Certification in Human Subjects' Protections

Introduction:

The UHCMC Institutional Review Board (IRB) collaborates with the other institutional review boards, including Case Western Reserve University (Case), MetroHealth Medical Center, Louis Stokes Cleveland Department of Veterans Affairs Medical Center and the Cleveland Clinic, in a common program for human subjects' protections certification. The Continuing Research Education Credit (CREC) program provides documented training on the protection of human subjects in research and meets the requirements for human subjects' certification for both the National Institutes of Health (NIH) and the UHCMC IRB.

Definitions:

Collaborative IRB Training Initiative (CITI) is a web-based educational program in the ethics of human subject research and may be used for both core initial certification as well as continuing education requirements. The program is sponsored by the University of Miami (Florida) and may be accessed at http://www.miami.edu/citireg/.

CREC stands for Continuing Research Education Credit.

Policy:

The UHCMC IRB requires certification of the Principal Investigator and all individuals obtaining consent (co-investigators, coordinators, RNs, etc) on any research protocol regardless of funding; while Case's policy on human subjects' certification requires certification of the Principal Investigator and all key personnel, as defined by NIH, on all federally funded grants administered through Case. **The UHCMC IRB strongly encourages all investigators and study personnel who interact with subjects to be certified.** In addition, the UHCMC IRB certification requirements are applicable to research determined by the IRB to be exempt from IRB review and approval.

Once certified, investigators must maintain valid certification by participating in ongoing continuing research education programs. The UHCMC IRB follows the Case requirements for re-certification. Certified investigators and research staff members (key personnel and especially individuals obtaining informed consent) must earn 12 CRECs (Continuing Research Education Credits) every three years to maintain their certification in human subjects' protections.

Protocols can be submitted to the IRB pending investigator certifications; however, approvals will not be issued until investigator certification is complete. If certification lapses, recertification must be complete before approval for the continuing review will be issued.

Failure to meet the requirements for human subjects' protections certification is considered a **major protocol deviation** and must be reported to the UHCMC IRB within 14 calendar days of discovery (see IRB Policy, Event Reporting- Unanticipated Problems, Adverse Events and Protocol Deviations). When research consent is obtained by an individual who is not certificated in human subjects' protections, it will become an issue of non-compliance and be processed as described in IRB Policy, Non-Compliance with Human Subject Regulations

A) Previously Certified at Other Institutions Now at Case/UH?

Investigators who come from other institutions are encouraged to achieve Case certification as soon as possible. The IRB will accept written evidence of certification in human subject protection from another institution for up to one year after initial Case appointment.

B) Investigators at Other Institutions on Protocols Approved by the IRB

Investigators at other institutions, who are named on a UHCMC IRB study and do not obtain consent using an IRB approved consent form, do not need to be certified. If the investigator obtains consent at his or her institution, the investigator must be certified in human subjects' protections following his or her institution's policy. Proof of certification from the investigator's institution must be submitted to the IRB.

C) Foreign Investigators

Foreign investigators named on IRB approved research studies who obtain consent from subjects must be certified using the Case requirements. If the principal investigator believes meeting the Case requirements is not possible, a waiver may be requested at the time the protocol is submitted for IRB review. The request for a waiver must include an alternative plan that ensures appropriate education in human subject protections. The IRB considers requests for waivers on a protocol-by-protocol basis.

D) Initial Certification Options

Initial certification lasts for three years. The only option for initial certification is the CITI Online Training course. All training is done via the Internet and can be completed in multiple sessions. Further details are available at the Case website.

E) Continuing Education Options

Once initial certification has been received, an investigator must accumulate 12 Continuing Research Education Credits (CRECs) every **three years** to be re-certified. For continuing education, investigators may combine CRECs from the Options below to meet the required 12 CRECs for re-certification. There are multiple options for earning CRECs for re-certification:

Option 1: CITI Core Course (only if it has not been taken before)

If an investigator has previously taken the Rochester Exam for certification, the CITI Core Course may be taken for 12 CRECs.

Option 2: CITI Refresher Course
If an investigator has previously taken the Rochester Exam or CITI Core Course for initial certification, the CITI Refresher Course may be taken for 4 to 12 CRECs.

Option 3: Attend Continuing Education Seminars at Case or the Affiliated Hospitals
The Case Office of Research Administration and UHC sponsor educational opportunities for investigators to earn CRECs to meet the re-certifications requirement. The CRECs associated with each conference are listed in the course materials.

Option 4: Attend Continuing Education Seminars at other Institutions
Investigators may earn CRECs towards re-certification by attending relevant conferences and programs on clinical research issues offered elsewhere. To obtain CRECs, investigators must submit a completed CREC Credit Application and supporting information to allow awarding of CRECs. The number of CRECs for the course is determined by Case from the materials provided by the attendee.

Option 5: Approved Online Courses
The Case website lists approved online sites that can be used to earn CRECs.

References and/or Regulatory Citations:

NIH Requirements for Education (October 26, 2006)
The CREC Program
CITI On-line Basic Training
CREC Research Seminar Calendar
Frequently Asked Questions
How to determine if you are Required to Participate in CREC
IRB Policy, Non-Compliance with Human Subject Regulations
IRB Policy, Event Reporting- Unanticipated Problems, Adverse Events and Protocol Deviations