# Preparation of a Research Proposal

This document describes how to prepare the research proposal or protocol.

**Title:**

Provide a succinct, but descriptive title.

**Investigators:**

List all investigators, their academic degrees and their affiliations. The IRB requires updated curriculum vitae from each investigator describing their professional experience. The principal investigator is responsible for the overall conduct of the study. The investigator can delegate activities associated with the study, but the responsibility cannot be delegated. The investigator, in addition to their professional experience, must have expertise in human subject protection, in aspects of clinical research and especially in administration of a study. Study administration includes:

- writing the protocol
- maintaining study files
- Maintaining records of correspondence with funding sources and review bodies such as the Institutional Review Board

**Summary or Abstract:**

State concisely the purpose of the project, proposed hypothesis, methods of collecting data and how it will be analyzed. The summary or abstract is best written after the other elements of the proposal have been addressed. The summary can be used to provide information for administrative approvals and as the written handout to nursing staff or others who have a need to know about the research. It may be used to submit to meeting or conference planners for presentation.

**Background and Literature Review:**

This portion of the protocol should include review of pertinent literature and include references to that literature. A search of MEDLINE should be completed. The Miami Valley Hospital (MVH) or Wright State University (WSU) libraries have access to the literature through OHIO Link and the internet. The librarians can provide assistance to conduct a search. Reviewers expect that all significant information discussed have associated peer–reviewed literature citations. They may want to independently confirm the writer's interpretation of a paper, especially when the interpretation is controversial. Methods and current practices and any novel approaches to the subject matter are especially important to document. The absence of a complete literature review is a common omission in research proposals.

**Specific Aims or Objectives:**

State the question(s) that the study is intended to answer. Without having clearly defined research questions, it is impossible to have a well-written protocol. If the questions are not completely thought out in advance, then the investigator cannot know what information to collect during the study. The study question influences the methods and the statistics used for analysis. Most statistical tests require that the question be defined before collection of the information. Even when associations or correlation with an event are the desired outcome, it is easy to let bias slip in if the question is not specified in advance.

**Significance to patient, institution, profession:**

This section of the protocol defines why the research is worth doing. A question may exist for which there is no answer, but it may not be worth doing a study to collect the information, either because the research would be inappropriate or even with the answer, no changes would or could be made. Research that might not be important to an individual subject might be important to an institution or a profession or society. How a particular study fills in knowledge gaps helps to understand the risk benefit ratio of the research. Knowledge gaps are places where information does not exist. (For example, there are large knowledge gaps in the use of drugs in children. Much of the dosing is ad hoc, generally based on body weight. Actual information about how children handle specific drugs is missing.)

**Preliminary Work:**

Complete this section if preliminary work is available. For laboratory-based and even clinical-based research, preliminary results are often important. There may be sources of funds to enable investigators to collect preliminary data. Preliminary data shows that the research is feasible and provides a stronger basis for estimating sample size. Preliminary data may also enable the investigator to sharpen methodological descriptions and avoid unforeseen pitfalls.

**Methods:**

In developing this section of the protocol, it is critical to gain the advice of experienced individuals. Studies that are not properly designed are inappropriate to conduct. The time and effort of the investigator or the reviewers will be wasted if the study cannot answer the questions.

- Describe the research design and procedures to be used to accomplish the specific aims of the project,
- Include the methods by which the data will be collected, analyzed, and interpreted
- Describe any new methodology and its advantages over existing methodologies
- Discuss the potential difficulties and limitations of the proposed procedures
- Provide a tentative sequence or timetable for the investigation
- Point out any procedures, situations, or material that may be hazardous to personnel and the precautions to be exercised
- Describe how patient/subject confidentiality will be maintained
- Identify the need for Informed Consent (IC) and HIPAA authorization. If it is not possible to this authorization, request waivers of IC and/or HIPAA authorization

**Other content areas:**

This section might include Subjects, sample size, cost or equipment needs.

