

# 10 Step Overview - How to do a Clinical Research Project

## A Resource for Residents

This document is a tool created for residents to familiarize themselves with the steps involved in undertaking a research project involving human subjects. As you read through this electronic document you may click on the links to find additional resources, information, and forms available on the internet. This document is meant only as a guideline as there may be additional requirements needed prior to starting a particular project, depending on the nature of the study. Additionally, please keep in mind that each step in the process will take time to complete and to start each process well ahead of deadlines.

**Step 1:** Identify a supervisor and decide on a research topic, a specific hypothesis to test and an experimental approach to answer your research question.

**Step 2:** Determine the feasibility of your project including:

- participant population
  - how and where will you recruit participants or identify subjects for a chart review keeping in mind privacy and confidentiality issues (see PHIA Guidelines below);
  - will you be using a comparison or control group?; if so, how will you select them?
- statistical requirements,
  - now is the time to determine how many study participants will be needed to answer your research question
  - what statistical help will you require? [See the MICH website for statistical services offered.](#)
- space, equipment and staffing if necessary
  - what support will you need?
- budget,
  - How much will the study cost? Where will these funds come from? Do you need to apply for a grant? Where might you apply?
  - Decide whether or not you will offer a subject stipend, or how you will cover expenses such as parking.
  - Keep in mind that even with a retrospective chart study there may be a cost for chart retrieval from the Medical Information Department if you cannot get this fee waived.
  - How will your study funds be administered once received and who will have “signing authority”?

*Consideration must be given as to where your study funds will be administered, once received. Depending on where you receive funding from, this may be the Health Sciences Centre, St. Boniface General Hospital or the University of Manitoba.*

**Step 3:** Create a write-up to explain your research project (protocol)

- If this is part of a grant application, follow the application instructions of the agency keeping in mind the deadlines, the need for institutional signatures and any internal reviews
- If this is not part of a funding application, your write-up of your proposal should include:
  - A brief description of the current scientific literature related to your project
  - The rationale for conducting your project (why is your research project important)
  - A hypothesis
  - A brief description of your scientific strategy for studying the hypothesis

- A brief outline of what you will be doing
- A time line (how long do you think it will take you to complete the project and write up your results?)

*Keep in mind that the protocol is a guidance document required for use through the duration of the study. It should be an outline, or a set of directions/ instructions of processes/ procedures that will be used in the conduct of the study. This will assist approval boards in understanding exactly how the study will be conducted.*

- Step 4:** Create a [Participant Information and Consent](#) form if required. If you are enrolling subjects between ages 7 and 13 yrs of age, you must also create an [assent form](#).  
Create any collection tools/aids that you will need to assist you in your project. Refer to the Ethics website to ensure you are following [PHIA guidelines](#) in regards to privacy in research.  
Ensure that each tool and revision is dated within the footer of the document.
- Step 5:** Complete and submit an [Ethics Submission form](#) and address it to either the Health Research Ethics Board -or- Biomedical Research Ethics Board (see [U of M Ethics website](#) to determine which to send to).  
Include all the required documents in the submission and ensure they are all dated. If you will be advertising for participants in your study, you must submit the advertisement for approval to Ethics. Approval at Public Relations offices is required to post any advertising at institutions.  
Check the ethics website for [monthly deadlines](#) as well as what documents are required in your submission.
- Step 6:** Submit other [institutional submission forms](#) as required. If you are conducting your research at any of the teaching hospital clinical facilities or using their medical records or laboratories, you will need to get institutional approval to do so. These can be found at the following links: [St. Boniface Hospital Office of Clinical Research, Health Sciences Centre](#) (found under 'Reference Documents' as HSC Impact form)  
There may be other approvals required if research is conducted at other institutions, please check with the administrator. Institutional approval committees review studies for impact on resources and services and you must have approval prior to start of your study. Keep in mind that for lab and pharmacy use, as well as several other departments, costs will most likely be assessed.  
If you are using any of the provincial data bases you will need to get approval from the [Health Information Privacy Committee](#).
- Step 7:** Only once you have received ethics and institutional approvals may you begin your study.
- Step 8:** Any [amendments](#) to the study protocol, consent form, and/or collection tools need to be submitted for approval by ethics. As stated previously, with any amendment, remember to update the date on that document.
- Step 9:** An [annual study status report](#) must be submitted to ethics each year if you wish to continue your research beyond the expiry date indicated on your Ethics Approval Letter.
- Step 10:** Once you have analyzed and completed your research project, submit a [final study status report](#) to ethics.

#### **FUNDING:**

Please refer to the [MICH website](#) for information on grants available for research.  
You may also find additional support through the [Health Sciences Centre Foundation](#) site.