UW Medicine
SCHOOL OF MEDICINE

Guidelines for Selective 1 – Empirical Research

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 you make an intellectual contribution to the project.

A. Research with Human Subjects If your proposed research project involves humans, and most often human tissues and information about humans, you need to obtain Institutional Review Board (IRB) approval and attend a workshop with a Human Subject Division Administrator **before data collection begins**. **In addition, you must complete the online training in the protection of human subjects** via the Collaborative IRB Training Institute (CITI) https://www.citiprogram.org/default.asp. Federal, state, and university regulations require that the use of human subjects in research be reviewed and approved by an Institutional Review Board (IRB). At the University of Washington, the Human Subjects Review Division carries out this function. Some projects can 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 as well. 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. Some projects can be determined by the Human Subjects Division not to require IRB approval. Please allow up to 8 weeks for securing approval for working with human subjects. **You are required to provide a copy of the IRB approval to Michelle Fleming prior to starting to work on the project. When applicable, stipend checks will not be dispersed until IRB approval has been received.**

You will be required to speak with a Human Subjects Division Administrator to receive instruction about the appropriate level of IRB review and the appropriate application form to fill out. (**UW IRB Administrator Contact: Geri Faris, gfaris@uw.edu, (206) 616-2345**)

B. Faculty Sponsor You will have the opportunity to work on your research with supervision and guidance from a faculty sponsor. Any regular or clinical faculty member in any health care related department at any WWAMI university is eligible to be a faculty 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 is the principal investigator on an ongoing research project that you connect with. Your sponsor must sign and approve your research proposal and review and sign-off on your final paper.

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, start first with the III Departmental Coordinator. A faculty member from each department has been designated III Departmental Coordinator. Ask the departmental coordinator for suggestions of faculty that may be interested in serving as faculty sponsor for your III project. Other resources are people you know: professors, guest lecturers, residents, fellows, other students, and preceptors. You might also consult departmental websites and faculty interest databases such as the Community of Science (COS) http://www.cos.com/. COS is the leading global resource for hard-to-find information critical to scientific research and other projects across all disciplines. When you first contact a potential faculty sponsor, be prepared to explain information about the III requirement.

C. Research Proposal A written proposal outlining your research plan must be submitted to the III Approval Committee for review. This review is primarily for feasibility and secondarily for scientific soundness. You will receive e-mail notice approximately 2 weeks after it is reviewed. The Committee 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 1-2 typed pages, but should provide sufficient information to give the committee a good idea of what you plan to do. The III Approval Committee includes 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.

Resources for Getting Started:

1. User's Guide to Biomedical Literature
   http://www.mebi.washington.edu/ebm-uwsom/articles.html

2. Formulating Questions & Locating Primary Studies for Inclusion in Systematic Reviews
   http://www.ncbi.nlm.nih.gov/pubmed/9273830

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

Background and rationale 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 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)?

Resource for research methodology: *The Practice of Searching Research-Conduct, Critique, and Utilization.* Burns, N. & Grove, S.K. 2001. W.B. Saunders Company. Philadelphia, PA.

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.).

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 may also use a web-based calculator such as this one from the University of Iowa: http://www.stat.uiowa.edu/~rlenth/Power/index.html or The University of California at Los Angeles: http://calculators.stat.ucla.edu.

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

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.

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.

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. For statistical help, try the "Selecting Statistics" website at www.socialresearchmethods.net/selstat/ssstart.htm

Possible difficulties Briefly describe possible problems you may encounter and your plan for handling them. Examples might include low rates of subject recruitment or untried lab techniques that do not work the way you expected them to.

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.

Timetable As best you can, lay out a realistic timetable for completing the key steps of the project.

D. 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. These programs include:

- Developmental Disabilities
- Family Medicine Research Externship
- ITHS TL-1 (multidisciplinary translational research)
- Medical Student Research Training Program (MSRTP)
- Medical Student Training in Aging Research (MSTAR)
- UW/Seattle Cancer Care Alliance/American Cancer Society Summer Fellowship

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

E. Deadlines

	Selective 1 (Empirical Research)	Selective 2 (Literature Review)	Selective 3 (R/UOP)	Selective 4 (ISIS Simulation Lab)	Selective 5 (IHOP)
Year 1 2014-2015	**MSRTP – Applications due January 5, 2015.** **All other Selective 1 options – Proposals due by March 31, 2015.**	**Proposal due by March 31, 2015.**	**Applications will be available online by the last Friday of Autumn Quarter; application deadline is last Friday in January.**	**Application due date determined by ISIS coordinator.**	**Application due date determined by IHOP coordinator.**
Year 2 2013-2014	**MSRTP – Poster presentation during Autumn Quarter 2014; final paper due January 30, 2015.** **All other Selective 1 options - Final paper due January 30, 2015.**	**Final paper due January 30, 2015.**	**Final R/UOP project is complete once final poster is presented during Autumn Quarter 2014. ****	**Final project due date is determined by ISIS coordinator.**	**Final project due date is determined by IHOP coordinator.** **Students are expected to present a final poster during Autumn Quarter 2014. ****

*TL1 and UW/ACS have application deadlines that differ from these dates. It is your responsibility to check deadlines for those programs. If you are accepted into one of these programs, you must also submit a Selective 1 proposal by the March deadline.

