

HAC Policies and Procedures for HAC Members and OHRP Staff

What is the Purpose of this Section?

This section provides information to the HAC members, alternates, advisors and OHRP staff on the following topics:

- Member Information
- HAC Member Education and Training
- Conflict of Interest
- HAC Roster Updates and Registration Updates with DHHS
- Emergency Use Protocols
- Exempt Protocols
- Expedited Protocols
- Full Review Protocols
- Amendments and Modifications
- Continuing Review
- Unanticipated Problems, Adverse Events and Serious Adverse Events
- Serious or Continuing Non-compliance
- Communication
- Minutes Documentation
- HAC Record Storage
- HAC Members Stipends
- HAC Administrative Office Staff Information

Member Information

What are the Federal Requirements for the HAC Composition?

Per federal rules and regulations, the HAC must be composed of the following:

- Have at least five members
- All members cannot be of the same profession
- All members cannot be of the same sex
- One member must be a non-affiliated member (not affiliated with the institutions served)
- One member must be a non-scientific member

What are the Responsibilities of an HAC Member?

The primary responsibility of the HAC member is to protect the rights and welfare of human research subjects. This obligation is maintained when the proposed research protocol is reviewed in compliance with applicable federal regulations, state and local laws and the interest of the local research community.

Are HAC Members Required to Attend Scheduled Training and Education Sessions?

Yes, all HAC members are required to attend scheduled training and education sessions. Please see the section on HAC Member Education and Training.

What are the Types of Members that Serve the HAC?

The members are full voting members, alternates for the full voting members (when applicable), the HAC Chairperson and Vice-Chairperson.

How are Affiliated Members Selected from MCG and MCGHI?

Affiliated members are selected from various departments as the need for expertise in a specific area presents itself. The HAC Chairperson, or the OHRP Assistant Director at the request of the HAC Chairperson, contacts the individual and the departmental chairperson to determine if an individual can serve.

How are Affiliated Members Selected from the Charlie Norwood VA Medical Center?

For Charlie Norwood VA Medical Center members, the Medical Center Director selects and appoints members to the HAC. These members are then appointed by the MCG President. The HAC includes three Charlie Norwood VA Medical Center members as voting members and no votes are taken on protocols that involve the Charlie Norwood VA Medical Center unless at least one of these members is present. These individuals must be physicians according to VHA regulations.

How Are Non-Affiliated Members Selected from the Community?

Non-affiliated members are selected from the community by word-of-mouth or by contacting the HAC Administrative Office.

Who Appoints the HAC Members?

The President of MCG appoints the HAC members based upon the written recommendation of the HAC Chairperson. Charlie Norwood VA Medical Center members are appointed by the Medical Center Director and are confirmed by the President of MCG at least every three years.

Who Prepares the Documentation to Appoint or Reappoint a Member or Alternate?

The OHRP Assistant Director is responsible for preparing the necessary documentation to appoint or reappoint a member or alternate. The OHRP Director serves as back-up for this action.

How are HAC Members Evaluated?

HAC members are evaluated every three years by the President with input from the HAC Chairperson, Vice-Chairperson, Full Member, Vice President for Research, and the ORHP Director and Assistant Director. Several criteria are used in the evaluation process such as meeting attendance over the term, preparedness, interest and availability to continue.

How Often do HAC Members Provide an Updated CV or Résumés to the HAC Administrative Office?

The dated and preferably signed CVs or résumés for HAC members and alternates are submitted at the time of initial appointment and then at each re-appointment for all members and alternates including the representatives from the Charlie Norwood VA Medical Center. These are available for review from the OHRP Assistant Director or designee.

What are the Terms of Service for an HAC Member?

Terms of service are three years although a term may be less depending on the situation. These are reviewed on a case-by-case basis.

Is There a Term Limit for an HAC Member?

No. There is no limit on the numbers of term that a member may serve.

Can an HAC Member's Service be Terminated?

A member may be terminated from service if the member requests termination, if the three-year term expires or if a confirmed issue of non-compliance involves the member.

Alternate Members**Why are Alternate Members Needed?**

Alternate members may be added to the Committee to serve in the absence of a regular member.

How are Alternate Members Selected?

Alternate members are selected with the expectation that they have equivalent expertise to the regular member.

How are Alternate Members Evaluated?

Alternate members are evaluated every three years by the President with input from the HAC Chairperson, Vice-Chairperson, Full Member, Vice President for Research, and the ORHP Director and Assistant Director. Several criteria are used in the evaluation process such as meeting attendance throughout their term, preparedness, interest and availability to continue.

Who Prepares the Documentation to Appoint or Reappoint a Member or Alternate?

The OHRP Assistant Director is responsible for preparing the necessary documentation to appoint or reappoint a member or alternate. The OHRP Director serves as back-up for this action.

Who Is Responsible for Notifying the HAC Administrative Office That an Alternate Member Will Attend for a Regular Member?

If an alternate member is to serve in the absence of a regular member at the meeting, the regular member should notify the HAC Administrative Office staff via email or phone call of the change.

Is the Alternate Member Expected to Fulfill all Responsibilities of the Regular Member?

Yes. The alternate member is expected to fulfill all responsibilities of the regular member.

Can the Alternate Member and the Regular Member Attend the Same Meeting?

Yes.

If Both the Alternate and the Regular Member Attend, Does this Have an Impact on the Quorum?

No. Only the regular member will count towards the quorum and is the only one authorized to vote.

Can the Alternate Member and the Regular Member Both Vote on a Protocol?

No. The alternate may only serve in a specified individual's absence and only one vote will be counted.

Vice Chairperson Appointment, Evaluation and Feedback

Who Appoints the HAC Vice-Chairperson?

The President of the Medical College of Georgia (MCG) appoints the HAC Vice-Chairperson.

Who Prepares the Documentation to Appoint or Reappoint the Vice-Chairperson?

The OHRP Assistant Director is responsible for preparing the necessary documentation to appoint or reappoint the Vice-Chairperson. The OHRP Director serves as back-up for this action.

Is There a Term Limit for the HAC Vice-Chairperson?

There is no limit on the number of terms that the HAC Vice-Chairperson may serve.

How is the Vice-Chairperson Evaluated?

The Vice-Chairperson is evaluated every three years by the President with input from the HAC Chairperson, Vice President for Research, and the OHRP Director and Assistant Director. Several criteria are used in the evaluation process such as meeting attendance throughout their term, preparedness, interest and availability to continue in this role, leadership and management ability.

Can the HAC Vice-Chairperson Approve Research Protocols If They Qualify for Exempt From Full Review or Expedited Review?

Yes. The HAC Vice-Chairperson may approve research protocols if the protocol qualifies for exempt from full or expedited review.

Can the HAC Vice-Chairperson Disapprove a Protocol Regardless of Level of Review?

No. The HAC Vice-Chairperson may not disapprove a protocol. All disapprovals, regardless of level of review, must be determined by the full committee.

Does the HAC Vice-Chairperson Assume the Duties of the HAC Chairperson in their Absence?

Yes. The Vice-Chairperson assumes the duties of the Chairperson during the absence of the Chairperson.

Chairperson Appointment, Evaluation and Feedback

Who Appoints the HAC Chairperson?

The President of the Medical College of Georgia (MCG) appoints the HAC Chairperson on a three year basis.

Who Prepares the Documentation to Appoint or Reappoint the Chairperson?

The OHRP Assistant Director is responsible for preparing the necessary documentation to appoint or reappoint the Chairperson. The OHRP Director serves as back-up for this action.

Is There a Term Limit for the HAC Chairperson?

There is no limit on the number of terms that the HAC Chairperson can serve.

How is the Chairperson Evaluated?

The Chairperson is evaluated every three years by the President with input from the Vice President for Research and the ORHP Director and Assistant Director. Several criteria are used in the evaluation process such as meeting attendance throughout their term, preparedness, interest and availability to continue in this role, leadership and management ability as well as staying abreast of current regulations, guidelines and national thought leaders.

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

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.

Conflict of Interest

What is the Definition of a Conflict of Interest?

Conflict of interest may be defined as: “A conflict between the private interests and official responsibilities of a person in a position of trust.” This definition is not limited to financial conflicts of interest.

What is a Conflict of Interest for an HAC Member, Special Expert or Consultant?

“Conflict of interest” means any situation in which it reasonably appears that a significant financial interest or other personal interest could compromise the integrity of work to be performed for MCG (for instance without limitation: in the design, conduct, or reporting of activities funded or proposed for funding by a sponsor; in the vendor selection process; in hiring or employment decisions; in research approval processes). A conflict of interest includes, without limitation, apparent or actual bias in the work to be performed for MCG, created by an individual’s personal relationships, or by an individual’s or family member’s significant financial interest or other interest in a company that does business with, competes or may compete with the Medical College of Georgia.

"Significant financial interest" means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interest); and intellectual property rights (e.g., patents, trademarks, copyrights and royalties from such rights). The term does not include:

- salary, royalties or other remuneration from MCG;
- income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities (in connection with approved outside professional activity);
- income from services on advisory committees or review panels for public or nonprofit entities (in connection with approved outside professional activity); or
- an equity interest that, when aggregated for the investigator and the investigator's spouse and dependent children, meets both of the following tests: [i] does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and (ii) does not represent more than a 5% ownership in any single entity; or
- other salary, royalties or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children, are not expected to exceed \$10,000 during the next twelve-month period.

EXCEPTION: When the proposed project involves human subjects and approval from the Institutional Review Board, the above monetary thresholds do not apply. In human subject research, the threshold for required conflicts of interest disclosure is any dollar or stock amount above zero.

Can the Conflicts be Research-Related?

Yes. The conflicts may also be research-related such as conflicts that arise out of an individual's participation in the conduct or oversight of clinical research or non research-related if unrelated to clinical research.

What Should a HAC Member or Consultant do if They Feel That a Conflict of Interest Exists for them Personally or Professionally?

If a HAC member or consultant feels that a conflict of interest may exist, that individual should excuse themselves from the review process.

