

OHRP Monthly Training Series



The Office of Human Research Protection is offering monthly training sessions from now through the end of November. These sessions are free-of-charge and open to anyone who is affiliated with research at MCG.

The monthly training sessions will feature the following **four topics**, and will be offered continually throughout the year:

- Continual Review
- Amendments
- Adverse Events, Serious Adverse Events and Unanticipated Problems
- Informed Consent Documents

If you would like to attend the sessions, email your

- **name**
- **office phone**
- **session title(s) and session date(s)**

to OHRP_TRAINING@mail.mcg.edu or call **KimKoss at 706.721.1481** for more information.

See **below** for the session descriptions, calendar dates, times and locations.



Continual Review

Hands-on session designed to walk research team members through the process of Continuing Review, and address the following:

- **Continuing review policies**
- **How to complete the HAC Form 107**
- **Other documents to include with the continual review submission**

Bring your Regulatory File/Binder and your Form 107 (if applicable). We will assist/direct you with the completion of your Form 107 Continual Review application.



Amendments

Session designed to navigate the research team members through the amendment submission process. Attendees will review:

- **How to complete the HAC Form 113**
- **Required documents to include with the amendment submission**



Adverse Events, Serious Adverse Events and Unanticipated Problems

In depth presentation designed to evaluate when and how to report:

- **Adverse events** (expected, unexpected, related, unrelated)
- **Serious adverse events** (the federal regulations that define serious adverse events)
- **Unanticipated problems** (defining unanticipated problems and how to recognize)

The HAC Form 110 will be reviewed for Adverse Events and Serious Adverse Events.
The HAC Form 113 will be reviewed for the Unanticipated Problems.



Informed Consent Document Training

This session is designed to review the required elements of an informed consent document. The class will overview the basics of the informed consent process, as well as a “hands on” exercise, where the attendees will:

- **Review an informed consent document**
- **Complete the checklist used by the Human Assurance Committee to review informed consent documents**

Training Schedule

May 27	Continual Review	CJ 3302	3:00 pm to 4:00 pm
June 16	ICDs	CJ 3302	3:00 pm to 4:30 pm
June 23	Amendments	CJ 3302	3:00 pm to 4:00 pm
June 25	Adverse Events, Serious Adverse Events, Unanticipated Problems	CA 2005	3:00 pm to 4:00 pm
June 29	Continual Review	CA 2005	3:00 pm to 4:00 pm
July 13	Continual Review	CJ 3302	3:00 pm to 4:00 pm
July 14	ICDs	CJ 3302	3:00 pm to 4:30 pm
July 21	Amendments	CJ 3302	3:00 pm to 4:00 pm
July 23	Adverse Events, Serious Adverse Events, Unanticipated Problems	CA 2005	3:00 pm to 4:00 pm
August 3	Continual Review	CJ 3302	3:00 pm to 4:00 pm
August 11	ICDs	CJ 3302	3:00 pm to 4:30 pm
August 25	Amendments	CJ 3302	3:00 pm to 4:00 pm
August 27	Adverse Events, Serious Adverse Events, Unanticipated Problems	CA 2005	3:00 pm to 4:00 pm
August 31	Continual Review	CA 2005	3:00 pm to 4:00 pm
September 8	ICDs	CJ 3302	3:00 pm to 4:30 pm
September 14	Continual Review	CJ 3302	3:00 pm to 4:00 pm
September 22	Amendments	CJ 3302	3:00 pm to 4:00 pm
September 24	Adverse Events, Serious Adverse Events, Unanticipated Problems	CA 2005	3:00 pm to 4:00 pm
October 5	Continual Review	CJ 3302	3:00 pm to 4:00 pm

October 13	ICDs	CJ 3302	3:00 pm to 4:30 pm
October 20	Amendments	CJ 3302	3:00 pm to 4:00 pm
October 22	Adverse Events, Serious Adverse Events, Unanticipated Problems	CA 2005	3:00 pm to 4:00 pm
November 2	Continual Review	CJ 3302	3:00 pm to 4:00 pm
November 10	ICDs	CJ 3302	3:00 pm to 4:30 pm
November 17	Amendments	CJ 3302	3:00 pm to 4:00 pm
November 19	Adverse Events, Serious Adverse Events, Unanticipated Problems	CA 2005	3:00 pm to 4:00 pm
November 23	Continual Review	CJ 3302	3:00 pm to 4:00 pm