

From the November 21st RESCUE Meeting

RESEARCH Coordinators United in Excellence Newsletter

Announcements

Ivy Tillman, OHRP - Announced that the HAC Administration Office is short by two people. There is only one person left working in the HAC office—Christy Wise.

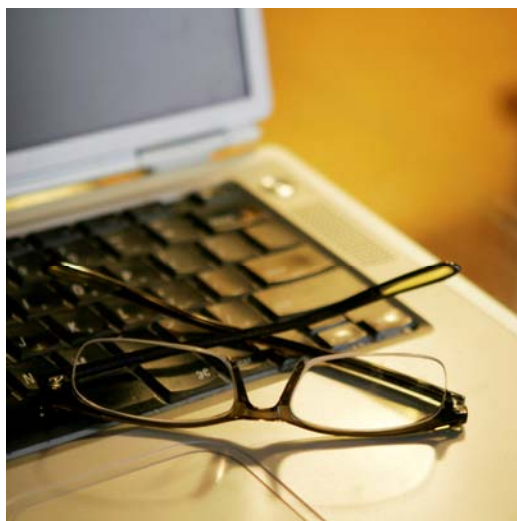
Sharon Willing has gone to work for Mary Anne Park in Surgical Research. Crystal Hucksam has transferred to Sponsored Program Administration, teamed with Cindy Mangrum.

Ivy asked that everyone be patient; Kim Koss, Clinical Research Training Coordinator, and Angie Randazzo, Business Manager, are both working in the HAC office, reviewing amendments.

Jennifer Kenrick, Auditor, is working on continuations, and Ivy Tillman is working on initial submissions. Hopefully, the positions will be filled by early 2009.

Kim Koss, OHRP - Reminder that there is an online powerpoint presentation available to anyone/everyone who has not had an opportunity to either attend a classroom session or attend the online webinar regarding the recent HAC policy updates and revisions.

HAC Policies Updates and Revisions Webinar Instructions—See Page Two



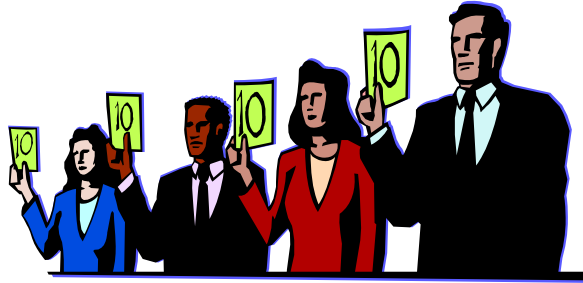
Updates on “**HAC Forms and Procedures**” (from Page One)

Webinar Instructions

- Go to the address <http://mcglive.wimba.com/>
- Run the “**set-up wizard**”
- Select the “**archives**” tab (not the “**open rooms**” tab)
- Look for the sessions titled “**Updates on HAC Forms and Procedures**”
- Don’t be alarmed if, when you get started, the screen takes a while to download, possibly up to five minutes
- While you are in the archived webinar, you may start and stop at any time, and restart again, at any point in the session

If you have any questions, please email Kim Koss, Clinical Research Training Coordinator, at kkoss@mcg.edu.

RESCUE Top Ten



HAC Policies Changes

All policy changes are effective November 1, 2008

I. Exempt Review

Addition of applicability criteria and guidance regarding studies which cannot be reviewed via exempt review:

Notable changes:

All research involving prisoners cannot be reviewed via exempt review.

Research on any FDA regulated product cannot be reviewed via exempt review.

Research that involves children and may fit one of the following criterion cannot be reviewed via exempt review:

4 (Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.)

5 (Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

-public benefit or service programs;

-procedures for obtaining benefits or services under those programs;

-possible changes in or alternatives to those programs or procedures; or

-possible changes in methods or levels of payment for benefits or services under those programs.

