

Established:

Updated: April 14, 2011

Next Review:

Responsible Unit: Research Ethics Board

Number of Pages: 2

TCPS 2 Definitions

For purposes of this guideline, the following definitions have been extracted from **TCPS 2**:

- **Research** – an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation (p. 15)
- **Risk** – a function of the magnitude or seriousness of the harm and the probability that it will occur (p. 22)
- **Minimal Risk Research** – research in which the probability and magnitude of the possible harms implied by participation in the research is not greater than those encountered by participants in those aspects of their everyday life that relate to the research – can be delegated review (p. 23)
- **Above Minimal Risk Research** – research in which the probability and magnitude of the possible harms implied by participation in the research is greater than those encountered by participants in those aspects of their everyday life that relate to the research – must be full board review (p. 77); must include scholarly and peer review (p. 20).

Review Process - Above Minimal Risk Research

1. Once an application has been received and the *Research Ethics Coordinator* has determined that it is complete, the Chair will determine if it is minimal risk or above minimal risk in accordance with the TCPS2, the current policy and REB flowchart
2. If the Chair has any doubt concerning the categorization of the research, the Chair will initiate a poll of REB members. Each member should review the complete application documentation within 5 working days and will be required to advise the Chair **in writing** of his/her categorization of the research along with the rationale.
3. If any one member of the REB deems the application to be above minimal risk, it will be deemed to be above minimal risk research and will be subject to a full board review at the next regularly scheduled REB meeting *after all required external reviews have been conducted*.

4. The Chair will provide a written recommendation to the REB as to the amount of honorarium to be provided to the scholarly reviewers bearing in mind the complexity of the review to be undertaken and common practices of other local REB's.
5. REB members will indicate **in writing** their agreement with the proposed honorarium to be paid. The REB members will also be required to identify **in writing** to the Chair the types of specialized expertise required to assess the application. REB members will be asked to further confirm **in writing** that the required expertise does not exist on the REB. The REB will assist the Chair by recommending **in writing** criteria to be used by the Chair to select appropriate scholarly or peer reviewers.
6. In making this assessment, REB members may suggest names to the Chair of individuals who meet the recommended criteria and would be suitable scholarly or peer reviewers. These may be either internal or external personnel. The Chair will also contact the Research Department and the Executive Dean of the relevant school to determine possible scholarly reviewer names.
7. The Chair will summarize the responses received and place a copy of this in the application folder.
8. Before the next regularly scheduled REB meeting, the Chair will outsource scholarly or peer review tasks to the ad hoc reviewers identified. The Chair will contact the potential reviewers selected and provide them with: information on the honorarium available, a conflict of interest and confidentiality statement to sign and an acknowledgement that, for the purposes of this application, the scholarly reviewers are considered to be ad hoc members of the REB. Together with the reviewers, the Chair will determine the date by which the reviewers expect to have feedback available for the applicant. External reviewers will be required to bring their scholarly or peer-review findings to REB within the date agreed to with the Chair.
9. The Chair, after consultation with the REB, may also outsource the REB review *itself* to another REB with specialized expertise. The Conestoga Board will remain the REB of Record in this instance. The Conestoga REB will assist the Chair in determining a list of suitable REB's to contact for the delegated review.
10. If the review is delegated to another REB, the delegated REB should be required to provide timely information back to the Conestoga REB *within a time period to be mutually agreed upon*.
11. The Chair will communicate with the applicant and advise him/her that this application has been deemed to be above minimal risk and will be subject to a full board review *and an external scholarly review*. This communication should also advise the applicant of the likely date by which they can expect a response *taking into consideration the fact that a full board review will be required at the next scheduled meeting, the REB review may be delegated to another Board and that scholarly review feedback will be required*.

12. The REB will review information received from the scholarly or peer reviewers together with any other REB to whom the review has been delegated *to ensure the review is complete and thorough.*
13. The Conestoga REB will summarize the results of these reviews and communicate back to the applicant.