UVM Department of Neurological Sciences
Clinical Research FAQs

Getting started

1. ***I have an idea for a research project. Who can I talk to?*** The UVM LCOM Research Navigators are a free resource that can help with all things research and point you in the right direction. Here's their website and here's their intake form. Please also feel free to reach out to Adam Sprouse Blum and Rebecca Burch. They are happy to talk through your ideas with you.
2. ***I have a rough idea for a research project, but I'm having trouble figuring out how to refine it into an actual project.*** See the Appendix at the end of this document for advice on developing your study idea.
3. ***Do I need IRB approval?*** The IRB has a self-assessment tool, which can be accessed here, to help you make that determination.
4. ***I need a small amount of money ($5,000-$10,000) to collect pilot data. Can you help?*** The Department has a fund which may be used to support this type of request. Requestors should send a brief summary (1-2 pages) of the proposed research along with an explanation of how the funds will be used to the Vice Chair of Education and Research, Margaret Vizzard (margaret.vizzard@med.uvm.edu) as well as the Department Chair.

Available resources

1. ***I need help from a biostatistician. Who can I ask?*** UVM offers free biostatistical consulting, including walk-in hours and appointments here.
2. ***What if I need temporary clinical coordinator support?*** The Office of Clinical Trials Research (OCTR) can provide research coordinators on an hourly basis. Reach out to Kimberly Luebbers (kimberly.luebbers@med.uvm.edu) for more information.
3. ***What if I need temporary nursing support, such as for blood draws or urine pregnancy tests?*** The UVM Clinical Research Center (CRC) can provide these services. Reach out to CRC Nurse Manager Joan Bertolet (joan.bertolet@uvmhealth.org) or complete the CRC Resource Request Form here.
4. ***I'd like to perform a literature review. Who can I ask?*** The librarians at the Dana Medical Library are experts at helping you put together a refined list of search terms and running the search across multiple appropriate databases (e.g., PubMed, Medline, Embase, Web of Science, etc.). You can schedule a meeting with them here.
5. **What elements should be included in my study design?** Reporting checklists can be found here. These are guidelines for how to report a study, not how to conduct one, but a well-done study will be able to report all of the relevant items.

Applying for funding

6. ***I have pilot data, now I want to apply for a grant. How do I find the best grant mechanism for my project?*** You can search for yourself by signing up for a Pivot-RP account here. You can also request help from the Office of the Vice President for Research (OVPR) using their request form here and selecting "Pivot-RP Funding Search."
7. ***Does UVM offer grant writing assistance?*** Yes, the Office of the Vice President for Research (OVPR) provides an extensive set of grant writing support services, which can be accessed here.

8. ***Where can I access sample NIH grant applications?*** Sample applications provided by the NIH can be accessed here.
9. ***I need help creating a grant budget. Who can I ask?*** The Office of Clinical Trials Research (OCTR) will review your protocol and work with you to create a budget. Their email is clinicaltrials@med.uvm.edu.
10. ***How do I submit my grant application?*** Investigator-initiated studies are submitted to UVM through Sponsored Project Administration (SPA). In our department, Bridget Brisson (bridget.brisson@uvm.edu) can help you with this. Please be sure to initiate this process at least 2 weeks before the grant is due as there are strict guidelines as to when the various documents need to be received so they can be reviewed and routed throughout the institution for signatures. See the attached flowchart for additional details.
11. ***Does SPA need to submit letters of intent and pre-proposals?*** No, typically not. If UVM doesn't need to sign off, you can submit it yourself.