If the HAC Member does have a Conflict of Interest, Can They Vote on the Protocol?

No. Members may not participate in the vote and must recuse themselves prior to that action if in attendance at the meeting and their attendance at that time does not constitute part of the quorum.

What if the Investigator Feels that a Conflict of Interest Exists Between an HAC Member and the Investigator?

If the investigator feels that a conflict of interest exists, the investigator may request in writing prior to the member assignment that an individual member not be assigned to review the protocol in question. The investigator must fully document the perceived conflict of interest. However, investigators may not select the HAC reviewers.

Can any HAC Member Vote on any Protocol Where their Vote May Represent a Conflict of Interest?

HAC members with a conflicting interest are:

- Excluded from the discussion except to provide information requested by the HAC.
- Required to leave the meeting room for discussion and vote and can not simply abstain from voting
- Not counted towards the quorum.

Who Identifies the HAC Member with a Conflicting Interest for Review by the Convened HAC?

HAC members self-identify a conflict of interest for the review by the convened HAC. If the Conflict of Interest Panel has determined a conflict of interest, the individual is responsible for notifying the appropriate committees.

Who Identifies the HAC Member with a Conflicting Interest for Review by the Expedited Procedure?

HAC members self-identify a conflict of interest for the research under expedited review. If the Conflict of Interest Panel has determined a conflict of interest, the individual is responsible for notifying the appropriate committees.

Does the IRB Withhold Approval Until the Evaluation and Management of the Financial Interest is Complete?

Yes. The HAC withholds approval until the evaluation and management of the financial interest was complete.

HAC Roster Updates and Registration Updates with DHHS

Who is Responsible for Reporting Changes in HAC Membership to DHHS?

The OHRP Assistant Director is responsible for reporting changes in HAC membership to DHHS. The OHRP Director serves as back-up for this action.

What is the Time Line for Reporting Changes in HAC Membership to DHHS?

Changes in HAC Membership are updated within 14 days of the member change.

Who is Responsible for Updating the HAC Roster?

The OHRP Assistant Director is responsible for reporting changes in HAC membership on the HAC Rosters. The OHRP Director serves as back-up for this action.

What is the Time Line for Updates to the HAC Roster?

HAC Rosters are updated within 14 days of the member change.

Who is Responsible for Posting the Updated HAC Roster on the HAC Web Site?

The Business Manager is responsible for posting the updated HAC Roster on the HAC web site within 14 business days unless there is an Information Technology (IT) restriction.

Who is Responsible for Maintaining the Archived HAC Rosters on the HAC Web Site?

The Business Manager is responsible for posting the updated HAC Roster on the HAC web site within 14 business days unless there is an Information Technology (IT) restriction.

Emergency Use

Emergency Use Exemption from Prospective HAC Approval

The emergency use provision in the Food and Drug Administration (FDA) regulations [21CFR56.102 (d)] is an exemption from prior review and approval of the HAC. The exemption, which may not be used unless all of the conditions described in 21CFR56.102 (d) exist, allows for a one time emergency use of a test article without prospective HAC review. This emergency use is to fulfill the physician's obligations to treat a seriously ill patient with all available modalities. This use allows physicians to have access to experimental or investigational treatments that would be prohibited in other settings. FDA regulations require that any subsequent use of the investigational product at the institution have prospective HAC approval.

NOTE: The HAC cannot approve a waiver of written informed consent for planned emergency research that is subject to Veterans Health Administration (VHA) regulations. For more information, please see the Charlie Norwood VA Medical Center section.

What Is Emergency Use?

Emergency use is defined as the use of an investigational drug or biologic product (i.e., test article) with a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain full Human Assurance Committee (HAC) approval [21CFR56.102(d)]. Unless it is an area that the chair has particular expertise in, he will consult with members of the committee who have such expertise. The exemption is granted by the HAC Chairperson or his designee.

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 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.

How Does the Investigator Request Emergency Use Exemption Review from the HAC?

They contact the HAC Chairperson at (706) 721-2991 and provide the following information:

- Name of the investigator.
- Telephone number of the investigator.
- Name of test article.
- Patient's name, sex, age, date of birth, medical record number and diagnosis.
- Is the patient enrolled in another research study?

What About Waiver Of Informed Consent For An Emergency Use?

Even for an emergency use, the investigator is required to obtain informed consent of the subject or the subject's legally authorized representative unless both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing **all** of the following [21 CFR 50.23(a)]:

1. The subject is confronted by a life-threatening situation necessitating the use of the test article.
2. Informed consent cannot be obtained from the subject because of an inability to communicate with, or obtain legally effective consent from, the subject.
3. Time is not sufficient to obtain informed consent from the subject's legal representative.
4. There is no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject.

When Is This Information Required to be Submitted to the HAC?

The investigator is required to complete the [HAC Form 101EMG](#), Emergency Exemption from Prospective HAC Approval, and return it to the HAC within five working days of the test article use in order for the HAC to determine that the circumstances met FDA regulations.

What if the HAC Chairperson or Designee Disagrees with the Emergency Use?

The HAC Chairperson or his designee will have discussed the use with members of the HAC who have expertise in the area. If the use is not deemed appropriate by the Chairperson and members, the HAC will work with the clinician to determine an alternative method of treatment.

What If the Investigator Thinks that this Emergency Use May be Needed Again?

The regulation, 21 CFR 56.104(c), allows one use (i.e., one course of treatment) without prior approval by the HAC. If it is anticipated that the situation may occur with other patients, the FDA suggests the HAC review a protocol (in this case, a plan for use in an emergency, not necessarily a research project) and an informed consent document so that a HAC-approved plan for use is in place when the next patient presents.

However, since life-threatening emergencies cannot always be planned, the FDA has allowed that if the only obstacle is lack of HAC approval, the product may be used a second time without the PI's submission of a full review protocol to the HAC for approval. This situation is discussed under the heading "Emergency Exemption from Prospective IRB Approval" in the sheet "Emergency Use of an Investigational Drug or Biologic" in the FDA Information Sheets for IRBs and Clinical Investigators.

What Documentation Does The Sponsor Usually Need to Release the Test Article to the Physician?

Sponsors (e.g., pharmaceutical companies or device manufacturers) usually require written documentation of HAC approval before shipping an investigational drug, even in emergency situations. Many sponsors will accept a statement from the HAC that the use meets the 21CFR56.104(c) requirements for emergency use without HAC approval.

Is Emergency Use and Compassionate Use the Same?

No.

What is Compassionate Use?

Physicians may use the term "compassionate use" to refer to the treatment of a seriously ill patient using an unapproved test article when all other available treatments have failed or are inappropriate.

Compassionate use of an investigational drug, biologic, or device is correctly channeled as one treatment mechanism that is only allowed after prospective review and approval by the HAC. The FDA must also approve these types of use as well in most instances. Prospective HAC approval is required even if the treatment only involves one patient.

What is Expanded Access with Treatment INDs or Individual Patient Access to Investigational Drugs/Devices for Serious Diseases?

The primary intent of these types of treatments is to give seriously ill patients access to experimental drugs or devices where no comparable or satisfactory alternative treatment is available. Expanded access studies involve systematic use of experimental treatments. These types of treatments are considered research and require both HAC approval and FDA approval in the form of an IDE (medical device) or an IND (drug/biologic). The sponsor of the test article is still required to conduct clinical trials and obtain marketing approvals in compliance with the regulations for non-expanded access trials.

Is Research Conducted in the Emergency Medicine Department (ED) or Emergency Room (ER) Considered to be Emergency Use Research?

Although research may be conducted in the ED or ER and is designed to evaluate emergency care treatments, this does not constitute "emergency use." As with all other clinical research,

prospective HAC review and approval are required before research in the ED or ER can start. The unique exception from informed consent for these studies is provided by federal regulations enforced by the FDA [21 CFR 50.24] and the Department of Health and Human Services (DHHS) Office for Human Research Protections [45 CFR 46.101(i)]. The waiver of written informed consent is described in the section on Informed Consent.

Is It Research If A Clinician Uses Innovative Treatment, or Off-Label Use, of An Approved Drug?

Emergency use provisions apply to investigational drugs, biologics, and devices. The off-label use or innovative use of a marketed drug or device for an individual patient treatment rather than for research purposes does not require HAC approval. However, treating a series of patients in a novel or innovative manner and analyzing the results for publication is considered to be research and requires prior HAC approval. A planned chart review that looks at the data obtained during the off-label use is also considered to be research and must be approved by the HAC prior to its use.

Exempt Protocols

How are Exempt Projects Reviewed?

Projects reviewed by the exempt procedure require a complete application and are conducted by the HAC Chairperson, or by one or more experienced reviewers who have been voting members for more than one year and have expertise in the area being considered. The HAC Chairperson will designate the individual.

What Tools are Available to the HAC Reviewer for Exempt from Full Review?

The HAC Chairperson or designee use the Exempt Review checklist to review the packet of information submitted by the Principal Investigator. The HAC Chairperson or designee must confirm that the protocol may be reviewed under the exempt from full review criterion:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, reputation or lead to loss of insurability.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
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: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Can the HAC Chairperson Approve Research Protocols if they Qualify for Exempt from Full Review?

Yes. The HAC Chairperson may approve research protocols if the protocol qualifies for exempt from full review.

Can the HAC Chairperson Disapprove a Protocol Regardless of Level of Review?

No. The HAC Chairperson may not disapprove a protocol. All disapprovals, regardless of level of review, must be determined by the full committee.

Expedited Review

What is the Process Followed by Reviewers to Evaluate Whether Research Undergoing Initial Review and Continuing Review Using the Expedited Procedure?

The regulations allow expedited review procedures for certain kinds of research involving no more than minimal risks (the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [45CFR46.102(I) and 21CFR 56.102(I)], for minor changes in approved research, and for certain categories of continuing review. These procedures are aligned with initial review of a protocol, review of amendments and continuing review.

