	Document Type	Version: 1.1
National Institute on Drug Abuse	Standard Operating Procedure (SOP)	Updated: 1.03.17
	Release Date: 12.07.16	Effective Date: 01.01.17

Title: Good Clinical Practice Training for NIDA Staff and Staff Supported by NIDA-Funded Research and Involved in the Design, Conduct, Oversight, or Management of Clinical Trials

PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to define the training requirements regarding good clinical practice (GCP) for National Institute on Drug Abuse (NIDA) staff and NIDA-funded investigators and their staff who are involved in the design, conduct, oversight, or management of clinical trials funded (all or in part) by NIDA[1].

BACKGROUND

In September 2016, a Policy Announcement from the NIH Office of Extramural Research (OER) was sent to all NIH staff announcing the Policy on Good Clinical Practice Training for NIH Staff Involved in the Conduct, Management, and Oversight of Clinical Trials and detailing the requirement that all NIH staff involved in the conduct, oversight, or management of NIH-funded clinical trials must receive training in GCP, consistent with principles of the International Conference on Harmonisation (ICH) E6[2]. In addition, the NIH issued a Notice detailing the Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials outlining the expectation that all NIH-funded investigators and clinical trial staff who are involved in the conduct, oversight, or management of clinical trials also be trained in GCP, consistent with principles of the International Conference on Harmonisation (ICH) E6.

Compliance with the ICH standard provides public assurance that the rights, safety, and wellbeing of trial participants are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.[3] GCP training complements other required training on protections for human research participants.

The ICH GCP guidance includes the following sections[4]:

- Institutions Review Board (IRB)/Independent Ethics Committee (IEC)
- Investigator
- Sponsor
- Clinical Trial Protocol and Protocol Amendment(s)
- Investigator's Brochure
- Essential Documents for the Conduct of a Clinical Trial

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[1] NIH Policy on GCP Training for Awardees: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html

[2] International Conference on Harmonisation (ICH), E6: http://www.ich.org/home.html | http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4.pdf

[3] E6 Good Clinical Practice Consolidated Guidance: http://www.fda.gov/downloads/Drugs/.../Guidances/ucm073122.pdf

[4] Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(r2): http://www.ich.org/fileadmin/public_web_site/ich_products/guidelines/efficacy/e6/e6_r2__step_4.pdf

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SCOPE and APPLICABILITY

This SOP applies to all individuals involved in the design, conduct, oversight, or management of clinical trials supported by NIDA. Individuals affected include NIDA staff (extramural and intramural), contractors, and NIDA-funded investigators and their clinical trials staff.

>   *NIDA Extramural Staff*: This includes program staff, contracting officer's representatives, health specialists, program analysts, nurse consultants, medical monitors, and other staff who are involved in the conduct, oversight or management of clinical trials. Their role may include oversight or management of the technical aspects of grants, cooperative agreements or contracts through which clinical trials are conducted, or participation in making decisions about the design, conduct, data reporting and oversight of clinical trials.

>   *NIDA Intramural Staff*: This includes principal Investigators (PIs), associate investigators (AIs) who are NIH full-time employees (FTEs) or Contractors (AIs who are at another institution are expected to complete their GCP Training at their home institution), staff who obtain consent from prospective participants, and staff whose primary role is related to clinical research, such as a research nurse or coordinator. Note: this SOP does not apply to staff that handle Personally Identifiable Information (PII) and are providing a service but do not directly participate in clinical research activities (e.g., pharmacy, IT staff).

>   *Staff Supported by NIDA-Funded Grants, Cooperative Agreements, Contracts or Interagency Agreements*: This includes all staff who are responsible for the design, conduct, oversight or management of clinical trials supported by grants, cooperative agreements, contracts or interagency agreements. This includes personnel supported by contracts or consortia or who work at remote performance sites, if they are participating in the conduct of clinical trials.

RELATED DEFINITIONS

Investigator[5]: The individual responsible for the conduct of the clinical trial at a trial site. If a clinical trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

Clinical Trial Staff[6]: Individuals, identified by the investigator, who are responsible for study coordination, data collection and/or data management of the clinical trial. The central focus of clinical trial staff is to manage participant recruitment and enrollment, to maintain consistent study implementation, data management, and to ensure integrity and compliance with regulatory and reporting requirements. These individuals may also obtain informed consent from prospective participants, enroll and meet with research participants, and/or collect and

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[5] NIH Policy on GCP Training for Awardees: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html
[6] NIH Policy on GCP Training for Awardees: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html

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record information from research participants. Clinical trial staff may also be called the research assistant, research coordinator, study coordinator, research nurse, study nurse or sub-investigator.

