



UNIVERSITY OF TORONTO

Office of the Vice-President, Research and Associate Provost

Ethics Review Office

USING THE RISK MATRIX

The risk matrix should be understood as a broad heuristic to help researchers frame risk factors for standard research ethics issues such as free and informed consent, privacy and confidentiality, and inclusion-exclusion criteria, as well as any special considerations such as relevant professional qualifications of the research team members. By locating a protocol on the matrix, researchers can determine both the review type (i.e. expedited or full) and level of continuing review (e.g. annual renewal or small possibility of site visit) appropriate to a project.

Determining Risk Level and Review Type

To evaluate risk for a protocol, consider:

- *Group vulnerability*—i.e., any pre-existing vulnerabilities associated with proposed participant groups, e.g., relating to pre-existing physiological or health conditions, cognitive or emotional factors, and socio-economic or legal status.
- *Research risk*—i.e., the probability and magnitude of harms participants may experience as a result of the proposed methods to be used and types of data to be collected, e.g., relating to physiological or health issues such as clinical diagnoses or side effects, cognitive or emotional factors such as stress or anxiety during data collection, and socio-economic or legal ramifications such as stigma, loss of employment, deportation, or criminal investigation (e.g., in the event of duty to report intent to cause serious harm, subpoena, or breach of confidentiality).

These factors should be summarized with overall assessments of group vulnerability and research risk (i.e., *low, medium, high*) by locating the protocol in the matrix below.

Group Vulnerability	Research Risk		
	Low	Medium	High
Low	1	1	2
Medium	1	2	3
High	2	3	3

Risk level = 1: Expedited Review

Risk level = 2 or 3: Full Review

See http://www.research.utoronto.ca/ethics/eh_rebs.html to determine the number of copies required.

The relevant REB will take the researchers' assessments of group vulnerability and research risk into account in order to make the final decision regarding which review type would be appropriate for a protocol.

Assessing risk may to some degree be affected by discipline-specific considerations—e.g., forensics, medicine, and nursing may involve work with participants in clinical settings, with attendant requirements for oversight and team qualifications. Departments will likely want to work with the Ethics Review Office (ERO) to decide how best to handle different levels of risk. Additional online resources may also be helpful, including:

- www.research.utoronto.ca/ethics
- www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm
- www.pre.ethics.gc.ca/english/tutorial/

Level of Continuing Review

Each of the three risk levels is also associated with a more rigorous program of continuing review. For a detailed explanation of UofT's Continuing Program, please see the Continuing Review Guidelines located http://www.research.utoronto.ca/ethics/eh_how.html#wha.

Generally, the three levels of continuing review can be summarized as follows:

Level 1: All protocols extending beyond one year require annual renewal in the form of a brief summary report commenting on:

- any changes to the protocol, forms, or personnel (e.g., status as students or employees)
- number of participants currently in the study, or who have completed the study, or who withdrew (including their reasons for withdrawing)
- any ethical concerns arising
- researchers should submit a Study Completion Report when data analysis has been completed in order to answer the original research question(s)

Level 2: In addition to being subject to Level 1 review, mid- and high-risk protocols have a small chance of receiving a routine site visit, including review of:

- *REB's file* documenting the approval process
- *researcher's consent files* documenting participant consent and eligibility

Level 3: in addition to being subject to Level 1 review, and having a small chance of being subject to Level 2 review, high-risk protocols have a small chance of receiving a routine site visit, including review of:

- *researcher's data files* documenting adherence to or deviation from protocol, reporting of adverse/unanticipated events, and data quality; this may include audio or video recordings, electronic or paper records, field notes, etc.
- under unusual circumstances, continuing review may also include direct contact with the research process (i.e., observing the consent or study procedures) if the researcher has received permission from the participant to do so, and the ERO and relevant REB determine that the risks to participants do not outweigh the benefits. Under similar circumstances, continuing review may also include contacting participants during or after participation (e.g., by phone, or by appending relevant questions to study protocols); relevant questions may include how they were recruited, who they interacted with and in what capacity, whether they were given an opportunity to ask questions, whether they felt pressure to participate or continue, whether they are satisfied with their experience as a participant, and whether they have any other questions or comments. Such procedures, however, are not expected to be the norm.

The risk matrix and explanation/justification will be taken into account when determining which category of Continuing Review the research will fall under (Level 1, 2 or 3). The University of Toronto REB will make the final decision of the risk level, and, in cooperation with the ERO, will determine the program of Continuing Review that will be followed. This determination will be communicated to the researcher in the ethics approval letter.