**HIPAA issues and confidentiality**:

For abstracting information from charts or databases a waiver of HIPAA authorization and IC is required. For the Privacy Board or IRB to grant such a waiver:

- *the protected health information (PHI) must involve no more than minimal risk*
- *there must be an adequate plan to protect identifiers from disclosure*
- *there must be an adequate plan to destroy identifiers at the earliest opportunity consistent with the conduct of research or a research justification for retaining identifiers*
- *there must be written assurance that the PHI will not be disclosed except as required by law*
- *there must be an explanation of why the research could not practicably be conducted without the waiver and without access to and use of PHI*
- *there must be a data form, which lists all data elements that will be abstracted from the record See the sample wording at the end.*
- *Premier Health utilizes the EPIC "inbasket" process to provide EMR access to researchers doing retrospective chart review. This process permits the researcher access to only those patient records specified in the research protocol. Contact the Clinical Research Center (CRC) at MVH for assistance with setting up an "inbasket" account for a retrospective study.*

**Protecting confidentiality of electronically stored data:**

Premier Health (PH) requires that data be stored on a PH file server which provides regular backup and security. Data must NOT be stored on the local C: drive of computers, or any other form of removable media. All data with PHI should be stored in a password protected file whether it is in Word, Excel, Access or some other database. PH IT customer support can assist the PI with arranging for data storage on a PH server. The Clinical Research Center (CRC) at MVH has computer workstations that meet these requirements as well as statistical programs to assist with data analysis. See the sample wording at the end.

**References:**

Complete a literature review and attach citations for the most pertinent literature.

**Appendices:**

Complete this section as needed. This includes:

- data collection forms
- definitions of data to be abstracted
- questionnaires
- informed Consent Document
- procedure for obtaining consent
- Schedule of Events
- Cost estimates

**Procedure for obtaining consents:**

It is important to document in writing HOW the PI will obtain consent, WHO will ask for consent, and HOW they will be trained in human subjects concerns. Recognizing that informed consent is an entire process, not just having a signature on a document presented along with many other documents. It is important that all members of the research team understand this fact.

**Administrative Issues:**

Identify all documents with the date prepared/revised and paginated, for example X of Y pages (the title page need not be paginated). On informed consent documents, each page should have a line for initials of the research subject. Changes to the protocol and or the consent must be noted as revisions and dated. Any changes to a protocol must be submitted to the IRB and have their approval before instituting the change and should be included in a dated, devised protocol and/or consent form.

For Active Duty Air Force personnel, protocols must also be reviewed and approved by the Wright Patterson Air Force Base IRB. For information on these requirements please contact the Clinical Research Center.

**Process:**

**Regardless of whether the review will be by the WSU IRB or external IRB, all protocols must first be submitted through the MVH Clinical Research Center (CRC) with the WSU-IRB petition and the HIRC application. On-site Human Investigation Research Council (HIRC) approval is required before submission to IRB.**

**Proposals where the Principal Investigator is a nurse:**

All nursing protocols must be reviewed by the Nurse Researcher or Research Facilitator from ***New Knowledge, Information and Innovation Council of Premier Health Nursing Shared Governance before submission.***

**HIRC Review:**

Following approval by either the WSU IRB or WIRB, the protocol will be reviewed by the MVH Human Investigation Research Committee (HIRC) as specified in the MVH Medical Staff Bylaws. This committee is responsible for FINAL approval of any research performed at MVH. The HIRC is responsible for review for a variety of operational requirement not directly the responsibility of an IRB. Examples of situations that could prevent or delay someone starting a research project even though approved by an IRB include:

- insufficient staffing
- unavailability of particular supplies
- oversight inspection by Ohio Department of Health or TJC

**Samples of wording that could be used in preparing a protocol that involves review of medical records:**

- We request a waiver of informed consent and HIPAA authorization for the use of protected health information. We believe that there is no more than minimal risk to individual privacy because all of the investigators handle medical information in a confidential manner on a regular basis. When we obtain the data, the information will be maintained in either a locked file cabinet in the investigators office or in a password protected electronic file such as an Excel spreadsheet. Electronic data will

be stored on a PH file server and never on a local computer hard drive or any type of removable media. Each subject will be assigned an identifier, case 1, case 2, etc to link data and names and medical record numbers will be blocked out on hard copy documents such as x-rays or laboratory results. When hard copy data is no longer needed, it will be disposed of in the hospital confidential information bins that are locked and shredded according to hospital policy.

- The information collected will not be reused or disclosed to any other persons except as required by law and for authorized oversight of the research by entities such as the Institutional Review Board or audits by the Privacy Officer. We intend to abstract data from patient charts seen in the past 7 to 8 years, consequently it is not practicable to obtain informed consent or HIPAA authorization and without reviewing all records it is not practicable to make conclusions about any relationships.