

Documentation of Education on the Protection of Human Subjects

The National Institutes of Health (NIH), as of October 1st, 2000, requires “**all key personnel**” involved in the design or conduct of research involving human subjects to demonstrate that they have completed education regarding the protection of human research subjects. Understanding GCP and the ethics of clinical research is a major part of this education. How long before the FDA follows suit for industry supported and sponsored clinical trials using human subjects?

This education requirement may be fulfilled in many ways, as there are no specific courses or reading materials prescribed. The NIH, however, does require a description of the education completed to be submitted prior to any award or grant for clinical research. To document that an Investigator has fulfilled this educational requirement they are asked to list educational activities in the protection of human research subjects completed in the last five years.

Examples of appropriate educational activities include:

- **Readings** - List books, brochures, or other materials concerning the use and protection of human research subjects which you have read and identify the author or source of these materials.
- **Courses** - List any courses, seminars, or workshops you have attended on the protection of human research subjects and the dates you attended. Identify the organization or office that provided the training. Provide evidence by the course certificate indicating your passing an examination.
- **Web-based Tutorials** - Identify all programs you have successfully completed and the URL of the web site you used. The NIH training module is at ohsr.od.nih.gov. For others see www.pmci.org.
- **Committee Participation** - If you have served on a human research committee or an IRB, please identify your role and the dates served.
- **Other** - List any other items or sources of training that you believe have helped you fulfill this education requirement.

Training sessions in GCP and other aspects of protecting human subjects are being organized around the country to help physicians meet this educational goal. Please note that this is now a NIH requirement but do not count on the FDA passing this opportunity by.

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