

# Campus-Wide Business Managers Meeting

Sarah J. White

Associate Vice Chancellor for Research

Office of Sponsored Programs

January 18, 2018

# NIH Forms E

- Replace the Forms D, SF424 packet for all NIH proposals submitted on or after:

**January 25, 2018**

- Cayuse SF424 has been updated with the new forms; need to take special care with subawards.
- Proposals which use the old Forms D templates will be rejected.
- All current (FORMS-D) Parent Announcements have been reissued with updated application forms (FORMS-E). Many activity codes will have two [Parent Announcements](#) - one designated as "Clinical Trial Not Allowed" and another as "Clinical Trial Required".
- Forms E is a redesigned application which focuses on putting all information concerning the use of human subjects in the same sections

# Why are the D Forms being replaced with the E-Series?

- NIH has revised the definitions of Clinical Research and Clinical Trial:
- [Clinical research](#) includes all research involving human participants. It does not include secondary studies using existing biological specimens or data collected without identifiers or data that are publicly available.  
(<https://humansubjects.nih.gov/glossary>)
- [Clinical trials](#) are clinical research studies involving human participants assigned to an intervention in which the study is designed to evaluate the effect(s) of the intervention on the participant and the effect being evaluated is a health-related biomedical or behavioral outcome

# Intervention

- An intervention is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.\
- For more information see the [NIH FAQ](https://grants.nih.gov/grants/policy/faq_clinical_trial_definition.htm#5227):  
[https://grants.nih.gov/grants/policy/faq\\_clinical\\_trial\\_definition.htm#5227](https://grants.nih.gov/grants/policy/faq_clinical_trial_definition.htm#5227)

# OSP Blog

- The OSP Blog provides members of the UTHSC research community with up-to-the minute information regarding institutional and sponsor policy and procedural changes related to sponsored programs administration.
- You will automatically get an e-mail when a new announcement (Like E-Forms) is written.
- You can opt out of receiving these announcement.
- Past blogs will be available on the OSP home page
- Comments for topics of interest are welcome: [swhite82@uthsc.edu](mailto:swhite82@uthsc.edu)

Mark your calendars and Stay tuned!

- Mark your calendar for a hands on session on NIH Forms E

910 Madison, 5<sup>th</sup> floor conference room, January 25  
at 9:00 AM

- Stay Tuned for other OPS outreach announcements!

Thank you!