Projects reviewed by this procedure require a complete application and are reviewed by the HAC Chairperson, or by one or more experienced reviewers who have been voting members for more than one year and have expertise in the area being considered. The HAC Chairperson will designate the individual(s). The investigator must include information in the Description of Research Proposal (DRP) as to why they feel that the submitted protocol meets the regulatory requirements for expedited review. The Principal Investigator (PI) may request expedited review but the Chairperson or his designee will make this final determination.

Research activity that presents no more than minimal risk to human subjects and involves procedures listed in one or more of the following categories may be reviewed by the HAC through the expedited review procedure. [63FR 60364-60367, November 9, 1998]

What Documents are Required for Initial Expedited Review?

The following documents are required:

- HAC Reviewers' Checklist for Expedited Review
- HAC Form 100, Clinical Study Document Cover Sheet
- HAC Form 101, Protocol Information
- Description of Research Proposal
- Complete sponsor provided protocol, if applicable
- Complete DHHS-Approved Protocol, if applicable
- Informed Consent Document and/or Children's Assent Document
- DHHS-Approved Informed Consent Document, if applicable
- Any questionnaires that may be used, if applicable
- Recruitment Plan Materials to include any advertisements or announcements that may be used, if applicable
- The entire grant application, if applicable regardless of funding source
- HAC Form 103, Human Biological Specimens for Genetic Research, if applicable
- Any letters or memoranda for all Committee members to review
- If investigator-initiated, a copy of the data capture forms

What Tools are Available to the HAC Reviewer for Expedited Review?

The HAC Chairperson or designee use the Expedited Review checklist to review the packet of information submitted by the Principal Investigator. The HAC Chairperson or designee must

confirm that the protocol may be reviewed under the expedited review procedures because it involves no more than minimal risk to subjects.

The expedited review criteria are:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) Research on medical devices for which (a) an investigational device exemption application (21 CFR Part 812) is not required; or (b) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick or venipuncture as follows: from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 450 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or from other adults and children¹, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects.45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance

Who is Responsible for Determining if the HAC Chairperson or Designee Have a Conflict of Interest Regarding the Expedited Review of a Protocol?

The HAC Chairperson or designee must determine if they have a conflict of interest regarding the protocol as defined by the MCG Conflict of Interest Policy.

Who is Responsible for Declaring a Conflict of Interest and to Whom is the Conflict Reported for an Expedited Review of a Protocol?

If a conflict of interest is noted, then the individual must declare that conflict immediately to the OHRP Director and the Conflict of Interest panel.

What Must the HAC Chairperson or Designee Determine when Reviewing a Protocol for Expedited Review?

The HAC Chairperson or designee must review the protocol to determine the following:

- Physical, psychological, social, legal, and economic risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk
- Physical, psychological, social, legal, and economic risks to participants are minimized whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes
- Physical, psychological, social, legal, and economic risks are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.
- Selection of subjects is equitable
- There are adequate provisions to protect the privacy of subjects
- There are adequate provisions to maintain the confidentiality of the data.
- Additional safeguards have been included in the study to protect the rights and welfare of participants likely to be vulnerable to coercion or undue influence

What must the HAC Chairperson or Designee Review for the Informed Consent Process and the Documentation of Informed Consent for Expedited Review?

The HAC Chairperson or designee must review the informed consent process and the documentation of the informed consent for expedited review using the Expedited Review Checklist to determine the following:

Will the informed consent process will be waived (*See Checklist of Criteria to Waive or Alter the Requirement to Obtain Informed Consent*)

OR

Will the requirement for written documentation will be waived (*See Checklist of Criteria to Waive the Requirement for Written Documentation of Informed Consent*)

OR

Informed consent will be sought from each prospective subject or the subject's representative in accordance with the regulations as follows:

- The investigator will obtain the legally effective informed consent of the subject or the subject's legally authorized representative
- The circumstances of consent provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate
- The circumstances of consent minimize the possibility of coercion or undue influence
- The information that will be given to the participant or representative will be in language understandable to the subject or the representative

- No information will be provided to the subject or the representative that waives or appears to waive any of the subject's legal rights, or that releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence
- All required and appropriate additional disclosures will be provided to the subject or the subject's representative. *(See Elements of Informed Consent Disclosure)*
- Informed consent will be documented in writing in accordance with the regulations
 - The consent document embodies the basic and appropriate additional elements of disclosure. *(See Elements of Informed Consent Disclosure)*
 - The participant or the participant's legally authorized representative will sign the consent document.
 - If the research is FDA-regulated, the participant or the participant's legally authorized representative will sign and date the consent document.
 - A copy of the consent document will be given to the person signing the consent document.
 - For VA research, a copy of the signed and dated consent document will be given to the person signing the consent document.
 - The investigator will give either the participant or the representative adequate opportunity to read the consent document before it is signed.

What Are the Elements of Informed Consent Disclosure?

The elements of informed consent disclosure are:

- A statement that the study involves research.
- An explanation of the purposes of the research.
- An explanation of why the subject is invited to participate in the research.
- An explanation of the expected duration of the participant's participation.
- A description of the procedures to be followed.
- The approximate number of participants involved in the study.
- Identification of any experimental procedures. *(May be omitted if there are none.)*
- A description of any reasonably foreseeable risks or discomforts to the participant. *(May be omitted if there are none.)*
- A statement that the particular treatment or procedure may involve risks to the participant, which are currently unforeseeable.
- A statement that if the participant is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable. *(Look for when the research involves pregnant women or women of childbearing potential, and the effect of the procedures have not been evaluated in pregnancy or a goal of the research is to define safety in pregnancy.)*
- A description of any benefits to the participant or to others, which may reasonably be expected from the research.
- A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant. *(Look for this on long-term clinical trials.)*
- An explanation of whom to contact for answers to pertinent questions about the research.
- An explanation of whom to contact about concerns or complaints about the research study.
- An explanation of whom to contact for answers to pertinent questions about the research participants' rights (George S. Schuster, DDS, PhD at 706-721-2991).

- An explanation of whom to contact in the event of a research-related emergency.
- A statement that participation is voluntary.
- A statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled.
- A statement that the participant can discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.
- Any additional costs to the participant that may result from participation in the research. *(Look for when additional costs are expected.)*
- An explanation of whether the subject will be paid/reimbursed for their participation in the research.
- Inclusion of Statement of Privacy Notice
- An explanation as to whether compensation is available when injury occurs, an explanation as to what it consists of or where further information may be obtained. *(May be omitted if the research involves no more than minimal risk.)*
- An explanation as to whether any medical treatments are available if injury occurs and what it consists of or where further information may be obtained *(May be omitted if the research involves no more than minimal risk.)*
- A statement that notes the possibility that the Food and Drug Administration may inspect the records. *(May be omitted for research that is not subject to FDA regulations.)*
- A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained. *(May be omitted if confidentiality will not be maintained.)*
- Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent. *(Look for when the protocol mentions this as a possibility.)*
- The consequences of a participant's decision to withdraw from the research. *(Look for when withdrawal from the research will have adverse consequence.)*
- Procedures for orderly termination of participation by the participant. *(Look for when such procedures are part of the protocol.)*
- Is there a description of the protected health information (PHI) to be used or disclosed, identifying the information in a specific and meaningful manner?
- Are the names or other specific identification of the person or persons (or class of persons) authorized to make the requested use or disclosure clearly designated?
- Are the names or other specific identification of the person or persons (or class of persons) clearly designated, indicating to whom MCG Health Systems may make the requested use or disclosure?
- Is there a description of each purpose of the requested use or disclosure?
- Is there an Authorization expiration date or expiration event for the duration that relates to the individual or to the purpose of the use or disclosure? (Note: "end of the research study" or "none" are permissible for research, including for the creation and maintenance of a research database or repository.)
- Is there a signature and date line for the individual or their legally authorized representative to sign and date?

- Is there also a line to indicate a description of the representative’s authority to act for the individual?
- Required Statements:
- Is there a statement indicating the individual’s right to revoke the Authorization and how to do so?
- Is there a statement that indicates whether treatment, payment, enrollment, or eligibility can be conditioned upon signing the Authorization and consequences of refusing to sign the Authorization (i.e., may not participate in the research)?
- Is there a disclaimer statement of the potential risk that PHI may be re-disclosed by the recipient and thus may no longer be protected the Privacy Rule?
- Is there a statement indicating whether the individual’s access to his/her health record is suspended during participation in the clinical trial and, if so, that it will be restored upon conclusion of the clinical trial?
- An explanation about who to contact concerning the privacy of the subject’s information: MCG Privacy Officer, Christine Adams at (706) 721-5631, or the Toll Free Hotline, 1-800-576-6623.
- Does the advertisement state or imply a certainty of favorable outcome or other benefits beyond what was outlined in the consent document and the protocol?
- Does the advertisement include exculpatory language?
- Does the advertisement emphasize the payment or the amount to be paid, by such means as larger or bold type?
- Does the advertisement promise “free treatment” when the intent was only to say participants would not be charged for taking part in the investigation
 - Does the advertisement make claims, either explicitly or implicitly, about the drug, biologic or device under investigation that were inconsistent with FDA labeling?
 - Does the advertisement use terms, such as “new treatment,” “new medication” or “new drug” without explaining that the test article was investigational?
 - Does the advertisement allow compensation for participation in a trial offered by a sponsor to include a coupon good for a discount on the purchase price of the product once it had been approved for marketing?

How is it Determined how Often Review should be Obtained more than Annually and how Often for Expedited Protocols?

This decision is based on the degree of risk assigned to the protocol.

How is the Risk Determination made for Expedited Protocols?

The risk determination is made by the HAC Chairperson or designee as minimal risk or greater than minimal risk.

What about the Considerations for Continuing Review for Expedited Protocols?

The HAC Chairperson or designee must determine if:

- Verification is to be obtained from sources other than the investigator that no material changes have taken place since prior HAC review

- Has information arisen that might affect the willingness of participants to continue to take part in the research?
 - If yes, will the information be provided to those subjects?