II. Safety Events- Unanticipated Problems, Unexpected Adverse Events, Serious Adverse Events

Definition of an unanticipated problem:

An event that is “unexpected” when its specificity and severity are not accurately reflected in the informed consent document

An event that is “related or probably related to the research procedures” if in the opinion of the investigator, it was more likely than not to be caused by the research procedures or if it is more likely than not to be caused by the research procedures or if it is more likely than not that the events affects the rights and welfare of current participants.

Deadline for reporting all safety events: see HAC Submission and Deadline website:

Protocol Deviations/Protocol Violations	Within five (5) business days
Unanticipated Problems	Within 72 hours of research team member becoming aware of the event
Adverse Events, Unexpected and Related	Within 72 hours of research team member becoming aware of the event
Serious Adverse Events	Within 24 hours of research team member becoming aware of the event
IND Safety Report	Submit summary at time of initial review and at continuing review

III. Investigational Drug Studies that involve an IND (Investigational New Drug Application to the FDA)

What are the Requirements for Studies that Require an IND or Are Exempt?

- 1) For studies in which the sponsor is the IND holder, the investigator is required to:
 - a) Provide a copy of the IND filing from the sponsor
 - b) Provide documentation from the sponsor or FDA that the IND is valid
 - c) Provide documentation from the FDA that the IND is exempt

Note that this documentation should be included in the initial submission for the study. HAC approval will not be granted without this required documentation.

Listed responsibilities of investigators who hold INDs

For studies in which the investigator is the Sponsor and IND holder, the following procedure should be followed:

- a) The PI will include in the protocol submission the following parts written to the specifications identified Title 21—Food and Drugs, Chapter 1—Food and Drugs Administration, DHHS, Subchapter D—Drugs for Human Use, Part 312 – Investigational New Drug Application Subpart D, responsibility of the investigator
- b) The PI must send a copy of all correspondence to and from the FDA in the initial submission, including investigator reports. A letter from the FDA regarding the IND status (including exemption) is also required for HAC approval.
- c) The HAC will ensure that at initial and continuing review, these elements are in compliance with:
 - § 312.50 - General responsibilities of sponsors.
 - § 312.52 - Transfer of obligations to a contract research organization.
 - § 312.53 - Selecting investigators and monitors.
 - § 312.54 - Emergency research under 50.24 of this chapter.
 - § 312.55 - Informing investigators.
 - § 312.56 - Review of ongoing investigations.
 - § 312.57 - Recordkeeping and record retention.
 - § 312.58 - Inspection of sponsor's records and reports.
 - § 312.59 - Disposition of unused supply of investigational drug.
 - § 312.60 - General responsibilities of investigators.
 - § 312.61 - Control of the investigational drug.
 - § 312.62 - Investigator recordkeeping and record retention.
 - § 312.64 - Investigator reports.
 - § 312.66 - Assurance of IRB review.
 - § 312.68 - Inspection of investigator's records and reports.
 - § 312.69 - Handling of controlled substances.
 - § 312.70 - Disqualification of a clinical investigator

d) Investigators must contact the Office of Human Research Protection to schedule a meeting to confirm that the PI is knowledgeable on the requirements associated with 21 CFR §312. Investigational New Drug Application

e) Investigators who are the Sponsor and IND holder are also responsible for registering the study in the Clinical Trials Registry (see HAC Policies and Procedures, Section 2 for more information).

IV. Investigational Device Studies that involve an IDE (Investigational Device Exemption Exemption Application to the FDA)

What are the Responsibilities for Studies in which an IDE is Required?

1) For studies in which the sponsor is the IDE holder, the investigator is required to:

a) Provide a copy of the IDE filing from the sponsor

b) Provide documentation from the sponsor or FDA that the IDE is required, or the device meets the IDE exemptions, or an abbreviated IDE is required is valid

Note that this documentation should be included in the initial submission for the study. HAC approval will not be granted without this required documentation.

