

HAC Policies and Procedures for HAC Members and OHRP Staff

HAC Member Education and Training

Are New Members (Regular And Alternate) Required to Complete CITI?

Yes, new members (regular and alternate) are required to complete CITI (Collaborative Institutional Training Initiative) web-based training. The required CITI learner group is “Group 4 – HAC Members Only”, which contains twenty (20) modules for required completion. The web address for CITI is www.citiprogram.org. Re-certification is required every three years of all HAC members (and all research personnel involved in research affiliated with the Medical College of Georgia.)

Are New Members (Regular And Alternate) Required to Complete an Orientation Session Prior to Serving?

Yes. Each new HAC member is required to complete an orientation session conducted by the Office of Human Research Protection. The orientation includes the following: HAC history, HAC member information, HAC responsibilities, fiscal year meeting information, packet information, action items information, etc.

Each attendee is given a binder with orientation information, HAC Policies and Procedures, HAC roster, HAC meeting dates and location directions, contact information, HAC Reviewer’s Checklist, and a copy of the Belmont Report.

In addition to the binder, orientation attendees are also given a copy of the “Code of Federal Regulations and ICH Guidelines and the GCP Reference Guide”, and a copy of “Protecting Study Volunteers in Research” as required reading.

How are Educational Topics Selected and Presented to the HAC Members?

Specific educational topics are presented to Committee members on an “as needed” basis such as when issues arise in the lay press, scientific journals and/or if a members requests the presentations.

Does Education of the HAC Members Occur Each Month?

A current topic is usually discussed at each meeting and documented in the meeting minutes.

HAC members also receive the following:

OHRP Tip of the Month Newsletter (On-line newsletter with research updates and timely tips for research personnel)

Research Administration Quarterly Newsletter (Multi-paged newsletter that encompasses all areas of research and research administration at the Medical College of Georgia)

RESCUE (RESearch Coordinators United in Excellence) Monthly Meeting Reminders

RESCUE is a group of research individuals that include registered nurses, pharmacists, physicians, dentists, dental hygienists, certified clinical research coordinators, research assistants

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and administrative support staff. The HAC members are also invited to attend these monthly meetings.

Issues discussed in the meetings range from institutional issues to new federal rules and regulations from the United States Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP).

The Office of Human Research Protection (OHRP) provides support for these meetings. A newsletter is posted to the OHRP web site after each meeting so those who were unable to attend may be notified of any changes.

Are there Regularly Scheduled Educational Sessions?

Quarterly educational sessions are conducted to provide timely information on issues in research. Previous topics have included, e.g.:

- Pediatric subjects
- Stem cell transplants and stem cell research
- Financial conflict of interest

Is There a Plan for the IRB Members and OHRP Staff Training?

Yes. The plan is posted on the web site.