What about the Considerations for Review of Amendments for Protocols that Undergo Expedited Review?

The HAC Chairperson or designee must determine if:

- Information has arisen that might affect the willingness of participants to continue to take part in the research?
- Is there indication that a change was made without prior HAC approval to eliminate apparent immediate hazards to participant?
 - If yes, is the change consistent with ensuring the subject's continued welfare?

Are There any Special Requirements for Expedited Reviews that may be Conducted at the Charlie Norwood Veterans Affairs Medical Center?

Yes. The HAC Chairperson or designee must review each protocol that will be conducted at the Charlie Norwood Veteran Affairs Medical Center to determine the following:

- Is tissue banking involved?
 - If tissue banking is involved, does the DRP indicate that tissue will be stored in a VA approved tissue bank?
- Are there data mining/warehousing issues?
- Is there assurance that non-veteran subjects will be enrolled in the research **only** when there are insufficient veterans to participate in the research?
- Payment of Research Subjects (The HAC may not approve paying subjects to participate in research when the research is integrated with a patient's medical care and when it made no special demands on the patient beyond those of usual medical care)
 - Payment of subjects is permissible according to one of the following criteria which apply to the research:
 - The research is not directly intended to enhance the diagnosis or treatment of the medical condition for which the participant was being treated, and when the standard of practice in affiliated non-VA organizations was to pay participants in this situation.
 - The research was a multi-institutional study and participants at collaborating non-VA organizations were paid for the same participation in the same study at the same rate proposed;
 - Payment of participants would be appropriate in other comparable situations;
 - The participant incurred transportation expenses that would not be incurred in the normal course of receiving treatment and were not reimbursed by another mechanism.
- Should the medical record for each subject be flagged to indicate participation in the study and the source of any more information for the study?
- Is there indication that a copy of the signed and dated consent document will be given to the person signing the consent document?

Are There any Special Requirements for Expedited Reviews Involving an Informed Consent Document that may be Conducted at the Charlie Norwood Veterans Affairs Medical Center?

Yes. The HAC Chairperson or designee must review each protocol that will be conducted at the Charlie Norwood Veteran Affairs Medical Center to determine the following:

- Will consent be obtained using the VA Form 10-86?
- Is there a signature and date line for the subject or the subject's legally authorized representative?
- For the witness signature: is there a note under the signature line explaining the role of the witness to the consenting process and subject's signature?
- Does the ICD include a statement that in the event of a research-related injury the VA will provide necessary medical treatment to a participant injured by participation?
- Does the ICD include a statement that a veteran-participant will not be required to pay for care received as a participant in a VA research project except in accordance with federal law and that certain veterans were required to pay co-payments for medical care and services provided by VA?

What do the HAC Members Review the Description of Research Proposal (DRP) to Determine if the Study is a Multi-Center Trial in which the Principal Investigator is the Lead Investigator?

The HAC reviews the DRP to determine if there is an assurance which adequately describes how the following information from sites will be managed.

Can the HAC Chairperson Disapprove a Protocol Regardless of Level of Review?

No. The HAC Chairperson may not disapprove a protocol. All disapprovals, regardless of level of review, must be determined by the full committee.

Full Review

Convened HAC Meetings

Who Determines that a Protocol Should Undergo Full Review?

The Chairperson or designee assigns each new protocol that does not meet the criterion for expedited or exempt review to the full review status.

Does the HAC Use a Primary Reviewer System?

Yes.

What is the Primary Reviewer System?

The Primary Reviewer System consists of a team of three HAC members selected by the HAC Chairperson or designee with appropriate scientific expertise who conduct an in-depth review of the protocol and all submitted documents.

Who Assigns the Reviewers to a Protocol?

Once a protocol is deemed to undergo full review, the Chairperson or designee assigns three reviewers to the protocol to serve as primary reviewers based on their appropriate scientific or scholarly expertise.

How are the Reviewers Assigned?

These reviewers are assigned based on their appropriate scientific or scholarly expertise as evidenced in their body of professional expertise, personal life experience and availability. Other factors may have an impact such as the number of protocols submitted for review that month, reviewer attendance, potential conflicts of interest, etc.

How are Members Assigned when Proposed Research Involves Vulnerable Subjects (Children, Pregnant Women, Cognitively Impaired, etc.)?

The HAC Chairperson is responsible for ensuring that the HAC membership includes at least one member who is an expert in the area of the proposed research.

Who is Responsible for Making Certain that at Least one Person who is Knowledgeable About or Experienced in Working with Vulnerable Subjects is Present at the Convened Meeting?

The HAC Chairperson or designee is responsible for making certain that at least one person who is knowledgeable about or experienced in working with vulnerable subjects in the protocol is present at the convened meeting.

What Does the HAC do When Special Expertise or Consultant is Needed that is External to the HAC Current Members?

At times, additional or special expertise (either scientific, legal or scholarly) or a consultant will be required for the HAC to adequately review a protocol. The use of special expertise or a consultant is at the discretion of the HAC Chairperson or designee. Additional expertise or a consultant is sought from leaders in the field. The decision of the expert or consultant is usually

presented in writing to the Committee members. The expert or consultant is not allowed to vote on the protocol.

Can a Protocol be Deferred to Another Meeting if the Appropriate Expertise is not in Attendance at the Scheduled Meeting?

The HAC Chairperson or designee may defer the protocol to another meeting if the appropriate expertise is not in attendance at the scheduled meeting. The HAC Chairperson or designee may also obtain consultation.

If Additional Special Expertise or Consultants have a Conflict of Interest, Can they Serve as the Special Expertise or Consultant?

They may only serve as the special expertise or consultant if the conflict of interest has been reported to the Conflict of Interest Panel and only if that Panel approves their service. The conflict of interest must be disclosed in writing to the convened HAC or the reviewer, as applicable.

If Additional Special Expertise or Consultants have a Conflict of Interest, Can they Participate in the Vote?

No. The individual with special expertise or the consultant may provide information at the request of the HAC but they may not participate in the vote and must recuse themselves prior to that action if in attendance at the meeting.

What if I, as an HAC Member or Staff, Feel that Undue Influence could have an Impact on my Decisions?

Officials of MCG, MCGHI and the Charlie Norwood VA Medical Center are prohibited from approving research that has not been approved by the HAC. Any undue influence must be reported to the OHRP Director. Upon notification, the OHRP Director will initiate an investigation within one week. The findings of the investigation will be reported to the institutional officials and recommendations for further actions will be made.

What are the Primary Reviewers Responsible for?

The primary reviewers are responsible for reviewing the submitted information in-depth while using the HAC Reviewers' Checklist and their own expertise. The primary reviewers are also responsible for providing a brief summary of the proposed research at the Committee meeting.

1. Evaluate risks to subjects and others.
2. Determine whether risks have been minimized.
3. Evaluate the anticipated benefits.
4. Determine whether risks to subjects or other are reasonable in relation to expected benefits.
5. Determine the level for continuing review based on the level of risk.
6. Evaluate the adequate management of information as relevant to the protection of subjects.
7. Evaluate whether the risk level assigned to the protocol would require observation of the informed consent process and if so, delegate this observation to OHRP staff.

What Tools Are Available to the Primary Reviewers?

The HAC Reviewers Checklist is the tool available to the primary reviewers. The primary reviewers must review the protocol to determine the following:

- Physical, psychological, social, legal, and economic risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk
- Physical, psychological, social, legal, and economic risks to participants are minimized whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes
- Physical, psychological, social, legal, and economic risks are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.
- Selection of subjects is equitable
- There are adequate provisions to protect the privacy of subjects
- There are adequate provisions to maintain the confidentiality of the data.
- Additional safeguards have been included in the study to protect the rights and welfare of participants likely to be vulnerable to coercion or undue influence

What Must the Primary Reviewers Review for the Informed Consent Process and the Documentation of Informed Consent?

The HAC Chairperson or designee must review the informed consent process and the documentation of the informed consent for expedited review using the Full Review Checklist to determine the following:

Will the informed consent process will be waived (*See Checklist of Criteria to Waive or Alter the Requirement to Obtain Informed Consent*)

OR

Will the requirement for written documentation will be waived (*See Checklist of Criteria to Waive the Requirement for Written Documentation of Informed Consent*)

OR

Informed consent will be sought from each prospective subject or the subject’s representative in accordance with the regulations as follows:

- The investigator will obtain the legally effective informed consent of the subject or the subject’s legally authorized representative
- The circumstances of consent provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate
- The circumstances of consent minimize the possibility of coercion or undue influence
- The information that will be given to the participant or representative will be in language understandable to the subject or the representative
- No information will be provided to the subject or the representative that waives or appears to waive any of the subject’s legal rights, or that releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence
- All required and appropriate additional disclosures will be provided to the subject or the subject’s representative. (*See Elements of Informed Consent Disclosure*)
- Informed consent will be documented in writing in accordance with the regulations
 - The consent document embodies the basic and appropriate additional elements of disclosure. (*See Elements of Informed Consent Disclosure*)

- The participant or the participant's legally authorized representative will sign the consent document.
- If the research is FDA-regulated, the participant or the participant's legally authorized representative will sign and date the consent document.
- A copy of the consent document will be given to the person signing the consent document.
- For VA research, a copy of the signed and dated consent document will be given to the person signing the consent document.
- The investigator will give either the participant or the representative adequate opportunity to read the consent document before it is signed.

What Are the Elements of Informed Consent Disclosure?

