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Health Sciences North
Horizon Santé-Nord

Annual Renewal/ Final Report Guidelines

1. INTRODUCTION

The Health Sciences North Research Ethics Board (HSN REB) conducts continuing review of approved research taking place within its jurisdiction at intervals appropriate to the degree of risk to which participants are exposed, but not less than once per year.

2. ANNUAL RENEWAL OF RESEARCH INVOLVING HUMAN PARTICIPANTS

Annual renewals (sometimes called annual approvals) are required of all investigators at minimum once per year. The research must be reviewed on or before the expiry of the current approval, even though the research activity may not have begun until sometime after the REB granted approval. Annual Renewals must be submitted until all contact with study participants has concluded, all data have been collected and analyzed, and the objectives of the approved study are met to the extent possible. With few exceptions, renewals of research must continue until the letters of appreciation and lay summaries of findings are shared with participants.

3. LEVEL OF REVIEW

Full REB review is the default requirement for renewals of research involving human participants. If the Annual Renewal is brought to full REB, then the approval must take place at a convened meeting at which a REB quorum is present.

The authority to approve Annual Renewal may be delegated to the REB Chair or his/her designate when there has been little or no change in the ongoing investigation. If this criteria is met, the Chair or designate will review the Annual Renewal as a delegated review. The Chair or designate can at any time put a request for annual renewal forward for review by the fully convened Board.

Annual Renewal will be reviewed by the Full Board if required by the study Sponsor, Funding Agency, or Regulatory Agency.

4. TIMELINES FOR FULL BOARD REVIEW

The HSN REB meets on the first Monday of the month with the exception of August. Submissions must be received the Research Services Office by the 15th of the month prior.
Submit 1 scanned copy by email to reb@hsnsudbury.ca and deliver the original signed copy + 4 copies to the Research Services Office.

The Annual Renewal Form should normally be submitted by the Local Principal Investigator 6 weeks before the study approval period ends.

5. STUDIES FUNDED BY THE US FEDERAL GOVERNMENT OR REGULATED BY THE US FOOD AND DRUG ADMINISTRATION (FDA)

Studies funded by the US Federal Government or regulated by the US Food and Drug Administration must be reviewed by the fully convened Board unless they clearly meet the following criteria:

a. The research is
    i. permanently closed to the enrollment of new participants;
    ii. all participants have completed all research related interventions; and
    iii. the research remains active only for long-term follow up of participants; OR
b. Where no participants have been enrolled and no additional risks have been identified; OR

c. Where the remaining research activities are limited to data analysis.

6. CRITERIA FOR ANNUAL RENEWAL

The Annual Renewal process must be substantive and meaningful, the rigor of which shall be in accordance with a proportionate approach to ethics assessment. In order for continuation of approval to be granted, the REB will determine that:

a. There is no conflict of interest that has emerged since initial REB approval and/or previous annual renewals that might adversely affect the safety or well-being of study participants.
b. The risk to participants continues to be minimal and reasonable in relation to the anticipated benefits.
c. There is no new literature which might affect the willingness of study participants to participate.
d. There have been no complaints from study participants which require further investigation.
e. Number of participants enrolled, withdrawn, dropped out and completed.
f. For regulated clinical trials, the reports of Data Safety Monitoring Boards and Sponsor-generated Safety Reports must also be favourable for continuation of the study.

7. EXTENSIONS OF APPROVAL PERIOD

There is no grace period extending the conduct of the research beyond the expiration date of REB approval for regulated clinical trials. Extensions beyond the expiration date will not be granted. If progress reports are not submitted as scheduled, the study will be suspended. No research related activities may occur after the approval expiration date unless the Local Principal Investigator (PI) contacts the REB and a determination is made that it is in the best interest of individual participants to continue during the lapse in REB approval.

The REB is fully authorized to do one or more of the following as deemed appropriate:

- Hold the review or approval of current or future submissions by the Local PI until the status of the expired study has been addressed.
- Notify the funding agency, industry sponsor or the appropriate regulatory authority of the expiry of the ethics approval for the study.
- Notify financial accounts personnel to advise them that the study is no longer approved and that no further funds from the account should be released.

It is ultimately the responsibility of the PI to provide in a timely manner the information needed by the REB to perform an annual review and any reminders or notices regarding the need to do so from the REB to PIs are a courtesy.

For all other research that is not a regulated clinical trial, if progress reports are not submitted as scheduled, the study will be permanently closed and a new submission will be required to reactivate.

8. THE POINT AT WHICH AN ANNUAL RENEWAL IS NO LONGER NECESSARY

Annual Renewal of a research project at least annually is required so long as the project continues to involve human participants and their research data. A research project continues to involve human participants as long as the investigators conducting the research continue to obtain:

a. Data about the participants of the research through intervention or interaction with them
b. Identifiable private information about the participants of the research (this includes obtaining biological specimens origination from living individuals)
   Obtaining identifiable information includes:
   i. Collecting or receiving identifiable private information (including identifiable biological specimens) from any source (i.e., not already in the possession of the investigator);
   ii. Collecting identifiable private information by observing or recording private behavior without interacting or intervening with the human participants; and

iii. Using, studying, or analyzing identifiable private information (including identifiable biological specimens), even if the information was already in the possession of the investigator before the research begins. This includes using, studying, or analyzing any of the following:
- Identifiable private information obtained by interacting or intervening with the human participants;
- Identifiable private information stored in documents, records, photographs, images, video recordings, or audio recordings provided to the investigators from any source;
- Identifiable private information stored in documents, records, photographs, images, video recordings, or audio recordings already in the possession of the investigator before the research begins;
- Identifiable private information obtained about an individual by interviewing other people (e.g., an individual's healthcare provider or teacher);
- Identifiable biological specimens provided to the investigators from any source;
- Identifiable biological specimens already in the possession of the investigator before the research begins.

A research project no longer involves human participants once the investigators have finished obtaining data through interaction or intervention with participants or obtaining identifiable private information about the participants, which includes the using, studying, or analyzing identifiable private information. Once all such activities described in the REB-approved protocol are finished, and in most cases after a lay summary has been provided to research participants, the research project no longer needs to undergo Annual Renewal.

At that point the PI should submit a Final Report using the Annual Renewal/Final Report Form which notifies the REB that they can formally close the REB file for that project.

9. FINAL REPORT

A Final Report should be submitted when contact with subjects for the purpose of data collection or research (e.g. for follow-up or verification) is complete. The Annual Renewal/Final Report Form should be completed and submitted before the expiry date. This ensures that the REB has an up-to-date and accurate record of on-going studies involving human subjects.

For industry sponsored studies, a Final Report should only be submitted to the REB office after the sponsor has conducted the close out visit. If the sponsor has no plans to conduct a close out visit, the Final Report must be submitted after all data clarifications have been completed and the sponsor has indicated to the PI that study files can be archived for long term storage.

Study results that are received after the Final Report has been submitted may still be submitted to the REB using a Supplemental Request Form.

Please note that, following completion or termination of a project, the researcher is obligated to continue to adhere to all stipulations regarding the use and confidentiality of the data described in the original application and not to use these data for other research purposes without application to and approval by the HSN REB.