Listed responsibilities of investigators who hold IDEs

For studies in which the investigator is the Sponsor and IDE holder, the following procedure should be followed:

a) The investigator will include in the protocol submission the following parts written to the specifications identified Title 21—Food and Drugs, Chapter 1—Food and Drugs Administration, DHHS, Subchapter H—Medical Devices, Part 812 – Investigational Device Exemptions, Subpart C- Responsibilities of Sponsors

b) The PI must send a copy of all correspondence to and from the FDA in the initial submission, including investigator reports. A letter from the FDA regarding the IDE or IDE status is also required for HAC approval.

c) The HAC will ensure that at initial and continuing review, that these elements are in compliance with:

- § - General responsibilities of sponsors.
 - FDA and IRB approval.
 - Selecting investigators and monitors.
 - Informing investigators.
 - Monitoring investigations.
 - Emergency research under 50.24 of this chapter.
- General responsibilities of investigators.
- Specific responsibilities of investigators.
- Disqualification of a clinical investigator.

d) Investigators must contact the Office of Human Research Protection to schedule a meeting to confirm that the PI is knowledgeable on the requirements associated with:

ii. 21 CFR §812. Investigational Device Exemptions

e) Investigators who are the Sponsor and IDE Holder are also responsible for registering the study in the Clinical Trials Registry (see HAC Policies and Procedures, Section 2 for more information).

V. *Emergency Use*

DHHS does not allow emergency use exemptions (i.e. federally funded research that is not regulated by the FDA does not allow emergency use exemptions).

What is a Life-Threatening Situation?

A situation in which a patient has a disease or condition where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival. The criteria for life-threatening do not require the condition to be immediately life-threatening or to immediately result in death. Rather, the subjects must be in a life-threatening situation requiring intervention before review at a convened meeting of the IRB is feasible.

Is Notification to the HAC of the Emergency Use of a Test Article Required Prior to Its Use?

Yes, the physician is required to notify the HAC prior to the emergency use of a test article so that it can be reviewed by the HAC Chair or their designee to determine that the circumstances follow FDA regulations, however, notification of emergency use of a test article to the HAC chairperson should not be construed as HAC approval.

The investigator is required to submit a report on the use of the test article within five working days. This report will be reviewed by the HAC Chair or their designee.

VI. *Continuing Review: Please see webinar for list of changes*

VII. *Waiver of Consent*

If I Request Waiver of Written Informed Consent or Waiver of Authorization, does this Request Automatically Require Review by the Full HAC?

No. The HAC Chairman will evaluate each protocol requesting waiver of consent and will determine if full review is required.

If the PI is requesting waiver of the requirement to obtain consent, the following information must be clearly documented and justified in the Description of Research Proposal (DRP):

1) The research involves no more than minimal risk to the subjects;

- (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- (3) The research could not practicably be carried out without the waiver or alteration; and
- (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation (include a description of the information that would be provided to subjects).

VIII. Description of Research Proposal

Additional information required regarding:

A) The provisions to protect the privacy interests of the subjects

i) How will subjects be approached about participating in the study in a private manner?

ii) How will the study be conducted so that subjects will be treated in a private manner?

iii) Include a plan to give subjects control of the release of private information, tissues, or biological specimens, as applicable?

iv) If applicable, how will privacy be handled for any information which may be viewed by the subjects as unusually sensitive or objectionable?

IX. Charlie Norwood VA Medical Center

Revised submission checklist

X. HAC Procedural Changes

HAC Goes Green!

In an effort to conserve paper and reduce costs associated with HAC submissions, researchers may submit 2-sided documents.

Track Changes

All amendments involving revisions to an HAC-approved document (DRP, ICD, advertisement, etc...) should include the following:

- 1) A copy of the revised document
- 2) A copy of the document using track changes to show the revisions

ICD Template

The ICD template in the HAC Policies and Procedures has been revised to include the new contact number for subjects' rights: "The Office of Human Research Protection at (706)-721-1483."