Your study is FUNDED!

First Steps When Starting a Research Study as a Principal Investigator:

First Steps	Description
1. **Schedule research team meetings**	Schedule a weekly meeting for 1 hour
2. **Obtain approval(s)** from regulators to conduct the study	Prepare IRB, Scientific Review Committee, etc. (PIs often prepare IRB as soon as grant is submitted).
3. Ensure that the study is in **compliance** with all regulations	Work with IRB staff personnel to clarify your questions. Do you need a Third Party Risk Assessment?
4. CON PIs need to have an **internal review** before submitting IRB application	Contact NNRC Administrator to arrange a CON IRB review prior to submission. Request CON faculty to review IRB before submission (see pg. 2). Cc # is assigned after IRB approval.
5. Plan to offer **Rewards Cards**	Provide stipends to participants at hourly rate
6. Meet with study **statistician** and plan data in 6 areas.	Data selection, data collection, data analysis, data handling, data reporting and publishing, and data ownership. Develop Codebook.
7. Plan to **store paper and electronic files**	Store paper records in locked cabinet in locked office. Store files on I drive, not personal drive.
8. **Prepare job descriptions** with details regarding roles for team members	Contact NNRC Administrator to prepare job descriptions; NNRC staff will assist
9. **Post** job descriptions at Unmc.edu/jobs	NNRC staff will assist
10. Recruit and Interview **applicants** for the positions	Project Manager usually your first hire and will assist with selection of hires for other positions.
11. **Select and hire** research team members	Contact NNRC Administrator regarding the process of approval for positions. These can take time; start ASAP; background check may be required.
12. Plan **orientation** to office space, clinical setting, and laboratory space (if applicable)	Work with Cara Mouw in Dean's Office to arrange office space, computer, phone, etc.
13. Prepare a **detailed list** of all research activities that must be completed before recruitment of first participant	Prepare an Operating Procedures manual to ensure all team members perform research activities in a consistent manner.
14. **Prepare research study database**	Faculty often use REDCaP to reduce need for manual data entry; work with statistician
15. **Plan spending. Order equipment and supplies** needed to conduct the study; start with small batch.	Work with NNRC staff about spending, WBS numbers, and rules on spending money, and ledgers to order supplies
16. Prepare clear, **detailed protocols** for recruitment, enrollment, randomization, orientation based on group assignment	Determine who will conduct each step and break into specific steps. For example, obtaining informed consent, data management, monitoring for adverse events, etc.
17. Plan for oversight to **assure adherence** to protocol, research fidelity	Plan how to document adherence to protocol and report any issues of non-adherence such as use of wrong consent form or adverse effects
18. **Orient personnel** at site where you will be recruiting/conducting the study	PI, project manager, other team members who will go to sites.

Nursing Research Committee
Procedure for Requesting an IRB Reviewer

One of the functions of the Nursing Research Committee (NRC) is to provide a review of scientific and scholarly merit and resource availability for faculty IRB applications. Review may also be delegated to qualified faculty.

A listing of potential reviewers consists of members of the Nursing Research Committee and volunteers.

Procedure
To request a reviewer for an IRB application, faculty should follow these steps.
1. Contact the NNRC Administrator to request a reviewer.
   a. Requesters should provide the following information at the time of request:
      i. Name of faculty member requesting a review
      ii. Title of study and/or type of study (Biomedical application, Social Science and Behavioral Research)
      iii. Risk level of study (minimal, > minimal)
      iv. Type of review (full board, expedited, exempt)
   b. Requesters should allow 10 work days for the review process

2. The NNRC Administrator will contact a member on the Scientific Reviewer List until someone agrees to review in 10 days or less.

3. The NNRC Administrator will notify the faculty requester and reviewer to begin the process.
4. If the faculty needs the IRB application reviewed in a shorter time frame, they may need to arrange for a reviewer themselves with the assistance of the NNRC.
5. The reviewer needs to be listed in the on-line IRB application under #11 as the scientific reviewer and provide the scientific/scholarly merit and resource review certification for the project.

The Advisor is responsible for arranging the review of a student's IRB application.

NRC IRB Review Policy & Procedure   Updated 7/26/2016