Preset Criteria for Determining Level of Delegated Review

The HREB applies a proportionate approach to research ethics review based on the level of risk presented by the research, in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2018 (TCPS2) and applicable regulatory requirements. This allows the HREB to provide a higher level of scrutiny for the ethically challenging research, while still requiring that the foreseeable risks, potential benefits and ethical implications will be considered in delegated reviews.

TCPS2 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.

The HREB utilizes a four-level set of criteria for conducting delegated reviews based on the level of risk presented by the research.

LEVEL 1

REVIEWER: HREA Administrator

RISK THRESHOLD: Administrative updates

EXAMPLES:

- Addition or removal of study team members with the exception of
    1. Principal Investigator and/or Co-Principal Investigator, which requires an amendment.
    2. Co-Investigators and/or study team members included in study documents, which requires an amendment.
    3. For-cause removals due to compliance and/or misconduct of study team members.

LEVEL 2

REVIEWER: Ethics Officer

RISK THRESHOLD: Administrative updates; Updates with no associated risk to study participants

EXAMPLES:

- Changes to header/footer of study documents such as version dates, pagination
- Editorial changes such as grammar, punctuation corrections
- Administrative changes to Investigator's Brochures and/or Product Monographs that do not require changes to study consent forms
- Minor protocol deviations that pose no risk to participants
- DSMB reports and Safety Updates when there are no modifications made to the protocol

LEVEL 3

REVIEWER: HREB Chairperson

RISK THRESHOLD: Minimal risk study updates and continuing reviews

EXAMPLES:

- Approval of Annual Renewals* (Continuing Review) and/or study documents* (such as consent forms) that do not:
    - affect the rights and welfare of research participants
    - involve increased risk
    - affect data integrity, or
    - require significant changes in research procedures
- Addition/Change of Principal Investigator (PI) or Co-PI
- Addition/Change of Co-Investigator(s) and/or study team members listed on study documents
- Removal of PI, excluding for-cause removals tied to research non-compliance or misconduct
- Minimal risk amendments, safety reports, study closures, and other study updates, unless full board review required per regulations/guidelines
- Addition of participant materials such as recruitment posters or scripts, diaries, validated questionnaires, and clinical trial identification/wallet cards

*Annual renewals and other study documents will be reviewed by the HREB full board, as required by regulations/guidelines.

LEVEL 4

REVIEWER: HREB Chairperson + Additional HREB Member(s)

RISK THRESHOLD: Minimal risk but exceeding Level 2 and 3

EXAMPLES:

- Minimal risk research studies
- Minimal risk study amendments, as determined by the Chairperson to require review by additional HREB Member(s)