The elements of informed consent disclosure are:

- A statement that the study involves research.
- An explanation of the purposes of the research.
- An explanation of why the subject is invited to participate in the research.
- An explanation of the expected duration of the participant's participation.
- A description of the procedures to be followed.
- The approximate number of participants involved in the study.
- Identification of any experimental procedures. *(May be omitted if there are none.)*
- A description of any reasonably foreseeable risks or discomforts to the participant. *(May be omitted if there are none.)*
- A statement that the particular treatment or procedure may involve risks to the participant, which are currently unforeseeable.
- A statement that if the participant is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable. *(Look for when the research involves pregnant women or women of childbearing potential, and the effect of the procedures have not been evaluated in pregnancy or a goal of the research is to define safety in pregnancy.)*
- A description of any benefits to the participant or to others, which may reasonably be expected from the research.
- A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant. *(Look for this on long-term clinical trials.)*
- An explanation of whom to contact for answers to pertinent questions about the research.
- An explanation of whom to contact about concerns or complaints about the research study.
- An explanation of whom to contact for answers to pertinent questions about the research participants' rights (George S. Schuster, DDS, PhD at 706-721-2991).
- An explanation of whom to contact in the event of a research-related emergency.
- A statement that participation is voluntary.
- A statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled.
- A statement that the participant can discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.

- Any additional costs to the participant that may result from participation in the research. *(Look for when additional costs are expected.)*
- An explanation of whether the subject will be paid/reimbursed for their participation in the research.
- Inclusion of Statement of Privacy Notice
- An explanation as to whether compensation is available when injury occurs, an explanation as to what it consists of or where further information may be obtained. *(May be omitted if the research involves no more than minimal risk.)*
- An explanation as to whether any medical treatments are available if injury occurs and what it consists of or where further information may be obtained *(May be omitted if the research involves no more than minimal risk.)*
- A statement that notes the possibility that the Food and Drug Administration may inspect the records. *(May be omitted for research that is not subject to FDA regulations.)*
- A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained. *(May be omitted if confidentiality will not be maintained.)*
- Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent. *(Look for when the protocol mentions this as a possibility.)*
- The consequences of a participant's decision to withdraw from the research. *(Look for when withdrawal from the research will have adverse consequence.)*
- Procedures for orderly termination of participation by the participant. *(Look for when such procedures are part of the protocol.)*
- Is there a description of the protected health information (PHI) to be used or disclosed, identifying the information in a specific and meaningful manner?
- Are the names or other specific identification of the person or persons (or class of persons) authorized to make the requested use or disclosure clearly designated?
- Are the names or other specific identification of the person or persons (or class of persons) clearly designated, indicating to whom MCG Health Systems may make the requested use or disclosure?
- Is there a description of each purpose of the requested use or disclosure?
- Is there an Authorization expiration date or expiration event for the duration that relates to the individual or to the purpose of the use or disclosure? (Note: "end of the research study" or "none" are permissible for research, including for the creation and maintenance of a research database or repository.)
- Is there a signature and date line for the individual or their legally authorized representative to sign and date?

- Is there also a line to indicate a description of the representative’s authority to act for the individual?
- Required Statements:
- Is there a statement indicating the individual’s right to revoke the Authorization and how to do so?
- Is there a statement that indicates whether treatment, payment, enrollment, or eligibility can be conditioned upon signing the Authorization and consequences of refusing to sign the Authorization (i.e., may not participate in the research)?
- Is there a disclaimer statement of the potential risk that PHI may be re-disclosed by the recipient and thus may no longer be protected the Privacy Rule?
- Is there a statement indicating whether the individual’s access to his/her health record is suspended during participation in the clinical trial and, if so, that it will be restored upon conclusion of the clinical trial?
- An explanation about who to contact concerning the privacy of the subject’s information: MCG Privacy Officer, Christine Adams at (706) 721-5631, or the Toll Free Hotline, 1-800-576-6623.
- Does the advertisement state or imply a certainty of favorable outcome or other benefits beyond what was outlined in the consent document and the protocol?
- Does the advertisement include exculpatory language?
- Does the advertisement emphasize the payment or the amount to be paid, by such means as larger or bold type?
- Does the advertisement promise “free treatment” when the intent was only to say participants would not be charged for taking part in the investigation
 - Does the advertisement make claims, either explicitly or implicitly, about the drug, biologic or device under investigation that were inconsistent with FDA labeling?
 - Does the advertisement use terms, such as “new treatment,” “new medication” or “new drug” without explaining that the test article was investigational?
 - Does the advertisement allow compensation for participation in a trial offered by a sponsor to include a coupon good for a discount on the purchase price of the product once it had been approved for marketing?

How is it Determined how Often Review Should be Obtained More than Annually and How Often for Full Review Protocols?

This decision is based on the degree of risk assigned to the protocol.

How is the Risk Determination Made for Expedited Protocols?

The risk determination is made by the convened HAC as minimal risk or greater than minimal risk.

What about the Considerations for Continuing Review?

The HAC must determine if:

- Verification is to be obtained from sources other than the investigator that no material changes have taken place since prior HAC review

- Has information arisen that might affect the willingness of participants to continue to take part in the research?
 - If yes, will the information be provided to those subjects?

What about the Considerations for Review of Amendments for Protocols?

The HAC must determine if:

- Information has arisen that might affect the willingness of participants to continue to take part in the research?
- Is there indication that a change was made without prior HAC approval to eliminate apparent immediate hazards to participant?
 - If yes, is the change consistent with ensuring the subject's continued welfare?

Are There any Special Requirements for Research that may be Conducted at the Charlie Norwood Veterans Affairs Medical Center?

Yes. The HAC Chairperson or designee must review each protocol that will be conducted at the Charlie Norwood Veteran Affairs Medical Center to determine the following:

- Is tissue banking involved?
 - If tissue banking is involved, does the DRP indicate that tissue will be stored in a VA approved tissue bank?
- Are there data mining/warehousing issues?
- Is there assurance that non-veteran subjects will be enrolled in the research **only** when there are insufficient veterans to participate in the research?
- Payment of Research Subjects (The HAC may not approve paying subjects to participate in research when the research is integrated with a patient's medical care and when it made no special demands on the patient beyond those of usual medical care)
 - Payment of subjects is permissible according to one of the following criteria which apply to the research:
 - The research is not directly intended to enhance the diagnosis or treatment of the medical condition for which the participant was being treated, and when the standard of practice in affiliated non-VA organizations was to pay participants in this situation.
 - The research was a multi-institutional study and participants at collaborating non-VA organizations were paid for the same participation in the same study at the same rate proposed;
 - Payment of participants would be appropriate in other comparable situations;
 - The participant incurred transportation expenses that would not be incurred in the normal course of receiving treatment and were not reimbursed by another mechanism.
- Should the medical record for each subject be flagged to indicate participation in the study and the source of any more information for the study?
- Is there indication that a copy of the signed and dated consent document will be given to the person signing the consent document?

Are There any Special Requirements for Research Involving an Informed Consent Document that may be Conducted at the Charlie Norwood Veterans Affairs Medical Center?

Yes. The HAC Chairperson or designee must review each protocol that will be conducted at the Charlie Norwood Veteran Affairs Medical Center to determine the following:

- Will consent be obtained using the VA Form 10-86?
- Is there a signature and date line for the subject or the subject's legally authorized representative?
- For the witness signature: is there a note under the signature line explaining the role of the witness to the consenting process and subject's signature?
- Does the ICD include a statement that in the event of a research-related injury the VA will provide necessary medical treatment to a participant injured by participation?
- Does the ICD include a statement that a veteran-participant will not be required to pay for care received as a participant in a VA research project except in accordance with federal law and that certain veterans were required to pay co-payments for medical care and services provided by VA?

What Should the HAC Members Look for when Reviewing a Protocol?

The members should review each protocol for the following requirements at the time of initial submission and at continuing review:

1. Evaluate risks to subjects and others.
2. Determine whether risks have been minimized.
3. Evaluate the anticipated benefits.
4. Determine whether risks to subjects or other are reasonable in relation to expected benefits.
5. Determine the level for continuing review based on the level of risk.
6. Evaluate the adequate management of information as relevant to the protection of subjects.
7. Evaluate whether the risk level assigned to the protocol would require observation of the informed consent process and if so, delegate this observation to OHRP staff.

When Would the Informed Consent Process Potentially Require Observation?

The informed consent process may require observation to protect subjects if:

- High risk trial
- Cognitive impairment of the subject
- Potential for coercion based on the type of study
- Training and education
- Other concerns that present during the conduct of the trial such as non-compliance.

What Documents do the Primary Reviewers Receive for Initial Full Review?

Primary reviewers receive the following information in their submission packets:

- HAC Reviewers' Checklist
- HAC Form 100, Clinical Study Document Cover Sheet
- HAC Form 101, Protocol Information
- Description of Research Proposal (see Section 8)
- Complete sponsor provided protocol, if applicable
- Complete DHHS-Approved Protocol, if applicable
- Informed Consent Document and/or Children's Assent Document

- DHHS-Approved Informed Consent Document, if applicable
- HAC Form 104, Research Medication Data Sheet, if applicable
- Investigator's Brochure or package insert, if applicable
- Completed and signed Form FDA 1572, if applicable
- HAC Form 105, Investigational Device Information Sheet, if applicable
- Copy of the signed investigator's agreement for device studies, if applicable
- Copy of the Manufacturer's information for device studies, if applicable
- Certificate of Confidentiality, if applicable
- Any questionnaires that may be used, if applicable
- Recruitment Plan Materials to include any advertisements or announcements that may be used, if applicable
- The entire grant application, if applicable regardless of funding source
- HAC Form 103, Human Biological Specimens for Genetic Research, if applicable
- Any letters or memoranda for all Committee members to review
- If investigator-initiated, a copy of the data capture forms

What Documentation do the Other Members Receive for Initial Full Review?

The remaining HAC members who are not assigned as one of the three primary reviewers receive the following:

- HAC Form 100, Clinical Study Document Cover Sheet
- Description of Research Proposal
- Informed Consent Documents and/or Assent Documents
- Any letters or memoranda for all Committee members to review
- Recruitment Plan Materials to include any advertisements or announcements that may be used, if applicable

Can the Other Reviewers Have Access to the Same Documentation as the Primary Reviewers?

Yes. The documents and supporting information listed above for the primary reviewers are available at any time to all committee members should they request the documents.

What Provides Documentation of the HAC Members Review?

