



Keep Calm using NNRC Resources

NIH Implementing New Clinical Research Requirements!

After January 25, 2018, clinical trial applications can no longer be submitted to a parent FOA. Institutes will provide new FOAs for clinical trials.

NIH has broadened the interpretation of a clinical trial to include many more types of studies. The concept of a clinical trial no longer refers to the study of a pharmacologic or other intervention. **How do I know if my study is a clinical trial?**

If you answer “yes” to each of these questions, your research will be considered a clinical trial by NIH:

1. Does the study involve human participants?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?
4. Is the effect being evaluated a health-related biomedical or behavioral outcome?

NIH has provided case studies at the following website to help you determine whether or not your study is a clinical trial.

<https://grants.nih.gov/policy/clinical-trials/case-studies.htm>

Do not assume. Contact your program officer to confirm.

If your clinical trial application is selected for funding:

- You will need to designate individual(s) to serve as the responsible party for the trial and to register and post results in the ClinicalTrials.gov system.
- NIH has issued a policy update on the use of single IRB for multi-site human subjects research. UNMC IRB is prepared to participate as a collaborating or central IRB.
- Good Clinical Practice (GCP) training is required of all UNMC investigators participating in human subjects research.

Join the NNRC and SPA teams at a Brown Bag Seminar to discuss this and other important policy changes on **Friday, January 12, 2018** at 12:00-1:00 pm CST. CNS 40120, Lincoln 307, Kearney 131, Norfolk 189 & Scottsbluff B130D

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TOPICS FOR THIS QUARTER

- New NIH Clinical Trials Policy

WEBSITE

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

CONTACT US at the NNRC

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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>

LB506 deadline is January 19, 2018!
System Science grant deadline is January 12, 2018!