Ochsner Research
Investigator-Initiated Research Roadmap

This document is intended to assist you as you plan and execute research projects. The steps outlined below are intended as guidelines, not requirements. The steps and timeline described below will need to be tailored to fit the specifics of your project. As a reminder, all human subjects research activity must be approved by the IRB ***before it begins****.*

You should be meeting regularly with all other members of your research team as it forms. This checklist will assist you in planning, and it is recommended that you bring the checklist to your study team meetings.

Step 1: Obtain Proper Training for Performing Research at Ochsner Health

There are required and recommended training modules for you to complete prior to being able to engage in research. We recommended that you do them before you submit your research project to the IRB.

Required Training (complete in first few months)

☐ CITI – Investigator and Clinical Research Coordinator Course (Can also link IRB website with account creation instructions). Even if you did CITI at another institution, you still need to sign into CITI as a Ochsner Health Employee.

Recommended Training: CITI – Good Clinical Practice (this is a much longer module and is recommended for any study that is deemed greater than minimal risk).

☐ CITI – Responsible and Ethical Conduct in Research

Step 2: Research Question

If you are new to research at Ochsner Health, we recommend you ask an experienced colleague to serve as a research mentor. Medical students, residents and fellows may not be principal investigators on a research study and must have a faculty mentor. Your mentor may or may not already have a study up and running that you can join. Joining an existing study is a great idea, but you should be meaningfully involved in collecting and analyzing data and, ideally (but not necessarily), designing and executing the study including obtaining IRB approval and/or funding.

☐ Identify a topic:.....

☐ Identify a Faculty Mentor: .....

☐ Perform a literature search around your topic (https://www.ncbi.nlm.nih.gov/pubmed or https://www.cochranelibrary.com/ , and resources in the Ochsner Medical Library).

(Step 2 Continued)

☐ Summarize the background of your topic that explains what is already known about, what we don't know yet, and why filling those gaps is important or useful.

It may be useful to conceptualize the problem in terms of NIH's criteria for significance. *Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? (See NIH review criteria #1.)*

☐ Form your question: What is the gap in knowledge you want to fill?* .....

.....

** A good research question is FINER: Feasible, Interesting, Novel, Ethical, and Relevant. See Farrugia, et al. 2010 (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2912019)*

Plan an initial consultation with all core and supplementary team members to discuss the study -- aims, hypotheses, study design, etc. Also discuss end goal (e.g., manuscript) and agree on expectations for co-authorship or acknowledgement of each team member. We strongly recommend you contact the Ochsner Center for Outcomes Research (OCOR) team for a free consultation.

☐ Form your hypothesis.

*A good hypothesis is specific, measurable, and one you can answer with the resources at your disposal. Consider using the PICOTS framework to focus your hypothesis: Population, Intervention, Comparison, Outcome, Timing, Setting.

☐

I hypothesize that: .....

.....

☐ If your work focuses on improving a gap in performance or process instead of a gap in knowledge, it may be a process improvement or quality improvement project. Ask an IRB specialist (irb@ochsner.org) or your Director of Clinical Research for more guidance.

STEP 3: Study Design

☐ Decide on design of study. Select appropriate box:

- ☐ Case-control
- ☐ Cohort
- ☐ Cross sectional
- ☐ Randomized Control Trial
- ☐ Basic Science/Translational
- ☐ Other: .....

☐ Decide on measurements. What will you measure and exactly how will you measure it? At this point you might want to break down the project into specific (scientific) aims/ sub-questions that you want to answer. .....

.....

(Step 3 Continued)

☐ Decide on a method of analysis. What statistical analysis/tests will you perform and why are these appropriate?* .....

.....

Resources for help on this: For feasibility, use Epic's SlicerDicer to query the potential number of patients your inclusion and exclusion criteria produce. Ask OCOR statisticians for assistance with data measurements and your statistical plan by completing a Request Form***.*** *Provide the information you have gathered in the above steps. They can identify resources to help you move forward, identify concerns the IRB might have, and help you with sample size calculation, etc.*

☐ Perform a power analysis - Work with a biostatistician or epidemiologist on this. You will need to provide them with an expected effect size from published literature with similar intervention and outcomes or a pilot study. Most often this is an estimate of a treatment/exposure group effect (e.g., difference in group means) and an estimate of the sample variance.

This study will require a total of _____ subjects,

based on a power of _____ and an alpha level of _____

How did you arrive at your sample size number, and what assumptions were made (e.g. what effect size are you anticipating, how did you determine the variance between groups): .....

.....

☐ Consider a timeline for your project. What are your milestones and how long will it take to achieve them.

☐ Consider alternative strategies to avoid obstacles or pitfalls.