The HAC Reviewers Checklist is a required document and is available on the HAC web site under Forms. It is provided in the HAC members packets. This signed form should be submitted with the member's notes and/or typed summaries. These are forwarded to the HAC Administrative Office during the convened meeting.

Can the Primary Reviewers Contact the Research Team Prior to the Meeting to Determine if any Issues can be Resolved Prior to the Meeting?

Yes. Another duty for primary reviewers is to contact the research team in advance to determine if any issues may be resolved prior to the meeting.

What do the HAC Members Review the Description of Research Proposal (DRP) to Determine if the Study is a Multi-Center Trial in which the Principal Investigator is the Lead Investigator?

The HAC reviews the DRP to determine if there is an assurance which adequately describes how the following information from sites will be managed.

Who Reviews the Final Copy of Printed Advertisements or the Final Audio/Video Taped Advertisements?

The HAC Chairperson or designee reviews the final copy of printed advertisements or the final audio/video taped advertisements.

What is the Process to Confirm that a Drug has a Valid IND Issued by the FDA or that the Drug Fell into One of the Exemptions from the Requirement for an IND?

The OHRP Business Manager confirms that each drug has an IND issued by the FDA and that the IND number is valid or that the drug falls into one of the exemptions from the requirement for an IND. This process is documented by attaching a copy from the FDA web site.

What is the Process to Confirm that a Device has a Valid IDE Issued by the FDA, that the Device Fulfills the Requirement for an Abbreviated IDE or the Device Falls into One of the Exemptions from the Requirement for an IDE?

The OHRP Business Manager confirms that when research was conducted to determine the safety or effectiveness of a device, to confirm that the device had a valid IDE issued by the FDA, the device fulfilled the requirements for an abbreviated IDE or the device falls into one of the exemptions from the requirement for an IDE. This process is documented by attaching a copy from the FDA web site.

When are the Meetings?

The full Committee meets on the fourth Monday of each month, unless otherwise changed by the HAC Chairperson. The HAC web site provides describes current submission deadline and meeting date information.

If a change in the meeting or application submission date is required, a message will be sent to research team members via the MCG Portal “Need to Know” and as a direct email from the HAC database as well as posted in the HAC Administrative Office (CJ- 2103). The web page will be updated with this information, also.

Where are the Meetings Held?

The HAC meetings are held in room CA-2105 of the Interdisciplinary Research Building Phase II (IRB II).

What Time Do the Meetings Start?

The HAC meetings begin promptly at 12:00 p.m. However, no votes are taken until a quorum (as defined later in the document) is present.

Is Lunch Served?

Lunch is provided for the HAC members, Administrative Office staff and guests. A snack is also provided later in the afternoon. A break is usually provided approximately every two hours.

Can an Investigator or Research Team Member Attend an HAC Meeting?

Yes. Attendance at a meeting is acceptable as a training and education opportunity. Guests such as students, new faculty members, staff or community members who wish to observe the HAC meeting in order to learn about research and who are not affiliated with a particular research protocol, or visitors from other Institutional Review Boards (IRB) may attend the HAC meeting if the following criteria are met:

- If the guests are required to attend by a faculty member as part of their curriculum, then the individual must contact the HAC Administrative Office staff by the Wednesday prior to the Monday meeting to confirm their attendance.
- The Chairperson or designee, prior to the meeting, must approve each visitor's request to attend.

Once the above criteria are met, and the Chairperson or designee approves the attendance of the individual, then the individual is responsible for approaching the OHRP staff when they enter the meeting. Also, any individual may be asked to leave the meeting if the Chairperson or designee determines a sufficient need.

Is There a Deadline for Contacting the HAC Administrative Office to Request to Attend the Meeting?

If requesting to attend a meeting, the visitor must contact the HAC Administrative Office as listed below by the Wednesday prior to the meeting in order to ensure that:

- A confidentiality agreement is available
- Lunch is available
- Appropriate number of copies of required materials is available
- The potential for any conflicts of interest is determined

Are Principal Investigators Required to Attend?

Investigator attendance at the HAC meeting is not required unless specifically requested. Sometimes, meeting attendance by the Principal Investigator (PI) alleviates questions regarding the protocol, informed consent and/or assent document(s). However, we strongly encourage the PI to contact the reviewers prior to the meeting or the members may contact the PI as needed.

Is There a Specified Appointment Time for Investigators to Attend to Present Their Study or Information to the Committee Upon the Request of the Committee?

If requested to attend to present a specific protocol, a window of time will be determined prior to the meeting to avoid an investigator having to miss clinical, teaching or research time. Please note that scheduled times are not exact as some protocols may require more or less discussion than others.

Who Must Complete a Non-Disclosure Statement to Attend the Meeting?

The non-disclosure statement is required of all visitors, guests, consultants and anyone asked to attend to provide additional expertise.

Who is Allowed to Stay in the Room During the Discussion and Vote?

In compliance with federal regulations, no member of the research team may be present in the room for the discussion that follows the informational portion of the HAC review. The research team member may be asked a question to clarify an earlier response but cannot be in the room during the discussion and vote.

What About the Confidentiality of Discussions and Information Presented at the HAC Meeting?

All information discussed in the HAC meetings is confidential. Official reports or letters to investigators regarding the status of the study must come through, or be approved by, the HAC Administrative Office and the HAC Chairperson or designee.

What Documents are Distributed at the Meeting?

The following documents are distributed at the meeting:

- Agenda
- Confidentiality Statements, as needed
- Educational Materials
- Ballots for Amendments and Continuing Review
- New Policies and Procedures
- New Forms
- Unanticipated problem reports such as adverse events, serious adverse events, or any other event that may result in increased risk to the research subject or others
- Reports of serious or continuing non-compliance
- Audit reports

The following documents are available for review at the meeting if needed:

- Full sponsor's protocol
- Amendments and support documentation
- Continuing Review and support documentation
- Reports of serious or continuing non-compliance
- Audit reports
- Protocol files

What's the Usual Business Process When Attending a Meeting?

The primary reviewers assigned to review a specific protocol will present the study to the convened HAC. If the investigator or research team member has been asked to (or requests to) attend the meeting they will be given approximately five minutes to answer questions related to the study. HAC members are not limited in their presentation, discussion or deliberation time. After the question and answer period, the investigator and/or research team will be asked to leave the room and wait in the reception area outside of the meeting room. The investigator and/or research team should not leave the area until the discussion and vote are concluded as the Committee may have additional questions for them. Anyone in attendance with a conflict of interest must leave the room during the discussion and vote. This includes HAC members, alternates, OHRP staff, special expertise or consultants.

How are Members and the Community Notified if a Meeting is Canceled?

Cancellation will be communicated via email, phone calls, signs and personal messages. A direct email from the HAC database will be sent and it will be posted in the MCG Portal under “Need to Know.”

What’s a Quorum?

Meetings begin when a quorum arrives and each required element is represented. A quorum is defined as 50% of the committee members plus one and must include at least one non-scientific member and at least one member present must not be affiliated with the institution. For VA related protocols, at least two of their appointees must be present and one of those two must be a physician for FDA regulated research.

Can Items be Discussed Before a Quorum?

Yes but no votes may be taken.

If a Quorum is Lost During the Meeting, can Items be Discussed?

Yes but no votes may be taken.

How Often has the HAC Lost a Quorum?

In the past ten years, the HAC has lost a quorum twice.

Who Attends the HAC Meeting from the OHRP?

The OHRP Director and Assistant Director attend the HAC meeting as their schedules permit. At least one of them will attend the meeting.

The OHRP Clinical Trials Training Coordinator will attend to present the Education and Training topic. The Clinical Trials Training Coordinator may also attend at least part of the meeting to determine any new or ongoing education and training needs that may be needed. If topics are introduced that require new or ongoing education and training needs then the OHRP Director or Assistant Director is responsible for providing this information to the Clinical Trials Training Coordinator. HAC members or OHRP staff may also request or recommend additional topics.

The OHRP Clinical Trials Auditor will attend to present information regarding the audits conducted during the time period from the previous meeting to the current meeting. The Clinical Trials Auditor may also provide information from observing the informed consent process, when specifically authorized to do so by the HAC.

The OHRP Office Specialists are assigned on a scheduled rotation calendar to attend the meetings. Their primary roles are to provide service to the HAC such as documentation of attendance and absences, conflicts of interests, votes (for, against and abstentions), guests, and regulatory compliance. They are also available to provide feedback on items that were noted during the administrative review.

Amendments and Modifications

What about the Considerations for Review of Amendments for Protocols?

The HAC must determine if:

- Information has arisen that might affect the willingness of participants to continue to take part in the research?
- Is there indication that a change was made without prior HAC approval to eliminate apparent immediate hazards to participant?
 - If yes, is the change consistent with ensuring the subject's continued welfare?

What Documents do the Primary Reviewers Receive for Expedited Review of Amendments?

The HAC Chairperson or designee serves as the primary reviewer and receives the following information for review:

- HAC Reviewers' Checklist
- HAC Form 113 with support documentation such as:
 - Revised informed consent documents/childrens assent documents
 - Summary of Changes
 - Clean version for stamping
 - Changes noted copy
 - Revised protocol
 - Summary of Changes
 - Site added or removed information
 - Copies of reports:
 - Unanticipated problem
 - Data safety and monitoring board report
 - Audit report
 - Other
 - Summary of Changes
 - HAC requested information with copy of email/letter/report from the HAC
 - Revised FDA Form 1572
 - Summary of Changes
 - Changes noted copy
 - Revised Investigational Drug Brochure/Revised Package Insert
 - Summary of Changes
 - Research Team Personnel Changes

What Documents do the HAC Members Receive for Full Review of Amendments?

