

Minimal Risk Studies

Article 1: Proportionate Approach

An expedited / delegated review procedure consists of a review of research involving human participants by the REB Chair or by one or more experienced reviewers designated by the REB Chair from among members of the REB. In accordance with the TCPS, full review by an REB is the default requirement, unless the REB decides to authorize delegated review based primarily on the harms that are expected to arise from the research. Research that may be reviewed by the REB through a delegated review procedure includes research activities that present no more than minimal risk to human participants and minor changes in approved research.

UBC's REBs retain the right to decide to put any application submitted for minimal risk review forward for full board review.

Article 2: Definition of Minimal Risk

Minimal risk is defined in the TCPS as follows: if potential subjects can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research, then the research can be regarded as within the range of minimal risk.

The following are categories of research that UBC's clinical REBs confidently expect to involve minimal risk.

Note: If a study is funded or supported by the US Federal government or is subject to the US Food and Drug Administration regulations, ONLY studies that meet the US definition of minimal risk AND that are listed in the US Federal Register may be considered as qualifying for delegated / expedited review. US funded and FDA regulated studies will generally not qualify for delegated / expedited review.

Article 3: Types of Research Studies that may qualify for Expedited / Delegated Review

3.1. Studies using previously collected / existing clinical data, medical records

1. Studies using existing database/ registries or linking information between databases

2. Studies using previously collected data from existing documents or records or charts (generally “retrospective chart reviews”)
3. Studies using *previously* collected clinical specimens where there is no further clinical need for the specimens

3.2. Studies intending to collect and analyse specific types of data

1. Studies that will involve only the collection of hair, nail clippings, deciduous teeth, excreta, salivary secretions, additional swabs or other external secretions that have been collected in a non-invasive manner and that may also be collected as part of routine clinical care.
2. Studies that involve only the collection of placenta or amniotic fluid as a consequence of childbirth, or fetal tissue collected as a consequence of therapeutic abortion or miscarriage.
3. Studies that involve only the collection of blood samples by venipuncture or a central line already present as part of clinical care installed as part of clinical care.
4. Studies that involve clinical data collected prospectively as part of clinical care.

3.3. Studies that involve only questionnaires or surveys

1. Studies that involve only questionnaires or surveys should generally be sent to the Behavioural Research Ethics Board, unless they are clinical in nature. If the questionnaires involve sensitive information from vulnerable populations or significant nuisance or inconvenience they will generally not qualify for expedited / delegated review.

3.4 Exercise Studies

1. Studies that will involve the collection of output data obtained as a result of moderate exercise undertaken by healthy volunteers
2. Studies that will involve the collection of output data obtained as a result of maximal exercise by healthy volunteers who are less than 40 years old. In these cases, the REB must receive and approve a safety protocol.

Note: Exercise in a patient population will generally be referred to the full board.

3.5. Scans

1. Studies (in non-vulnerable populations) using data recorded using non-invasive procedures such as EEG, EKG, MRI, ultrasound or x-rays will generally meet the criteria for minimal risk.

Note: X-rays will not be expedited if the radiation exposure is in excess of 0.1 mSv (the approximately equivalent of one return transcontinental airline flight).

3.6. Stem Cell Research

1. Stem cell research qualifies for delegated review with the exception of any research that concerns the derivation of stem cell lines from human somatic tissue, umbilical cord or placenta OR research involving the grafting of stem cell lines into humans.
2. Research that uses permanent stable cell lines in laboratory research (i.e. in vitro) does not require ethical review.

3.7. Observational research on Standard Treatment(s)

1. Observational research on standard treatment(s) where the treatment(s) is (are) determined clinically and not assigned by research methodology (e.g. randomization)

3.8. Individual Case Studies and Quality Assurance/Quality Improvement

1. Case reports do not meet the definition of research; this is considered to be a medical / educational activity. UBC and affiliated investigators are not required to obtain REB approval prior to beginning the activity. The UBC REBs expect, however, that patients will be made aware that the author / investigator plans to create a report which may be published, about their case. Case reports for REB purposes are a retrospective analysis of one or two clinical cases. If more than two cases are involved in the analytical activity, the activity will normally constitute “research” and be subject to review.
2. Quality assurance projects are not research, although they may involve risks to the participants. Project leaders are referred to the UBC REB adopted Guidance: “When Does Your Project Warrant Review by a Research Ethics Board” [\[link\]](#) for assistance in determining whether a project is research or quality assurance.
3. Investigators may apply to UBC’s REBs for acknowledgement from the applicable REB of the fact that a particular quality assurance project or a specific case report does not constitute research and does not require ethical review. Investigators should inform the applicable REB if the journal does not accept the REBs decision.

Article 4. Types of Minimal Risk Studies That Require Full Board Review

Notwithstanding the provisions of Article 3 above, the following types of studies may require full board review depending upon board specific policy.

1. Studies whose purpose it is to collect or use “tissue / DNA” for the purpose of creating a “tissue /DNA “bank or adding new sources of tissue to a “tissue/DNA” bank.
2. Studies whose purpose it is to collect or use “tissue / DNA” for genetic research related to determining susceptibility of acquiring a disease; or studies whose purpose it is to collect or use “tissue/DNA” for genetic research the results of which could be potentially harmful to participants if disclosed.
3. Studies whose purpose is the derivation of stem cell lines from human somatic tissue, umbilical cord or placenta OR research involving the grafting of stem cell lines into humans.
4. Minimal risk studies where a waiver of consent or alteration of the required elements of informed consent is being requested.

The following types of studies do **not** require full board review when a waiver of consent or an alteration of the required elements of informed consent is being requested.

- a. Retrospective chart reviews,
- b. Studies using data obtained from previously banked anonymized tissue that is not linked to other sources of data,
- c. Studies using data from provincially regulated databases/registries (e.g Medical Services Plan, BC Centre for Disease Control) or from disease specific registries with data collected from subjects who have already consented to its use for the sort of research being done.
- d. Prospective chart or medical record reviews where the data is anonymous, has been anonymized, or is de-identified and the code is held by an approved privacy guardian and there is no potential harm to the subject.
- e. Prospective chart or medical record reviews where members of the research team are not in contact with subjects during the data collection and where the researcher has provided an appropriate justification for why contacting the participants to obtain consent would be impracticable.