacy is considered to be publicly available information.

Exemption from CFREB review is based on the information being accessible in the public domain, and that the individuals to whom the information refers have no reasonable expectation of privacy. These two conditions must be met for the research activity to be exempt from review.

4. Research involving the observation of people in public places does not require CFREB review when:
 - 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
 - c. any dissemination of research results does not allow identification of specific individuals.

Article 2.3 of the TCPS discusses observational research and requires that researchers and the CFREB pay close attention to the environment in which observation takes place, the expectation of privacy that individuals in public places may have, and the means of recording observations, when determining whether observational research is exempt from review (see also TCPS Article 10.3).

CFREB review would be required if researchers propose to make video- or audio-recorded observations of people in public places and the dissemination of the research results would allow identification of specific individuals. In these situations there is a potential infringement of privacy.

There are publicly accessible digital sites where there is a reasonable expectation of privacy. When accessing identifiable information in publicly accessible digital sites, such as internet chat rooms and self-help groups with restricted membership, the privacy expectation of contributors to these sites is much higher. Observational studies in such contexts will require CFREB review (TCPS Article 2.2; see also TCPS Article 10.3).

5. CFREB review is not required for research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information. (TCPS Article 2.4)

Secondary use refers to the use in research of information or human biological materials originally collected for a purpose other than the current research purpose. Common examples are social science or health survey datasets that are collected for specific research or statistical purposes and then re-used to answer other research questions. Information initially collected for program evaluation may also be useful for subsequent research. Other examples include health care records, school records, biological specimens, vital statistics registries, or unemployment records, all of which are originally created or collected for therapeutic, educational, or administrative purposes, but which may be sought later for use in research. (TCPS Article 5.4)

Information is identifiable if it may reasonably be expected to identify an individual, when used alone or combined with other available 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. The term “personal information” generally denotes identifiable information about an individual. (TCPS Article 2.1)

6. Quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management, or improvement purposes, do not constitute research for the purposes of the TCPS and therefore do not require CFREB review. (TCPS Article 2.5)

The distinction between research and program evaluation/quality improvement activities is not always clear. The intent to present or publish the findings are not factors that determine whether the activity is research requiring ethics review. The primary intent and purpose of the activity is the key consideration: is the intent and purpose to produce findings that can be used to improve practice or service delivery within an organization, classroom, or training program? For example, are you evaluating the success of a training program and using the findings to improve future program delivery? Would the project be carried out even if the results might not be applicable anywhere else? Who is the primary audience for the results – individuals within your organization or the scholarly community? Is the publication of the findings in the scholarly literature a primary goal? The CFREB pays special attention to these questions when deciding whether an exemption applies to your situation.

If data are collected for the purposes of quality improvement studies or program evaluation activities, and later proposed for research purposes, it would be considered secondary use of information not originally intended for research, and at that time may require CFREB review to be compliant with the TCPS. Be sure to check with the CFREB in these situations.

Decisions on Exemption from CFREB Review

The CFREB makes the final decision on exemption from research ethics review. Researchers (especially graduate students) may require a formal written decision from the CFREB attesting to the fact that certain research activities are exempt from ethics review. Please contact the CFREB for clarification and advice on your specific situation (cfreb@ucalgary.ca).

Chair, Conjoint Faculties Research Ethics Board (CFREB)