Clinical Trial[7]: A clinical trial is defined by NIH as 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. For additional details, please see: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html.

Good Clinical Practice[8]: A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

ROLES and RESPONSIBILITIES

NIDA Staff: Division/Office/Center/IRP Directors and Branch Chiefs (Leadership) are responsible for making decisions regarding training requirements and monitoring. The direct supervisor determines 1) which staff are required to take training and 2) the frequency (at a minimum, all staff must maintain GCP training through refresher courses in GCP every three years), and 3) documentation procedures to verify and record that training has occurred. The Leadership assure that staff maintain compliance with the training requirements and guidelines set forth in this SOP. Newly employed staff or current staff with modifications in responsibility that meet the scope and applicability of this SOP should be GCP-trained prior to initiating their new role and responsibilities.

Staff Supported by NIDA-Funded Grants, Cooperative Agreements, Contracts or Interagency Agreements: The Principal Investigator (PI)/Project Director (PD) as listed on the grant, cooperative agreement, or contract award is responsible for assuring applicable staff associated with the grant/cooperative agreement/contract/study are in compliance with the NIH policy (at a minimum all staff must maintain GCP training through refresher courses every three years), that appropriate documentation is available, and that their staff maintain compliance with the training requirements and guidelines set forth in the NIH policy.

PROCEDURE

All individuals (NIDA staff and staff supported by NIDA-funded grants, cooperative agreements, contracts or interagency agreements) involved in the conduct, oversight or management of clinical trials should demonstrate knowledge in GCP consistent with principles of the

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[7] NIH Definition of Clinical Trial: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html
[8] Definition of Good Clinical Practice: http://www.fda.gov/downloads/Drugs/.../Guidances/ucm073122.pdf

International Conference on Harmonisation (ICH) E6 [9] prior to performing their job functions/oversight. At NIDA, each Division/Office/Center/Program will establish the standards for GCP training for their staff and clinical site staff according to the specific needs of the program/grant/cooperative agreement/contract/study.

Depending on the needs of the program/grant/cooperative agreement/contract/study, knowledge may be demonstrated by any of the following:

- A certification of completion for a course in which GCP knowledge is demonstrated. Examples of free online courses include:
    - GCP Training by NIAID[10]
    - GCP Training by NIDA[11]

- A certification from a recognized clinical research professional organization such as Association of Clinical Research Professionals (ACRP) or Society of Clinical Research Associates (SOCRA) in which basic GCP knowledge is required in order to attain certification.

- A transcript reflecting a passing grade(s) from an accredited institution in a course or program in which basic GCP knowledge is required in order to earn a passing grade.

Any staff with existing documented GCP Training may use their certificates if:

- it meets the ICH E6 standards;
- it meets the individual needs of the program/grant/cooperative agreement/contract/study; and
- it is within 3 years from the date of training.

Good Clinical Practice guidance and regulations are frequently revised and updated. Therefore, it is required that GCP training is repeated/updated at least every 3 years.

DOCUMENTATION

NIDA Staff: NIDA staff should maintain training records and make them available to supervisors upon request. Division/Office/Center/IRP Directors and Branch Chiefs should document training of their assigned staff to include a listing of trainee name(s), date of training, name/affiliation of trainer or training module, and course title. Course outline/syllabus might also be included.

Staff Supported by NIDA-Funded Grants, Cooperative Agreements, Contracts or Interagency Agreements: The PI/PD should maintain training records and make them available to

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[9] International Conference on Harmonisation (ICH), E6:
http://www.fda.gov/downloads/Drugs/.../Guidances/ucm073122.pdf
[10] https://gcplearningcenter.niaid.nih.gov/Pages/default.aspx
[11] https://gcp.nidatraining.org

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appropriate NIDA Program Official (or designee) upon request. Documentation of training should include a listing of trainee name(s), date of training, name/affiliation of trainer or training module, and course title. Course outline/syllabus might also be included.

REFERENCES

- Policy on Good Clinical Practice Training for NIH Staff Involved in the Conduct, Management, and Oversight of Clinical Trials

- Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials

LINK

- https://www.drugabuse.gov/funding/clinical-research/regulations-policies-guidance/clinical-trials-stewardship

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