UW Medicine
UW SCHOOL OF MEDICINE

III Requirement

Guidelines for Selective 1 – Data Gathering/Hypothesis-Driven Inquiry

Empirical research poses a hypothesis regarding the relationship between variables and attempts to validate the hypothesis through observation. An empirical research study can take the form of a basic laboratory study, a survey, a secondary analysis of an existing data set, a chart review, a qualitative study, or a prospective clinical trial. The research may be initiated by the student or by the sponsoring faculty member, as long as the student makes an intellectual contribution to the project.

1. Research with Human Subjects If the proposed research project involves humans, and most often human tissues and information about humans, you need to obtain Institutional Review Board (IRB) approval and complete a training module with a Human Subject Division Administrator **before** data collection begins. IRB applications are available at the UW Human Subjects Division site. Use the Contact Lookup Tool to determine the right IRB contact to commence the process of submitting or finalizing your IRB application. (You may also submit an inquiry via e-mail to: hsdinfo@uw.edu). Some projects may be determined by the Human Subjects Division not to require IRB approval. However, this determination must be made by the Human Subjects Division. If your research project involves other organizations/institutions, you may need to apply for and receive approval from their Institutional Review Board. Discuss IRB approval with your faculty sponsor before submitting your proposal. The UW School of Medicine takes the protection of human subjects in research very seriously and monitors students' compliance with human use regulations. We want medical students to understand the obligation of the physician and scientist to protect the rights of research subjects.

Human Subjects Review applications are not difficult, provided you clearly and specifically articulate your research methods, particularly those pertaining to subject recruitment and protection of privacy. Most student projects qualify for either exemption or minimal risk review, and Human Subjects Division personnel understand and try to accommodate the time constraints on medical students. Please allow up to 8 weeks for securing approval to work with human subjects (before beginning your research). **You are required to provide a copy of the IRB approval to the Curriculum Office (somcurr@uw.edu) prior to starting to work on the project. (When applicable, stipend checks will not be dispersed until IRB approval has been received.)**

2. Faculty Sponsor You will work on your research with supervision and guidance from a faculty sponsor. A regular or clinical faculty member in any healthcare-related department at any WWAMI university is eligible to be a sponsor. The sponsor's role is to help you plan your study, meet with you as necessary during the execution of the project, and provide feedback on your final paper. In some cases, the sponsor may be the principal investigator on an ongoing research project. Your sponsor must approve and sign your research proposal, review your final paper, and submit an evaluation.

The sponsor you choose and the relationship you build will be among the most important considerations in making this experience successful, enjoyable, and valuable. Sponsors need to be:

1. Experienced, interested and familiar with your topic.
2. Familiar with the methods you are planning to use in your study.
3. Available to you through phone, email, and scheduled meetings.
4. Someone with skills and knowledge that complement those you bring to the project.

In your search for your faculty sponsor, think about the people you know: professors, guest lecturers, college mentors, and preceptors. You might also consult departmental websites and faculty interest databases. When you first contact a potential faculty sponsor, be prepared to explain information about the III requirement.

3. Research Proposal A written proposal outlining your research plan must be submitted to the Curriculum office for review in the winter term of your first year. This review is primarily for feasibility, and secondarily for scientific soundness. You will receive e-mail notice approximately 2 weeks after the proposal has been reviewed. Faculty Advisors will approve your proposal, ask for further information, or ask that you revise your proposal.

A successful proposal (and a successful study) begins with a simple, clear purpose. This purpose should be reflected in each of the components of the study described below. The purpose will dictate which subjects to choose, what study design to use, what variables to measure, and what analyses to perform.

The proposal should be brief—generally 2-2 ½ typed pages—but should provide sufficient information to give the reviewers a good idea of what you plan to do. Reviewers include members from a variety of clinical and basic science departments, so write your proposal for a broad audience. If additional information can best be presented in non-narrative form (graph, bulleted list, flow diagram, etc.), include that as well.

Following are guidelines explaining what to include in your proposal. Because each study is different, not all items will be pertinent to every study.

Background: Provide a brief introduction to the problem you are investigating. This might include:

- What is the research problem?
- Why is the problem important?
- What is already known about the problem and what remains unknown?
- How will your study contribute to this field of knowledge?

Question and hypothesis to be investigated: As much as possible state your research question in specific, measurable terms. A hypothesis is a testable assertion about the relationship between variables in your study. If you are investigating a clinical rather than a theoretical question, the hypothesis should include an effect size. For example, "Hospital length of stay will be at least 10% lower in the intervention group than in the comparison group." The study hypothesis is different from the null hypothesis, which is only a statistical construct.

Study design and methods: The study design is the logical structure of the study. This has to do with how subjects are selected and grouped and whether an intervention is imposed. It does not have to do with the way data will be collected (chart review, survey, etc.).

