

Good Clinical Practices

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Good Clinical Practices

- A set of ethical and scientific quality standards for designing, conducting recording and reporting clinical trials.
- In September 2016, NIH issued a policy that established *the expectation* that NIH-funded investigators and staff who are involved in the conduct, oversight or management of CTs should be trained in Good Clinical Practices.

Good Clinical Practices

- The Policy was *effective as of January 1, 2017*
- NIH does not expect all training to be completed January 1 as long as steps are being taken to meet the training expectation.

Good Clinical Practices

- Identifying courses that cover recommended materials, are easy to access, and where completion can be readily tracked
- Designing a process that is not overly burdensome
- Focusing first on meeting NIH policy expectations
- Aware that some campus units may want to extend GCP training beyond NIH awards.

Good Clinical Practices

- Most likely will rely primarily on the GCP course available through the Collaborative Institutional Training Initiative (CITI) site.*
- Recognize the need to also identify a course that is oriented toward behavioral studies.

*UCLA already uses CITI for human subject and animal research training.

Good Clinical Practices

- Conferring with the campus clinical research community
- Drafting campus guidance
- Answering questions as they arise