The following documents are scanned and placed on a common computer drive for review. HAC members that do not have access to the common computer drive receive the following information in their submission packets:

- HAC Reviewers' Checklist
- HAC Form 113 with support documentation such as:
 - Revised informed consent documents/childrens assent documents
 - Summary of Changes
 - Clean version for stamping

- Changes noted copy
- Revised protocol
 - Summary of Changes
- Site added or removed information
- Copies of reports:
 - Unanticipated problem
 - Data safety and monitoring board report
 - Audit report
 - Other
 - Summary of Changes
- HAC requested information with copy of email/letter/report from the HAC
- Revised FDA Form 1572
 - Summary of Changes
 - Changes noted copy
- Revised Investigational Drug Brochure/Revised Package Insert
 - Summary of Changes
- Research Team Personnel Changes

Continuing Review

What about the Considerations for Continuing Review?

The HAC must determine if:

- Verification is to be obtained from sources other than the investigator that no material changes have taken place since prior HAC review
- Has information arisen that might affect the willingness of participants to continue to take part in the research?
 - If yes, will the information be provided to those subjects?

What Documents do the Primary Reviewers Receive for Continuing Expedited Review?

The HAC Chairperson or designee serves as the primary reviewer and receives the following information for review:

- HAC Reviewers' Checklist
- HAC Form 107, Clinical Study Status Report:
 - Research team personnel to include their demographic and education information
 - Amendment description and approval dates
 - Continuation history (if applicable)
 - Protocol deviation/violation history
 - Adverse event/serious adverse event listing
 - IND safety report summary, if applicable
 - Unanticipated problems, if applicable
 - Relevant recent literature
 - Interim findings
 - Relevant multi-center trial reports
 - Summary of any subject withdrawals and the reasons for those withdrawals
 - Summary of any complaints about the research
 - Number of subjects to include the minority status
 - Number of subjects to include the members of the vulnerable populations
 - A current version of the Description of Research Proposal that has been reviewed by the PI to ensure it is an up-to-date description of the conduct of the protocol from a human subjects protection perspective.
 - Informed Consent Document and/or Children's Assent Document currently in use by the Principal Investigator
 - Informed Consent Document and/or Children's Assent Documents that are newly proposed, if applicable
 - Recruitment Plan Materials to include any advertisements or announcements that may be used, if applicable
 - The grant annual status report, if applicable, regardless of funding source
 - Any letters or memoranda for all Committee members to review
 - If investigator-initiated, a copy of the data capture forms if not submitted at the time of initial review or if the forms were changed

What Documents do the HAC Members Receive for Continuing Full Review?

The following documents are scanned and placed on a common computer drive for review. HAC members that do not have access to the common computer drive receive the following information in their submission packets:

- HAC Reviewers' Checklist
- HAC Form 107, Clinical Study Status Report:
 - Research team personnel to include their demographic and education information
 - Amendment description and approval dates
 - Continuation history (if applicable)
 - Protocol deviation/violation history
 - Adverse event/serious adverse event listing
 - IND safety report summary, if applicable
 - Unanticipated problems, if applicable
 - Relevant recent literature
 - Interim findings
 - Relevant multi-center trial reports
 - Summary of any subject withdrawals and the reasons for those withdrawals
 - Summary of any complaints about the research
 - Number of subjects to include the minority status
 - Number of subjects to include the members of the vulnerable populations
 - A current version of the Description of Research Proposal that has been reviewed by the PI to ensure it is an up-to-date description of the conduct of the protocol from a human subjects protection perspective.
 - Informed Consent Document and/or Children's Assent Document currently in use by the Principal Investigator
 - Informed Consent Document and/or Children's Assent Documents that are newly proposed, if applicable
 - Recruitment Plan Materials to include any advertisements or announcements that may be used, if applicable
 - The grant annual status report, if applicable, regardless of funding source
 - Any letters or memoranda for all Committee members to review
 - If investigator-initiated, a copy of the data capture forms if not submitted at the time of initial review or if the forms were changed

What Documents are Available if Needed?

The following documents are available for review at the meeting if needed:

- Full sponsor's protocol
- Amendments and support documentation
- Continuing review and support documentation
- Reports of serious or continuing non-compliance
- Audit reports
- Protocol files

What Tool Does the HAC use when HAC Approval Expires without Request for Continuing Review?

The HAC uses the “HAC Approval Expiration, Suspension or Termination Internal Routing Form” to document that necessary steps are taken when a principal investigator has not submitted a request for continuing review.

What Actions Are Taken if an Investigator did not Provide Continuing Review Information to the HAC or the HAC has not Approved a Protocol by the Expiration Date?

If the HAC does not receive the completed HAC Form 107, Clinical Study Status Report, by the due date noted on the form, then the protocol approval is allowed to expire. The Principal Investigator is notified by the HAC Administrative Office staff that:

- All activities must stop, including recruitment, advertisement, screening, enrollment, consent, interventions, interactions, and collection of private identifiable information.
- A list of subjects for whom stopping research activities would cause harm must be submitted immediately to the HAC Chairperson or designee via the HAC@mcg.edu email address for all researchers including those who conduct research at the Charlie Norwood VA Medical Center.

The HAC Chairperson or designee review the protocol and the list of subjects to determine if the interventions and interactions on current subjects continue only when the HAC finds and determines an over-riding safety concern or ethical issue involved such that it was in the best interests of individual subjects. If the protocol is allowed to continue, then the PI must submit a protocol submission packet in compliance with the submission processes.

If there are issues related to continuing review and the HAC has not approved a protocol by the expiration date, then the protocol approval expires and the protocol approval is allowed to expire. The Principal Investigator is notified by the HAC Administrative Office staff that:

- All activities must stop, including recruitment, advertisement, screening, enrollment, consent, interventions, interactions, and collection of private identifiable information.
- A list of subjects for whom stopping research activities would cause harm must be submitted immediately to the HAC Chairperson or designee via the HAC@mcg.edu email address for all researchers including those who conduct research at the Charlie Norwood VA Medical Center.

The HAC Chairperson or designee review the protocol and the list of subjects to determine if the interventions and interactions on current subjects continue only when the HAC finds and determines an over-riding safety concern or ethical issue involved such that it was in the best interests of individual subjects. If the protocol is allowed to continue, then the PI must submit a protocol submission packet in compliance with the submission processes.

Unanticipated Problems, Adverse Events and Serious Adverse Events

What is the Process for Reviewing Unanticipated Problems that Involve No More Than Minimal Risk to Self or Others?

The following documents are reviewed by the OHRP Director and the HAC Chairperson or designee reviews the following information:

- HAC Reviewers' Checklist
- OHRP Evaluation of Unanticipated Problems Form
- HAC Form 113 with support documentation such as:
 - Revised informed consent documents/childrens assent documents
 - Summary of Changes
 - Clean version for stamping
 - Changes noted copy
 - Revised protocol
 - Summary of Changes
 - Site added or removed information
 - Copies of reports:
 - Unanticipated problem
 - Data safety and monitoring board report
 - Audit report
 - Other
 - Summary of Changes
 - HAC requested information with copy of email/letter/report from the HAC
 - Revised FDA Form 1572
 - Summary of Changes
 - Changes noted copy
 - Revised Investigational Drug Brochure/Revised Package Insert
 - Summary of Changes
 - Research Team Personnel Changes

What Documents do the HAC Members Receive for Unanticipated Problems that Involve More Than Minimal Risk to Self or Others?

The following documents are scanned and placed on a common computer drive for review. HAC members that do not have access to the common computer drive receive the following information in their submission packets:

- HAC Reviewers' Checklist
- OHRP Evaluation of Unanticipated Problems Form
- HAC Form 113 with support documentation such as:
 - Revised informed consent documents/childrens assent documents
 - Summary of Changes
 - Clean version for stamping
 - Changes noted copy
 - Revised protocol
 - Summary of Changes
 - Site added or removed information
 - Copies of reports:

- Unanticipated problem
 - Data safety and monitoring board report
 - Audit report
 - Other
 - Summary of Changes
- HAC requested information with copy of email/letter/report from the HAC
- Revised FDA Form 1572
 - Summary of Changes
 - Changes noted copy
- Revised Investigational Drug Brochure/Revised Package Insert
 - Summary of Changes
- Research Team Personnel Changes

What Documents do the HAC Members Receive for Adverse Events?

The following documents are reviewed by the HAC Vice-Chairperson via the expedited procedure and are reported to the HAC Members, Alternates, Advisors and Institutional Officials via the HAC Meeting Agenda and HAC Meeting Minutes:

- HAC Form 110 with support documentation such as:
 - Revised informed consent documents/childrens assent documents
 - Summary of Changes
 - Clean version for stamping
 - Changes noted copy
 - Copies of reports:
 - Other
 - HAC requested information with copy of email/letter/report from the HAC

What Documents do the HAC Members Receive for Serious Adverse Events?

The following documents are reviewed by the HAC Vice-Chairperson. They are scanned and placed on a common computer drive for review. HAC members that do not have access to the common computer drive receive the following information in their submission packets:

- HAC Form 110 with support documentation such as:
 - Revised informed consent documents/childrens assent documents
 - Summary of Changes
 - Clean version for stamping
 - Changes noted copy
 - Copies of reports:
 - Other
 - HAC requested information with copy of email/letter/report from the HAC

Serious or Continuing Non-Compliance

Who is Responsible for the Initial Review of Reports of Non-Compliance?

The HPA serves as the primary individual for screening each incident of non-compliance. Upon consultation with the HAC Chairperson or CRRRI representative, the HPA will initiate an investigation to determine if the incident of non-compliance is serious or continuing non-compliance. The HPA, in consultation with the HAC Chairperson, Vice President for Research, representative from the Office of Legal Affairs, Provost and President determines if each allegation of non-compliance has a basis in fact.

How do I, as an HAC Member, Receive Reports of Serious or Continuing Non-Compliance?

HAC members are notified via the meeting agenda of any reports of serious or continuing non-compliance. These reports are made available to the members via the common computer drive or submitted in their packets for those who do not have access to the common computer drive. These are discussed at the HAC meetings by the full convened HAC.

What is Included in the Reports of Serious or Continuing Non-Compliance?

The following documents will be included:

- OHRP Audit Report and other support documentation
- HAC Form 113
- Support documentation from the research team site
- Corrective action plans, if applicable
- Notification to any external sponsors or regulatory authorities

Who Serves as the Primary Reviewer to Receive Reports of Serious or Continuing Non-Compliance?