**III-3 and III-5 projects have several assignment components due during the summer program experience; all III-3 and III-5 students must display their posters in Student Poster Session Autumn Quarter 2012.

F. Final Paper

The title should be brief and narrowly focused. It will become a permanent part of your curriculum vitae, so give it considerable thought.

The abstract is a succinct summary of the paper's methods and results. The abstract should be about 300 words or less. Structured abstracts are generally easier to read - these include short subheadings such as: Background, Objective, Methods, Results and Conclusions. The Background section of the abstract is sometimes omitted and incorporated into the Objective(s). The results presented in the abstract should include the main results that are pertinent to the primary objective or hypothesis. The results should include specific

details (such as means and standard deviations or odds ratios with 95% confidence intervals) with results of the statistical tests (p values). The conclusions should be supported by the results shown in the abstract.

The introduction provides a rationale for why the study was done. Think of the introduction as a funnel. It can begin with a broad introduction to the issues, but quickly narrows its focus to the specific research problem being investigated. It should first convince the reader that there is an important research problem needing resolution and second, lead the reader to conclude that the obvious next step in solving the problem is your study. By the end of the introduction, the reader should understand what your study will be about and why it is an important study to do.

The methods section ought to contain enough detail to enable another investigator to replicate your study. This should include how subjects were selected (inclusion and exclusion criteria), how subjects were contacted and recruited, what measurements were taken and what statistical methods were used. If you are following methods that have been published elsewhere, you can refer to the citation rather than describe the methods in detail. (For example: Radiographs were graded following the recommendations of Spencer, et al. [13])

The results section is the heart of the paper. The first results reported describe the sample in detail. This includes survey response rate, subject demographics, etc. If the study uses new or questionable methods, data regarding their validity should also be presented early. Following this, report the data that is most significant to the primary hypothesis of the study. Be sure to include numerical values, means, proportions, odds ratios, and not just p-values. Secondary results can be presented later, but you do not need to report all the data you collected. Do not choose what to include based on statistical significance but on the objectives of the study. The results should be presented in a well-organized manner.

The text should refer to tables and graphs but should not reiterate the information contained in them. The text can, however, guide the reader toward the message contained in the table or graph: "Table 1 shows that the treatment and control groups were comparable in age and disease severity," or something like, "Pain was about 30% lower in the treatment group relative to the control group at all three times of measure, as shown in Figure 3."

The discussion should be an interpretation of the results. Begin by providing an answer to the research question posed earlier. Include the limitations of your study and how those limitations could influence the results. Comment on the validity and generalizability of the study. After considering the weaknesses, what is the meaning of the study for the field of medicine? What questions has the study resolved? What questions or directions for future research has the study generated?

References: List of references cited in your paper.

Resources for Writing:

1. Writing a Scientific Research Paper
   http://www.bio.davidson.edu/courses/Bio111/Bio111LabMan/Preface%20C.html

2. Tips & Guidelines for Scientific Writing
   http://www.biochem.arizona.edu/marc/Sci-Writing.pdf

The following guidelines are given to reviewers for Selective 1 papers:

Section	Required Criteria	Criteria of Excellence
Introduction	Demonstrates general understanding of relevant concepts and adequate literature review (i.e., reviewed studies relevant to research question; not missing important studies; not drawing inappropriate conclusions).	Demonstrates clear understanding of relevant concepts and thorough literature review, which is well articulated and makes interesting or creative points.
Question	Important *or* interesting/creative	Important *and* interesting/creative
Method	Generally appropriate to the question with no fatal flaws.	Appropriate design, which is clearly articulated**,** power addressed, clear description of measures and procedures.
Results	Results accurate but (a) not particularly well articulated/illustrated, (b) showing small misunderstandings of the data or design, or (c) missing details expected in a published article	Results accurate and well articulated; appropriate use of statistics, tables and figures; inclusion of treatment effects, not just p-values.
Discussion / Conclusion	Demonstrates adequate understanding of the results and the relation of the results to the literature. Articulates limitations of the study.	Draws interesting implications, strong understanding of the results in relation to the literature, clearly articulates both the limitations of the study (including threats to internal validity and generalizability) and the future directions suggested by the study.
Presentation	Reasonable organization and readability, formatted in style for refereed journal, few spelling or grammatical errors.	Well-organized, readable, clear, style appropriate for refereed medical journal, almost no spelling or grammatical errors.