UNIVERSITY OF MANITOBA

Bannatyne Campus Research Ethics Boards
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Health Research Ethics Board (HREB)
Policy Statement on Retrospective Chart or Record Reviews

1.0 Purpose:

To describe the procedures and submission criteria required to obtain Health Research Ethics Board approval to conduct a retrospective chart or record review.

2.0 Introduction and Tri Council Policy Statement

Retrospective chart/record reviews necessarily involve the *secondary use of data* in that information and data contained in charts/records that was collected for a specific purpose(s) is later examined for a purpose(s) other than the reason it was initially collected. The major risk associated with such reviews revolves around the potential that an individuals' identity contained in the charts/records reviewed may be inadvertently revealed in reports, presentations, and/or publications derived from the retrospective review. Because of the usual absence of strong experimental control of a range of potentially important variables that may have significantly affected the chart/record data, retrospective chart/record reviews typically cannot provide definitive causal relationships to be drawn from the data. However, they are potentially extremely valuable in formulating research hypotheses that may then be prospectively examined using appropriate experimental methodology, thus permitting stronger conclusions to be drawn. The potential value of retrospective reviews often justifies the risk to confidentiality associated with their use.

The Tri Council Policy Statement on the Use of Human Subjects in Research requires Research Ethics Board (REB) approval for studies involving the secondary use of data whenever the data contains personal identifying information. Research Ethics Boards are guided in their consideration for approval of such retrospective chart/record review submissions by the following principles (additional conditions to the four guidelines stated below may also be required at the discretion of the REB):

1. Identifying information must be essential to the retrospective research that is proposed.
2. Researchers must take appropriate measures to protect the privacy of all individuals whose charts/records are being reviewed in order to maximize the maintenance of confidentiality and to minimize potential harms to the individuals.
3. Individuals to whom the data refers must not have objected to their data being subjected to secondary use.
4. Researchers must **not** contact individuals to whom the data refers without prior written authorization from the Research Ethics Board.

Additional HREB considerations in considering Retrospective Chart/Record Reviews

1. The proposed review poses no more than minimal risk to subjects.
2. The questions/objectives of the review have scientific merit.
3. The data being collected and reviewed **are** being done so without the intention of contacting the individuals in the future.
4. The data being reviewed **have** been collected as a part of routine procedure and/or normal standard of care.

3.0 Criteria to be addressed by researchers related to requests for Retrospective Reviews

1. State the purpose, hypotheses, and study questions to be examined in the review.
2. Outline the benefits expected from the research

3. Provide background information and/or literature supporting the potential benefits to follow from the proposed review.
4. Indicate why subject approval to review their charts/records is impractical, impossible, and/or would adversely affect the research.
5. Describe in **general terms** how the information to be collected relates to the study's purpose, hypotheses, and study questions. If the information does not relate directly to these, provide an explanation why the information is being collected.
6. Provide a detailed description of the methods that will be used to protect the privacy and confidentiality of the individuals whose information is being reviewed, including addressing the four points below:
    a. Data capture should be done only on paper or electronic forms that are coded and do not contain personal identifying information.
    b. Describe the means by which electronic and/or paper master lists with personal identifying information linked to the data capture forms are securely maintained.
    c. Identify all individuals who will have access to the master list with personal identifying and the data capture information and how access to this information is secured and monitored.
    d. Please provide assurance that all individuals with access to data have signed appropriate oaths of confidentiality with respect to not divulging any information collected as part of the review.

7. Provide a copy of the data capture sheet detailing precisely what information is being collected from which source(s). **If in the course of collecting information using the approved data capture sheet it becomes evident that additional data is required, please contact the REB and request an amendment to the approved data capture sheet.**
8. Indicate how the charts/records to be reviewed are to be obtained
9. Provide evidence either prior to or following REB approval of the approval of the custodian of the records and/or institutional support for the review as is required by any applicable institutional policies.
10. Provide an approximation of the number of charts/records that you expect to review.
11. Specify where the charts/records are maintained and where the abstracting of the information from them will occur, paying particular attention to the privacy and security of the work environment in which the information extraction is to occur.
12. Specify the approximate time period during which information from the charts/records will be extracted (e.g. April-May, 2008).
13. Specify the approximate time range over which the information in the charts/records was collected (e.g. all patients seen between 2000-2008).
14. Describe the methodology and data analysis to be used in the chart/record review process.
15. Outline your intentions with respect to how the data will be used with respect to reports, presentations, and/or publication.
16. Specify the population being studied, including the ages and conditions of the subjects.
17. Indicate whether or not an electronic data base be created in the process of the review, and if so:
    a. Indicate whether the database will be used only for the purpose of data analysis
    b. Indicate any intention to maintain the data for a period of time beyond the data analysis phase of the review.
    c. Indicate whether or not the database that will be used is compliant with the Personal Health Information Act of Manitoba (PHIA). Describe how the database meets this requirement. Information can be found on the Bannatyne Campus Research Ethics Board website at "**Requirements for PHIA Compliancy for Databases".**

4.0 Procedures

Submission and Screening

1.0 The Principal Investigator is to submit <u>2 copies</u> of the following documentation by the meeting deadline date
- Bannatyne Campus Retrospective chart/record review submission form
- Protocol (**<u>NOTE:</u>** A protocol is not required if this submission form is completed in full.)

- Data capture sheet
- CV template(required with first ethics submission for the calendar year)

2.0 The submission will be screened and reviewed by HREB Chair or delegated to an REB member by the HREB Chair and REB coordinator. In most circumstances it will usually only be reviewed by the HREB Chair and REB coordinator.

Time lines

Expedited review does not refer to a timeline but rather to the level of review conducted by the REB. Chart or records review submissions received by the full board submission date will be reviewed within 10-14 days of the full board REB meeting.

Letters of conditional review or certificates of approval will usually be sent to Principal Investigator within 5-7 business days following the monthly full board meeting if the submission deadline was met.