Working with the IRB

12. ***Where can I access IRB templates?*** All of the templates are stored in the UVMClick – IRB forms library here.
13. ***What training will I need to participate in research?*** In general, you will need to complete Human Subjects as well as Good Clinical Practice (GCP) trainings. See here. Note: There are three GCP training options. Choose the one that best fits your needs.
14. ***Who do I need to list as Key Personnel on my IRB protocol?*** In general, everyone involved in the study. However, if there are staff members carrying out their usual roles in the hospital, and there is nothing additional being done as part of the study, they may not need to be added (e.g., nuclear medicine staff performing a standard scan). When in doubt, check with your IRB analyst.
15. ***I'm working on a protocol but have some questions for the IRB. Who can I contact?*** Each department has an IRB analyst assigned to them. You can find your department's analyst using the drop down menu here. Our department's analyst is currently: Diana Naser (diana.naser@uvm.edu).
16. ***I need to get a survey/consent form into REDCap. How do I do that?*** First set up your free REDCap account through UVM here. Then check out the training resources here, or contact the REDCap administrator for help (redcap.administrator@med.uvm.edu).
17. ***Does the IRB review cancer-related studies?*** Yes, but these protocols are also reviewed by the UVM Cancer Center Protocol Review and Monitoring Committee (PRMC) prior to IRB approval.
18. ***Do I need to register my clinical trial?*** Almost all medical journals require clinical trials to be registered prior to enrollment of the first patient. The NIH defines a clinical trial as "a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes." The trial registry used in the United States is ClinicalTrials.gov. If you think you might want to publish the results of a Quality Improvement project, err on the side of registering the study. UVM has additional information, including a ClinicalTrials.gov determination tool, available here.

Drug/device studies

19. ***I was approached by a drug/device company to participate as a site for a clinical trial. I'm interested, what do I do?*** These studies are managed by the Office of Clinical Trials

Research. As a first step, the company will typically send you a Confidential Disclosure Agreement (CDA) to be signed by a UVMMC representative (usually Kimberly Luebbers in the OCTR) and the PI, which you can then forward to Mark Tomase (mark.tomase@med.uvm.edu). Once the CDA is in place, the sponsor will send the protocol and draft agreement. Additional details can be found here. Note: If the study is cancer-related, these studies are generally managed by the Cancer Center Clinical Trials Office (CTO) instead of the OCTR. You can view their website here.

20. ***How is the budget reviewed and handled for industry studies?*** The contract and budget should be sent to Mark Tomase (mark.tomase@med.uvm.edu) for review, who may request input from the PI to ensure that the amount offered will cover the work being done.
21. ***Can I use the consent form that the company sent us*?** Typically, no. The consent form will need to be edited to include UVM IRB-specific language which can be found on the IRB forms page here. Once you make these edits, the sponsor needs to approve them before they are sent to the UVM IRB.
22. ***What is the Coverage Analysis and Budgeting Form*?** This form is used to clarify where funds are coming from (e.g., what aspects of the study get billed to the study *vs* to the patient's insurance). The completed form should be sent to Karen Brautcheck (karen.brautcheck@uvmhealth.org) and Trenda Jones (trenda.jones@uvmhealth.org) who will then send you a Billing Plan for review.
23. ***When do I engage with the Investigational Drug Service (IDS) Pharmacy?*** You should contact Jill Rockwood (jill.rockwood@uvmhealth.org) at the IDS Pharmacy early (e.g., once you have the protocol in hand to ensure they are able to manage the study drug. On the off chance they cannot, there may be no reason to proceed.
24. ***Where can I find Regulatory Documents and Resources?*** The OCTR has a SharePoint site, with a page dedicated to this. Resources you will find here include a Study Initiation Checklist, Regulatory Binder Guidance, and an IRB Initial Submission Checklist, among others.

Other

25. ***What if I need something not listed here?*** Please reach out to Adam Sprouse Blum (adam.sprouse-blum@uvmhealth.org) or Rebecca Burch (rebecca.burch@uvmhealth.org) for help.

Last updated September 30, 2024

Appendix: Formulating a research plan

- Formal statement of research question. “We aim to…”
- What is the study design?
    - Examples include clinical trial (open label or blinded, single arm or double arm), chart review, prospective observational, database analysis, case report. This is not always simple! If you aren’t sure what design best fits, please contact one of us listed under FAQ 1.

  For the following questions, be as detailed and granular as possible.
  You may also want to look at the reporting checklists under “What elements should be included in my study design?” (FAQ 5) above.

- Define the study population
    - Age, sex or gender, source of patients or participants, inclusion/exclusion criteria
- Define intervention or exposure
    - If intervention, what/where/how delivered/how long? Who will deliver it?
    - If exposure, how and when will it be measured?
- Will there be a control group?
- What is the outcome measure of the study?
    - Method of measure, timeframe for assessment? Who will assess?
- For a systematic review or meta-analysis, the above questions should be answered regarding which studies will be included.