- Is this an experimental study (where you impose an intervention) or an observational study (where you collect data but do not intervene)?
- If it is experimental, is there a separate control group or will you compare the same subjects before and after the intervention?
- If it is observational, are subjects chosen and grouped based on their outcomes (e.g., survival status) or based on their antecedent conditions (e.g., smoking status)?

The study design and methodology should include the following:

a. **Population.** The generalizability of your results depends, in part, on the population you study, so it is important to specify what that population is. Inclusion criteria define the broad category of subjects to be included (e.g., women 18-40 years of age, who have never been pregnant and who are currently using oral contraceptives). Exclusion criteria define small

subsets of otherwise eligible subjects who will be excluded (e.g., women with BMI < 22 or who are not fluent in English). Also describe how you will identify subjects (patients from a particular practice, volunteers from posted flyers, etc.).

b. Sample size. From the goals of the study, it is possible to calculate an estimate of the ideal sample size—a sample that is large enough to demonstrate the effect you are looking for but not so large that resources are wasted. Using the recommended sample size may not be practical for you, but you should still know what it is. Sample size calculations are best made in consultation with a biostatistician.

You will need the following information for most studies.

Study goal	**Values you need**
Compare 2 groups using means	Difference between means of each group Standard deviation of scores in each group Significance level (.05 is conventional) Number of tails (2 is conventional) Desired power (.80 is conventional)
Compare 2 groups using proportions	Difference between proportions Significance level (.05 is conventional) Number of tails (2 is conventional) Desired power (.80 is conventional)
Estimate a single mean value	Standard deviation of scores Acceptable level of error (95% confidence interval) Population size (if small)
Estimate a single proportion	Estimate of proportion value Acceptable level of error (95% confidence interval) Population size (if small)

c. Variables and measurements. List variables by category: independent, dependent, or confounder. Independent variables (or exposures) are putative causal factors being investigated. Dependent variables (or outcomes) are the results being investigated. Potential confounders (or control variables) are additional factors that, if not considered, can lead to misinterpretation of the main results. Most measurable factors can and do play different roles in different studies, so make the category clear. Also, describe how variables will be measured and defined. For example, if your study compares non-drinkers, social drinkers, and heavy drinkers, how will those categories be defined? If your study looks at pain as an outcome, how will pain be measured?

Attach drafts of instruments, scales, questionnaire forms, etc. to your proposal. Whenever possible, use instruments that have been used by other investigators with similar populations. This will save you work, will usually provide some insight into the reliability and validity of the instrument, and may enable you to compare your results directly with those of others. If you are developing a new questionnaire, justify why this is necessary.

d. Procedures for data acquisition. Describe the sequence of events that will take place during the study. For some studies, this can be done from the subject's point of view. Step-by-step, describe what will actually take place.

e. **Methods for data analysis.** How will you use the measurements you collect to test your hypothesis? The statistical procedures you choose will depend on the purpose and study design of your project along with the scale of measurement of the variables.

Expected significance of results: Briefly describe what you expect will be the significance of the results you achieve.

Student's role in the project: Empirical research is seldom a solitary endeavor! If you will be working as part of a research team, describe what your responsibilities will be.

Preliminary literature search: List 5-10 references that address your research question.

Timetable. Lay out a realistic timetable for completing the key steps of the project over the ten-week length of the project.

4. Funded Summer Research Opportunities The School of Medicine offers several summer research programs that provide students a stipend and may be used to fulfill your III requirement. If applying to one of these programs, you **must** still submit a Selective 1 proposal (**excluding** MSRTP projects, which have their own proposal form and deadline). These programs include:

- Developmental Disabilities
- ITHS TL-1 (multidisciplinary translational research)
- Medical Student Research Training Program (MSRTP)
- Medical Student Training in Aging Research (MSTAR)

These programs are competitive and have their own application and reporting procedures.

5. Poster & Final Paper. Students are invited to create and present a poster for their Selective 1 projects at the applicable regional poster session in the autumn following the summer of their research. Your poster should include a short introduction and background to your study, the study design and methods used, the results, a brief discussion of the significance of your findings, and a summary/conclusion.

Final papers and faculty evaluation forms are due in March of the student's second year. The student must be the primary author of the paper, even if the student has collaborated with another student or faculty member, or plans to submit the paper for publication under joint authorship. Papers used to fulfill requirements for other courses are not accepted.

Your faculty sponsor is required to review your final paper and submit a faculty evaluation form. Be sure to send her/him your paper for review with enough time to make final edits before the submission deadline. You will submit your final paper along with the faculty evaluation form to the Curriculum office.

6. Timeline. Following is a rough timeline of the Selective 1 process.