
UCLA Policy 917: Good Clinical Practice Training and Certification

Draft Public Review

Issuing Officer: Vice Chancellor for Research and Creative Activities
Responsible Department: TBD
Effective Date: TBD
Supersedes: New

I. PURPOSE & SCOPE

II. DEFINITIONS

III. POLICY STATEMENT

IV. PROCEDURES

V. REFERENCES

I. PURPOSE & SCOPE

On September 16, 2016, the NIH issued Policy NOT-OD-16-148 requiring Good Clinical Practice (GCP) training for all NIH-funded investigators and clinical trial site staff responsible for the conduct, management, and oversight of NIH-funded clinical trials effective January 1, 2017. The NIH GCP training policy is one aspect of a multi-faceted NIH initiative to enhance the quality, relevance, feasibility, efficiency, and transparency of NIH funded clinical trials through stewardship reforms.

Since GCP is an international standard, the purpose of this Policy is to require GCP training for all key personnel on all UCLA studies that meet the NIH definition of a Clinical Trial, prior to IRB review, regardless of the source of support.

This Policy applies to studies as defined by:

1. Principal Investigators within one of the Schools under the UCLA Health Sciences (Medicine, Nursing, Dentistry) OR
2. Any UCLA Principal Investigator whose study requires access to UCLA Health patients, resources, or services (for example UCLA health data, investigational pharmacy, laboratory medicine, imaging, clinical space, etc...). Please refer to online [FAQ](#) for more guidance.

II. DEFINITIONS

For the purposes of this Policy:

Clinical Trial as defined by the NIH, is a research study in which one or more human subjects are [Prospectively Assigned](#) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial, 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](#). Please refer to NIH Clinical Trial Decision tool (<https://grants.nih.gov/ct-decision/index.htm>).

Collaborative Institutional Training Initiative (CITI) is the platform used by the UCLA Office of Human Research Protection Program (OHRPP) for research education including other required certificates such as Human Subjects Protection and HIPAA Research Training.

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting clinical trials/research that involve the participation of human subjects.

Health-Related Biomedical or Behavioral Outcomes as defined by NIH, is the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.

Intervention as defined by NIH, is 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.

Principal Investigator is defined in [UCLA Policy 900](#).

Prospectively Assigned as defined by NIH, is a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters).

III. POLICY STATEMENT

Key Personnel who are involved in the conduct, oversight, or management of Clinical Trials that meet the NIH [definition](#), regardless of funding source, are required to complete training in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonization (ICH) E6 (R2) and to meet the [NIH standard](#) prior to submission of protocols to the IRB.

GCP certification will need to be renewed every 3 (three) years through a refresher module.

IV. PROCEDURES

GCP certification will be available through the existing UCLA Collaborative Institutional Training Initiative ([CITI](#)) program already used by UCLA for Human Subjects Protection Training and HIPAA Research Training.

V. REFERENCES

1. UCLA Policy 900: Principal Investigator Training
2. UCLA Policy 916: Protocol Review and Approval of Clinical Trials
3. [UCLA Guidance and Procedure: OHRPP Education and Training](#)
4. [Education and Training | UCLA Office of the Human Research Protection Program](#)
5. [Human Subjects Protection Certification via CITI | UCLA Office of the Human Research Protection Program](#)
6. UCLA [IRB Electronic Submission System](#)

Issuing Officer

Vice Chancellor for Research and Creative Activities

Questions concerning this policy or procedure should be referred to
the Responsible Department listed at the top of this document.
