DEPARTMENT OF CONTRACTS & GRANTS

YOUR PARTNER IN RESEARCH ADMINISTRATION

NewsFlash!

The National Institutes of Health (NIH) has implemented several key reforms to clinical research studies, specifically involving a Clinical Trial. A summary of the below NIH Clinical Research Updates is attached:

- New expanded definition of a Clinical Trial, including a tool to determine if your research meets the new definition.
- New requirements for Clinical Trial applications, including:
    - Use of a specific Funding Opportunity Announcement (FOA) that allows clinical trials
    - Use of a specific Application Package: FORMS-E
        - New Human Subjects and Clinical Trials Information Form
        - Inclusion of a Clinical Trial Dissemination Plan
        - Use of a Single Institutional Review Board (sIRB) Plan for multi-site research
        - Limitation on what can be included as Appendix Materials
    - Good Clinical Practice Training for investigators and staff who are involved in the design, conduct, oversight, or management of clinical trials

Please review the attached summary of the Key NIH Clinical Research Updates and distribute to any faculty conducting clinical research.
Additional resources can be located at:

- NIH Tool: Does your human subjects research study meet the NIH definition of a clinical trial?
- NIH Clinical Trial Requirements for Grants and Contracts
- NIH Clinical Trials – Frequently Asked Questions
- Clinicaltrials.gov Registration at USC

Please contact the DCG Officer assigned to your department with any questions regarding the new NIH Clinical Research reforms and/or Clinical Trial Application.