Requirements for Human Subject Protection (HSP)/Good Clinical Practice (GCP) Training Frequently Asked Questions

This section provides answers to the frequently asked questions regarding the Requirements for Human Subject Protection (HSP)/Good Clinical Practice (GCP) Training.

1. Who needs to complete HSP and/or GCP training?

DAIDS collaborator staff who are involved in the design or conduct of Division of AIDS (DAIDS)-supported clinical research must receive HSP training.

NIH defines clinical research as:

Research with human subjects that is:
1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes: (a) mechanisms of human disease, (b), therapeutic interventions, (c) clinical trials, or (d) development of new technologies.
2) Epidemiological and behavioral studies.
3) Outcomes research and health services research
Studies falling under 45 CFR 46.101(b) (4) (Exemption 4) are not considered clinical research by this definition.
Please see definition at: https://grants.nih.gov/grants/glossary.htm#C

In addition, DAIDS collaborator staff who are involved in the design, conduct, management, or oversight of DAIDS-supported clinical trials must also receive GCP training.

NIH defines a clinical trial 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.
Please see entire definition at: https://grants.nih.gov/grants/glossary.htm#C

2. Who is responsible for ensuring that training in HSP and/or GCP is completed by DAIDS' collaborator staff?

The recipient [for example, Principal Investigator (PI)] of a grant or contract is responsible for ensuring that all personnel receive training appropriate for the individual's level of involvement in the research.
The award recipient PI is also responsible for ensuring that new staff (added after the initial award) receive this training before beginning any tasks on DAIDS-supported clinical research, or clinical trials.

For questions regarding the appropriate level of training for staff, please contact your DAIDS program officer or the Protection of Participants, Evaluation and Policy Branch (ProPEP) at (DAIDSProPEP@mail.nih.gov).

3. How do I satisfy the DAIDS training requirements?

While DAIDS does not 'endorse' specific educational trainings, DAIDS notes that there are a number of readily available curricula for these trainings.
Additionally, NIAID offers a combined HSP and GCP training that can be found at: https://learningcenter.niaid.nih.gov.

The training requirements are listed in the policy:
https://www.niaid.nih.gov/sites/default/files/gcp_hsp_policy.pdf

4. What training resources are currently available?

The NIAID provides online training (see https://learningcenter.niaid.nih.gov). There may also be training available through other mechanisms.

5. How should training be documented?

Training records must be maintained onsite by the contract/grant award recipient and include the trainee's name, date of training, name/affiliation of organization providing the training, and title of the course.

6. How often must DAIDS' collaborator staff be trained?

DAIDS collaborators and their staff involved in clinical research and/or clinical trials (see above) must receive training before beginning any clinical research/trial tasks on a DAIDS-supported clinical research/trials, and must renew training every three years, thereafter.

New clinical research site personnel (hired after the initial grant/contract award or research/trial initiation) must receive HSP and/or GCP training, as appropriate to their role, prior to conducting any clinical research/trial tasks, unless the training was received previously within the past three years and documentation is available.