

## UC SAN DIEGO GOOD CLINICAL PRACTICES (GCP) TRAINING REQUIREMENTS

As of January 1, 2017, all NIH-funded investigators and staff who are involved in the design, conduct, oversight, or management of clinical trials, must be trained in Good Clinical Practices (GCP).

### **Why Do I Need to Complete Training**

The principles of GCP help assure the safety, integrity, and quality of clinical trials by addressing elements related to the design, conduct, and reporting of clinical trials. GCP training describes the responsibilities of investigators, sponsors, monitors, and IRBs in the conduct of clinical trials. Please note that GCP training is separate from human subjects training required for Institutional Review Board (IRB) submissions.

### **Where can I Obtain the Required Training**

GCP training may be achieved through a class or course, academic training program, or certification from a recognized clinical research professional organization. There is no particular GCP course or program that must be taken. Some, free-of-charge, options include:

1. [CITI](#) training
2. The [National Institute on Drug Abuse](#)
3. [The National Institute of Allergy and Infectious Disease](#)
4. [National Center for Advancing Translational Sciences](#) has developed a GCP training program geared to behavioral clinical trial investigators

### **When does the Training Need to be Completed**

All responsible parties must complete their GCP training before their involvement in the clinical trial. NIH requires that the GCP training be renewed at least every three years.

### **Who is Responsible to Ensure the Training has been Completed**

Recipients of GCP training are expected to retain documentation of their training. Principal Investigators and Departments are responsible for tracking the completion of training requirements associated with extramural awards. Documentation of the training is subject to review by the funding agency and UC San Diego Research Compliance and Integrity Office upon request.

### **Does UC San Diego Monitor to Ensure that GCP Training has been Completed**

The Research Compliance and Integrity (RCI) Office facilitates research, innovation and education, responsibly for global excellence and is responsible for broad oversight, resources and education for the integrity and compliance issues relating to the conduct of research. RCI will work with the various sponsored projects offices to identify the awards that require GCP training. RCI will conduct monitoring based on the information included in the grant application/proposal. The results of the monitoring will be provided to the applicable Principal Investigators and their Department Chairs/Deans. RCI will also provide training and education on the GCP training requirements.

### **Training Information & Resources**

GCP training can be completed through the CITI Program: <https://www.citiprogram.org>. For additional information or assistance, please contact the Research Compliance and Integrity Office at (858) 822-4939, [rci@ucsd.edu](mailto:rci@ucsd.edu).