NIH-Funded Clinical Trial Information

Definition of a Clinical Trial

→ A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

→ In summary, if the answers to all of the below questions are yes, the project meets the definition of a clinical trial:

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

Funding Proposal Submission Requirements

→ Applications/proposals involving clinical trials must be submitted to a funding opportunity announcement or request for proposal that explicitly states it will accept clinical trials.
→ The NIH application must include the FORMS-E.

Additional Training Requirements

→ Yes, Good Clinical Practice (GCP) training is required for all study team members involved on the project. UCCS makes this training available through CITI.
→ Initial training must be completed prior to your Institutional Review Board (IRB) application submission.
→ The GCP training must be renewed every three years.

Additional ClinicalTrials.gov Reporting Requirements

→ Registration – The study must be registered on ClinicalTrials.gov within 21 days after the first subject is enrolled. Registration information includes descriptive information, recruitment information, location and contact information, and administrative data.
→ Updates – The information in the clinical trial records must be updated at least once every 12 months.
→ Results – The study results must be reported on ClinicalTrials.gov within 1 year of the final collection of data. Results information includes participant flow, demographic and baseline characteristics, outcomes and statistical analyses, adverse events, the protocol and statistical analysis plan, and administrative information.

Where to Find Help

→ UCCS IRB Standard Operating Procedures and Website
→ UCCS Good Clinical Practice Website
→ UCCS Clinical Trial Website
→ NIH Video: Overview of New NIH Policies on Human Subjects Research
→ NIH Clinical Trials Policy website
→ NIH guidelines on use of the new Human Subjects and Clinical Trial form (part of the NIH funding application package, Forms-E)
→ ClinicalTrials.gov registration and reporting of results

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