HEALTHBRIDGE RESEARCH ETHICS BOARD REVIEWING PROCESS

MEETING REQUIREMENTS AND ELEMENTS OF THE REVIEW

Meeting requirements

Researchers should be aware that ethical review may, in the ordinary course, take three weeks to complete. Cases involving significant ethical concerns may take substantially longer. It is the researcher's responsibility to ensure that there is adequate lead time available for ethical review in relation to other deadlines. Research with human subjects will not commence prior to the issue of ethics approval (e.g., recruitment).

HBREB will review in a timely fashion all properly submitted applications, according to its established review procedure

- Meetings will be planned in accordance with the needs of the workload
- HBREB members will be given enough time in advance of the meeting to review the relevant documents
- Meetings will be minuted; there will be an approval procedure for the minutes;
- The applicant, sponsor and/or investigator may be invited to present the proposal or elaborate on specific issues
- Independent consultants may be invited to the meeting or to provide written comments, subject to applicable confidentiality agreements

Elements of the review

- Scientific design and conduct of the study (appropriateness of the study design, statistical methodology including sample size calculation, justification for use of control arms, adequacy of provisions made for monitoring and auditing to conduct the research, adequacy of the site, manner in which results may be reported and published)
- Recruitment of research participants (characteristics of the study population, means by which initial contact and recruitment is to be conducted, inclusion and exclusion criteria),
- Care and protection of the participants (suitability of investigator(s) qualifications and experience for the proposed study, any plans to withdraw or withhold standard therapies for the purpose of the research, medical care to be provided to research participants during and after the course of the research, adequacy of medical supervision and psycho-social support, steps to be taken if research participants voluntary withdraw during the course of the research, arrangements, if appropriate, for informing the research participant general practitioner, insurance and indemnity arrangement)

- Protection of research participant confidentiality (a description of the persons who will have access to personal data, measures taken to ensure confidentiality and security of personal information concerning research participants)
- Informed consent process (a full description of the process for obtaining informed consent, adequacy and completeness of written and oral information to be given to the research participants or their representatives, the provision made for receiving and responding to queries and complaints from research participants
- Community consideration (the impact and relevance of the research on the local community, the steps taken to consult the community in the design of the research, influence of the community in the consent of individuals, extent to which research contributes to the capacity building within the community, manner in which research results will be made available to participants and the community)
- Information letters and consent forms should be set as one document - The name of the funding agency should appear in the Information Sheet/Consent Form below the title of the study and names of the investigators, and above the first introductory paragraph.

DECISION MAKING AND COMMUNICATION OF THE DECISION

Decisions of the Ethics Board shall be reached by consensus, wherever possible. If the Board cannot achieve consensus, however, the decision shall be based on majority vote. In making decision on applications for the ethical review of biomedical research, HBREB will take the following into consideration:

- A member should withdraw from the meeting for the decision procedure concerning an application where there arises a conflict of interest – the conflict of interest should be indicated to the chair person prior to the review of the application and recorded in the minutes
- A decision may only be taken when sufficient time has been allowed for review and discussion of an application in the absence of non-members (e.g, the investigator, representatives of sponsor, independent consultants) from the meeting, with the exception of HBREB staff
- A decision should only be made at meetings where a quorum (as stipulated in the HBREB's written operating procedure) is present
- The document required for a full review of the application should be complete
- Only members who participate in the review should participate in the decision;
- Advice that is non-binding may be appended to the decision
- In case of conditional decision, clear suggestions for revision and the procedure for having the application re-reviewed should be specified
- HBREB shall accommodate reasonable requests from researchers to participate in discussions of their proposals, but the researchers may not be present when the Board makes its decisions. When the Board identifies factors that may jeopardize the well-being of human participants, such issues should be resolved co-operatively by the Board and the researcher.
- When the Board considers a negative decision, it shall provide the researcher with its reasons for doing so, and give the researcher an opportunity to reply.

- A negative decision on an application should be supported by clearly stated reasons; position of those disagreeing with the decision shall be communicated to the researcher, in order to sensitize him/her to the potential risks of the project.

Communicating a decision

HBREB decisions shall be communicated in writing to the applicant within two weeks of the meeting at which the decision was made. Communication of the decision would include:

- Exact title of the research proposal reviewed
- The clear identification of the protocol of the proposed research or amendment, date and version number (if applicable) on which the decision is based
- The names and (where possible) specific identification number (version numbers/dates) of the documents reviewed, including the potential research participant information sheet (material) and informed consent form
- The name and title of the applicant
- The name and title of the site
- The date and place of decision
- Clear identification of the protocol, date and version number
- The name and the specific identification and number of documents reviewed
- Clear statement of the decision reached
- Any advice by the HBREB
- In the case of a conditional decision, any requirements by the HBREB, including suggestions for revision and the procedure for having the application re-reviewed
- In the case of a positive decision, a statement of the responsibilities of the applicant; for example, confirmation of acceptance of any requirements imposed by the HBREB; submission of progress reports; the need to notify protocol amendments

APPEALS OF ETHICS BOARD DECISIONS AND FOLLOW UP

Appeals

A researcher, who disputes the Research Ethics Board decision, may appeal that decision to HBREB who will consider a second review of the protocol. If HBREB maintains its decision, it will transfer the protocol to another Research Ethics Board who serves as appeal board for HBREB. If there is a cost for the second Board it will be borne by the applicant. However, because ethics review and the observance of research ethics is based on the collegial relations among the Board and researcher, a request for appeal must be the last resort. The appeal board must be satisfied, before an appeal is heard, that the researcher and the Ethics Board have exhausted all reasonable attempts to resolve disagreements co-operatively and collegially. Bases for appeal are restricted to claims of procedural irregularity, lack of due process, and exceptions to precepts of natural justice, such as bias. Decisions by the second ethics Board are final.

Follow up

HBREB is engaged to follow up the progress of all studies for which a positive decision was taken until the termination of the research. The follow up procedure would take the following into consideration:

- Quorum requirements, review and communication procedure may vary for the initial decision on an application
- Follow up review intervals may vary according to the nature and the events of the research projects, though, each protocol should undergo a follow up review at least once a year
- Some instances or events require the follow up review of the study (protocol amendment likely to affect the rights, safety, well-being of the research participants – serious unexpected adverse events related to the conduct of the study or the study product – any event or new information that may affect the benefits and risks of the study
- A decision of the follow up should be issued and communicated to the applicant, with an indication of a modification, suspension or termination of the HBREB's original decision or confirmation that the decision is still valid
- HBREB should receive a notification of the applicant at the completion of the study
- HBREB should receive a final summary and a final report of the study