
UCLA Policy 917: Good Clinical Practice Training and Certification

Issuing Officer: Vice Chancellor for Research and Creative Activities
Responsible Department: Vice Chancellor for Research and Creative Activities
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I. PURPOSE & SCOPE

On September 16, 2016, the National Institutes of Health (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 Institutional Review Board (IRB) review, regardless of the source of support.

This Policy applies to studies proposed by:

- (1) A Principal Investigator(s) 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 (e.g., UCLA health data, investigational pharmacy, laboratory medicine, imaging, clinical space, etc.). Refer to [FAQs](#) 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 [Interventions](#) (which may include placebo or other control) to evaluate the effects of those interventions on [Health-Related Biomedical or Behavioral Outcomes](#). Refer to the 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 required by the IRB and the Institution.

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); psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention); 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).

Key Personnel is defined as the Principal Investigator, other investigators and research personnel who are directly involved in conducting research with study participants or who are directly involved with handling private information related to study participants during the course of a research project. Key Personnel also include faculty sponsors who oversee student Principal Investigators in their conduct of human subjects research.

III. POLICY STATEMENT

Key Personnel involved in studies that meet the NIH [definition](#) of Clinical Trials, 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](#) defined in NOT-OD-16-148 prior to submission of protocols to the IRB.

GCP certification must 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 the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Research Training.

V. REFERENCES

1. UCLA Policy 900: Principal Investigator Eligibility
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](#)
7. [International Conference on Harmonization \(ICH\) E6 \(R2\)](#)

Issuing Officer

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