



# Keep Calm using NNRC Resources

**NINR Data Safety Monitoring Plans/Boards:** NINR has its own requirements for data safety monitoring plans (DSMP) for clinical trials. **See page 2 for the requirements.**

**The Importance of the NIH Biosketch** – NIH has been sending warnings for biographical sketches that do not comply with guidelines. It is possible that an incorrect biosketch may result in a rejected application in the future. Read and follow the instructions!

**NIH Policy on Next Generation Researchers Initiative** - see page 2 for how NIH IC's will prioritize awards of Early Stage and Early Established Investigators.

Effective January 25, 2018, all grant applications with plans to conduct clinical trials must be submitted in response to an FOA which specifically states that clinical trials are allowed. Check your FOA carefully and contact the Program Officer prior to submission.

## 2 CON Research Awards Available

\$10,000 Seed Research Award & a \$5,000 Leininger Qualitative Transcultural Nursing Research Award. Deadline for applications - November 17, 2017. Application materials are available on the NNRC website (address listed on the right) or from Barbara Hoover-Schultz.

## MNRS Seed Grant Available – \$10,000

## MNRS New Investigator Grant Available - \$10,000

## MNRS Dissertation Research Grants Available - \$2,500

<https://www.mnrs.org/research-amp-awards/grant-opportunities/grant-opportunities> Applications Due: October 31, 2017

**Reminder:** If a funding agency allows faculty salary, funded effort must be included in the budget (even for small grants). University policy is to limit “in-kind” effort.



## NNRC Quarterly Newsletter

October  
2017

Volume 7

### TOPICS FOR THIS QUARTER

- NINR Data Safety Monitoring Plans
- NIH Biosketches
- NIH Policy on Next Generation Researcher Initiative
- FOAs and clinical trials

### WEBSITE

<http://www.unmc.edu/nursing/research/index.html>

### CONTACT US at the NNRC

Dr. Ann Berger, Associate Dean for Research (FT) 402 559-4957

Barbara Hoover-Schultz, Administrator (FT) 402 559-6634

Lauren Lesiak, Pre-Award Coordinator (FT) 402 559-8081

Carol Meyer, Post-Award Coordinator (PT, Tuesdays & Wednesdays 8-4:30, Thursdays 8:00-12:00) 402 559-5459

For internal funding opportunities check out the VCR's website at:

<https://www.unmc.edu/vcr/funding/internal-funding-ops.html>



# Keep Calm using NNRC Resources

Page 2

## **Policy of the NINR for Data and Safety Monitoring of Extramural Clinical Trials**

If a general DSM is submitted with an application and your application is being considered for funding, you will need to provide an updated DSM with the Just in Time request.

All clinical trials supported by NINR should have some form of monitoring based on a DSM plan. The level should be commensurate with the size and complexity of the trial, level of risk, and phase of the trial. Data and safety monitoring may be conducted by:

- 1. an Independent Safety Monitor (ISM) or**
- 2. a Safety Monitoring Committee (SMC) or**
- 3. a Data and Safety Monitoring Board (DSMB)**

The elements of the DSM plan include the following:

**Section A:** Monitoring entity or who will monitor (PI, ISM, SMC, or DSMB)

**Section B:** Procedures (monitoring safety, minimizing risk, protecting confidentiality)

**Section C:** Procedures for identifying, reviewing, and reporting adverse events

**Section D:** For Multi-site studies, procedures to ensure compliance with the DSM

**Section E:** Assessment of external factors that may have an impact on the safety or the participants or on the ethics of the research study.

**Section F:** The advanced plans for interim and/or futility analysis (as appropriate).

See [https://www.ninr.nih.gov/sites/default/files/NINR\\_DSM\\_Policy\\_2014\\_FINAL.pdf](https://www.ninr.nih.gov/sites/default/files/NINR_DSM_Policy_2014_FINAL.pdf) for complete details.

## **Policy Supporting the Next Generation of Researchers Initiative**

As an effort to support the next generation of researchers, NIH Institutes will prioritize awards to:

### **Early Stage Investigators (ESI)**

- Completed terminal research degree within the past 10 years
- Has not previously receive a substantial NIH independent research award (i.e., R01)

### **Early Established Investigator (EEI)**

- Within 10 years of receiving first substantial NIH independent research awards as an ESI if
  - Has lost or is at risk of losing all NIH research support if not funded by competing awards this year, or
  - Is supported by only one active award

**Principal Investigators should ensure Commons profile is accurate**

**For a Multi-PI application to be given ESI/EEI prioritization, ALL PIs must have ESI/EEI designation!**