

GUIDELINES FOR EXPEDITED REVIEW FOR MINIMUM RISK RESEARCH

(Ref: National Statement S 2.27 to 2.29, HREC Handbook pp C32-C33 & E86-E88)

The RWH Human Research Ethics Committee may undertake expedited review of research. In so doing, review of such research may depart from the normal review process, that is, review firstly by the RWH Research Committee and if found satisfactory, progressed to the RWH Human Research Ethics Committee for consideration.

1. CRITERIA FOR EXPEDITED REVIEW

- 1.1 Expedited review should **not** be used as a way to circumvent normal review process. Researchers are requested to plan their application to the Research and Human Ethics Committees well in advance to meet submission closing deadline.
- 1.2 One primary reason for requesting expedited review is the ‘**time factor**’, e.g. in the case of Masters and AMS (medical) students who are required to undertake research at a rather tight time frame.
- 1.3 Notwithstanding 1.2 above, justification for expedited review is that the **research involves minimal risk to participants**, not on the grounds of researchers’ claim to the need of urgent review of their project.
- 1.4 Research with **potential for physical or psychological harm are generally not to be considered** for expedited review.
- 1.5 **Other situations** where review are **not normally be expedited** include where vulnerable populations are involved or where conflict of interest may arise, e.g. role of clinicians & researcher, or patients & treatment health professionals.
- 1.6 In some circumstances, often created by research funding time constraints, a faster review than is normally available is sought. Where the research involves more than minimal risk, departing from the normal review process is generally not encouraged.

2. CRITERIA ----- RESEARCH SUITABLE FOR EXPEDITED REVIEW

- 2.1 Examples of situations in which expedited review **may be permitted** include:
 - 1) Amendments to an approved project where such amendments do not affect the substance of the original protocol and where no major new ethical issues are raised.
 - 2) Protocol amendments for safety reasons, that is, in order to protect the welfare of participants in a trial
 - 3) Requests for extension for an approved project with no modification of protocol
 - 4) Approval of recruitment and publicity material for approved projects
 - 5) Change of Associate and Co Investigators
 - 6) Provision of a retrospective statement that the quality assurance study has been conducted in an ethical manner to assist journal editors to assess articles presented for publication.
- 2.2 The following research applications will **not generally** be considered for expedited review:
 - 1) New research applications that do not involve students (see 1.2 above)
 - 2) Drug trials
 - 3) Research involving invasive physical procedures

- 4) Research exploring sensitive personal or cultural issues
- 5) Amendments to approved projects where such amendments affect the substance of the original protocol and where major new ethical issues are raised.

3. EXPEDITED REVIEW SUB-COMMITTEE (ERSC)

3.1 Authority

- 1) The ERSC is a sub-committee of the RWH Human Research Ethics Committee.
- 2) The ERSC is authority to approve a request subject to ratification by the full Human Research Ethics Committee at its next meeting.

3.2 Membership

- 1) Chair, RWH Human Research Ethics Committee -- Chair
- 2) Chair, RWH Research Committee
- 3) RWH Associate Director of Women's Services
- 4) Administrative Officer, Research and Ethics Secretariat --Secretary

4. EXPEDITED REVIEW PROCEDURE

- 4.1 In general, applications considered for expedited review should provide the same information as normal applications.
- 4.2 While researchers may request expedited review, that determination remains within the Human Research Ethics Committee's control.
- 4.3 The Secretary will ascertain, in consultation with Chair, RWH Research Committee, that the request meets the criteria for review.
- 4.4 If the request appears to meet the criteria, the Secretary will circulate the request to members of ERSC for consideration, with reply to return within one calendar week.
- 4.5 The ERSC may recommend i) the request be accepted, ii) that conditions or changes be required, or iii) the request be referred for further discussion to the full Human Research Ethics Committee.
- 4.6 The researcher will be advised of decision of the ERSC.
- 4.7 The decision of ERSC will be ratified by the RWH Research Committee and RWH Human Research Ethics Committee at the next meeting.