☐ Submit your project to the IRB. Only Ochsner faculty may do this. Ochsner IRB offers the Protocol Builder that makes writing investigator-initiated protocols faster and easier. It helps to ensure protocols meet IRB and regulatory standards. Contact the IRB (irb@ochsner.org) to request an account.

☐ Create any data collection instruments you will need. This may take the form of questionnaires, excel spreadsheets, RedCap data forms (preferred), etc. Place a request through The Hub to receive access to REDCap (an 'existing application').

☐ Obtain IRB approval. **No data collection or interaction with research subjects may occur until after you have IRB approval; this includes studies determined by the IRB to fall in the Exempt category of review.** If you have not done so before, you must register for an eIRB account at https://eirb.ochsner.org/ ; click here Request New Account or at the bottom left of the screen to request an account. We'll set up your account & the system will notify you that it's ready.

☐ Set up your regulatory binder (if needed). If your study meets the definition of Human Subjects research, you will need a binder for keeping records of your study activities, including deviations from your protocol, adverse events, training and communication with your research team, enrollment, etc. Templates are available to help you out with this, just ask your Director of Clinical Research.

STEP 4: Collect and analyze data

☐ Contact OCOR to request data (if applicable)

☐ Carry out your study including any planned interventions, data gathering, and analysis. **Remember:** Statistical and bioinformatic help is always just an email away. Make sure you are keeping your data safe and comply with any data requirements specified in your IRB application (if applicable).

Do not keep any patient information on a personal laptop, a cloud-based service (e.g. Google Docs or Drop Box), or any other storage device that is not secured by Ochsner Health's IS Department.

STEP 5: Summarize and report your findings

Nothing crushes progress and creativity like a blank page. Start by reading some papers that are the same topic as yours, or that used a similar study design. This will get the authoring juices flowing. Most journals have some specific formatting requirements (although increasingly, you can make your initial submission in any sane format you want and then worry about the formatting details later if your paper is accepted). But the basic elements are about the same regardless of the journal you are interested in. If this study was funded, remember to check your award agreement to determine whether sponsor review and/or approval may be required prior to publication.

MANUSCRIPT TEMPLATE

Title of your article.

Authors' names and affiliations.

At Ochsner Health we follow the authorship recommendations of the International Committee of Medical Journal Editors. The ICJME recommends that authorship be based on the following 4 criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Subjects: Neurosurgery, melanoma

----------new page----------

Abstract (200-300 words summarizing your work).
Background: Why this study needed to be done.
Methods: What we did.
Results: What we found including numeric results with p-values for key findings.
Conclusions: What it means.

Background (sometimes called introduction)
About a page introducing your topic, why it is relevant, what is already known, and what gaps you are trying to fill with your work. Include citations to important other studies leading up to yours as well as landmark review papers or other historical papers that lay the groundwork for what is known about your topic.

Methods
Study Design: State the direction of study (prospective or retrospective) and the design (e.g., chart review, case series, cohort, etc.)
Subjects: Include how participants were recruited, inclusion/exclusion criteria, sample size calculation, etc. Be sure to state: This study was approved (or determined to be exempt) by our Institutional Review Board.
Study Procedures: Describe what you did in enough detail that another researcher can replicate your study. Include assessments, software used to collect or process images, etc.
Statistical methods: What statistical analysis methods were used and why. Was adjustment for multiple comparisons used? Were the individuals involved in the analysis blinded? What software including version was used?

Results
Describe your results in a logical order, using sub-headings to identify major components of your project as needed. Specify the p-value, and statistical test used wherever possible [*e.g.* We found that patients in our HFNC holiday group had lower rates of re-admission (12% vs. 21%, p=0.001 test for difference between proportions)]. Make sure it is clear how many patients are in each group you are talking about.

When applicable, the results section should include a study flow diagram depicting patient enrollment, exclusion, dropout, etc. as well as a table summarizing key clinical and demographic characteristics in each group of interest. Additional tables and figures should be included to show

the data and analysis performed in your study. Note that while you will discuss the tables and figures in the body of your manuscript, the tables and figure themselves typically go at the end of your manuscript.

Conclusions

What can we conclude from your study? How does this compare to prior studies? What gaps have been filled? Be sure not to over interpret your results, but state clearly what new information has been gleaned and how this compares, contrasts, or adds to existing information. Note limitations of the study and future directions for this research.

References

Use EndNote, or Zotero if you need a free alternative, to keep track of your references and generate your reference list. These programs come with numerous templates (and you can create your own too) to allow you to quickly format your references to the specifications of the journal you are submitting to. Submit a request to IS to download this software.

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Tables and Figures (with captions), generally one per page.