The HAC Chairperson or designee serves as the primary reviewer.

What Range of Actions can be Considered by the HAC?

The HAC has several options that can be considered as a response to the report of serious or continuing non-compliance such as:

- Suspension of the study or degrees of suspension such as:
 - Suspension of study enrollment
 - Suspending any activity on the study as long as subject on active treatment are adequately cared for
- Asking the OHRP to audit the study or all of the studies under this investigator
- Requiring continuing review more often than annually
- Requiring a change in principal investigator (PI)
- Requiring the addition of a mentor for the PI
- Requiring additional education and training for the PI and research team
- Requiring monthly or quarterly reports on the activity of the study
- Terminating the HAC approval for the study thereby requiring all study related activity to cease immediately

- Requesting confirmation from outside experts or consultants related to the activity of the study
- Requiring additional information from the PI
- Revise the informed consent document
- Inform enrolled subjects
- Increase monitoring of subjects to include observation of the informed consent process

Are There other Instances when the HAC can Suspend or Terminate Research?

The HAC can suspend or terminate research that:

- Was not being conducted in accordance with the IRB’s requirements.
- Had been associated with unexpected serious harm to participants.

What does the HAC have to Consider When Approval is Suspended or Terminated?

The HAC has to consider the following when approval is suspended or terminated:

- Consider actions to protect the rights and welfare of currently enrolled participants.
- Consider whether procedures for withdrawal of enrolled participants took into account their rights and welfare.
- Consider informing current participants of the termination or suspension.
- Have any adverse events or outcomes reported to the IRB.

What Tool Does the HAC use when HAC Approval is Suspended or Terminated?

The HAC uses the “HAC Approval Expiration, Suspension or Termination Internal Routing Form” to determine that human subjects are protected.

What is the Process for the HAC to Notify the Regulatory Agencies, and Appropriate Organizational Officials?

The process for this notification is the same as notification of research non-compliance as outlined in the MCG Human Research Protection Program Policies and Procedures.

Communication

How Does the HAC Administrative Office and OHRP Communicate to the HAC Members About Protocols, Amendments or Continuing Reviews that Were Approved Via the Expedited or Exempt Criteria?

Members are notified of protocols, amendments and continuations that were approved via the expedited or exempt criteria by the agenda and the minutes of the full committee meeting. The meeting agenda is sent to the members, advisors and OHRP staff via email prior to the meeting. For those members who do not have an email address or may experience outages, the agenda may be sent via Federal Express or hand-delivered as necessary. Hard copies of the agenda are distributed at each meeting.

After the meeting, the minutes are distributed via email. For those members who do not have an email address or may experience outages, the minutes may be sent via Federal Express or hand-delivered as necessary. Hard copies of the minutes are available if needed.

For additional information or guidance, please refer to the HAC Policies and Procedures for Investigators.

Minutes Documentation

Who Prepares the HAC Meeting Minutes Documentation?

The HAC Chairperson, Vice-Chairperson, OHRP Assistant Director and the HAC Administrative Office staff compile information during the meeting for inclusion in the minutes.

How is the Attendance of Members Documented?

The HAC Administrative Office prepares a spreadsheet based on the current HAC roster for each meeting. If members will be absent and an alternate will attend in their stead, this is noted in the discussion portion of the agenda and on the spreadsheet. If the member and the alternate are absent, this is noted in the discussion portion of the agenda and on the spreadsheet. The spreadsheet is also used to track members, alternates and staff as they enter and exit the room as well as any guests who may attend. This spreadsheet is attached to the minutes of the meeting and filed in the HAC Administrative Office. The current roster is also attached to the minutes of the meeting.

How are Late Arrivals or Early Departures of HAC Members Managed?

Late arrivals or early departures of HAC members are managed by the HAC Chairperson or Vice-Chairperson. The agenda lists all protocols to be reviewed as well as any absences or attendance needs of the committee members. The order of the agenda items may be shifted as needed to ensure that the primary reviewers are present. The minutes and the attendance sheet document the management of this issue.

What are the Levels of Approval for the Meeting?

Protocols may be approved, have deferred approval, tabled or disapproved. It is important that the various factors be balanced with regard to providing appropriate subject protections without unnecessarily delaying the project. The pathway followed is a judgment call by the primary reviewers and the full committee. It is based upon whether adequate information was provided by the principal investigator to the Committee to permit full evaluation of the protocol with regard to human subjects' protection issues. There may be issues that will improve the overall submission but do not directly impact on the ability of the Committee to evaluate the study. Therefore, the following guidance is provided, recognizing that these decisions are based upon the judgment of the committee and cover a wide spectrum.

What is Approved?

Protocols that receive full approval do not require any additional changes.

What is Deferred Approval?

Most protocols fall into this category. The approval is deferred pending a satisfactory response from the PI to the HAC's requests for changes or clarifications (i.e., stipulations) to address deficiencies found in the protocol submission packet. The changes or clarifications requests most frequently pertain to components of the Description of Research Proposal (DRP), Informed Consent Document (ICD), Children's Assent Document (CAD), HAC forms, and Regulatory Issues.

What are Minor Revisions?

These involve clarifications of procedures or situations that do not involve subject safety. These revisions can permit approval following review of the responses by the Chairperson or designee.

What are Major Revisions I?

These involve significant issues relating to subject safety or study design. The responses from the Principal Investigator (PI) are sent to primary reviewers who bring the responses to the next Committee meeting for discussion. Risk-benefit determination cannot be made as these become major revisions that require committee re-review at the next convened meeting.

What are Major Revisions II?

These involve clarification of specific major issues in the protocol that involve study design or procedures. The responses from the PI will be circulated to the primary reviewers and the entire Committee. If the responses are satisfactory to the majority of the Committee, then HAC approval is granted by the Chairperson or designee and these responses are not returned to the convened meeting. The Committee is notified of the final decision by the agenda.

When are these Decisions Made?

The decision for the appropriate pathway is made by the Committee at the time of initial review.

Are There Examples of Items that May fit into the Above Categories?

Description of Research Proposal (DRP): There must be adequate information provided to permit the reviewers/Committee to understand the background/rationale for the study, the selection of the subject population and the risks and benefits. Questions as to the adequacy in these categories will be determined by the Committee and a decision rendered. The follow-up procedures may fit in any of the above categories and may, at the discretion of the Chairperson or designee, be moved to a more stringent category, depending upon the response. They will not be moved to a less stringent category.

Informed Consent (IC)/Children's Assent (CA) Document (D): The degree of deficiency will vary considerably determining the level of re-review as follows:

- The Chairperson or designee may review the revised Informed Consent (IC)/Children's Assent (CA) Document (D) or
- The primary reviewers [and IT and Privacy Officer(s) if necessary] followed by that of the Chairperson or designee with subsequent approval by that individual on behalf of the full Committee may also require review

At the discretion of the Chair/person or designee, they may be moved to a more stringent category, depending upon the response. They will not be moved to a less stringent category.

HAC Forms: Due to a lack of understanding by the research team member, these problems generally result in incorrect or incomplete information. These responses will be reviewed by the Chairperson or designee and the Privacy Officer and/or IT reviewer if appropriate and approved by the Chairperson or designee on behalf of the convened Committee.

Regulatory Issues: These problems usually relate to missing or inadequate information regarding FDA information, Conflict of Interest, and Institutional Policies and Procedures. These will usually be resolved by the Chairperson or designee, in consultation with institutional and/or Federal Officials as necessary. They may be brought to the convened Committee if necessary.

What is a Tabled Protocol?

The protocol must essentially be rewritten and totally re-reviewed at a subsequent meeting.

What Does the HAC Document in the Meeting Minutes?

HAC meeting minutes document the following:

- Education and training topic for the meeting
 - Guests who attended the meeting
 - Reminders about confidentiality of the HAC meetings
 - Information only items
 - Absence of an HAC member
 - An alternate member serving instead of the regular member
 - Any suspension and terminations by the HAC Chairperson
 - Serious and continuing non-compliance and the management plan of those incidents, as appropriate
 - Votes for each protocol as numbers for, against, or abstaining.
 - Actions taken by the HAC
 - Separate deliberations for each action
 - The basis for requiring changes in research if applicable
 - The basis for disapproving research if applicable
 - A written summary of the discussion of controverted issues and their resolution
 - Justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document
 - The names of HAC members, consultants or special expertise that left the meeting because of a conflicting interest, along with the fact that a conflicting interest was the reason for the absence.
 - For initial and continuing review, the approval period.
 - Determinations required by the regulations and protocol-specific findings justifying:
 - Waiver or alteration of the consent process
 - Research involving pregnant women, fetuses, and neonates.
 - Research involving prisoners
 - Research involving children
 - For VA research:
 - The approval of research contingent on specific minor conditions by the HAC Chairperson or designee, to be documented in the minutes of the first HAC meeting that took place after the date of the approval.
 - The determination of the level of risk.
- (1) Activities related to pregnant women must not be undertaken unless:
- (a) Except if appropriate studies on animals and non-pregnant individuals have been completed, and data for assessing potential risks to pregnant women and fetuses is provided.

(b) The purpose of the activity is to meet the health needs of the mother or the particular fetus, the risk to the fetus is minimal, and, in all cases, is the least possible risk for achieving the objectives of the activity.

(c) Individuals engaged in the activity will have no part in:

1. Any decisions as to the timing, method, and procedures used to terminate the pregnancy; or
2. Determining the viability of the fetus at the termination of the pregnancy.
3. Introducing any procedural changes, for research purposes, into the procedures for terminating the pregnancy.

(2) No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of research activity

(3) No pregnant woman may be involved as a subject in a research activity unless:

(a) The purpose of the activity is to meet the health needs of the mother, and the fetus will be placed at risk only to the minimum extent necessary to meet such needs; or

(b) The risk to the fetus is minimal.

(c) The mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if:

1. The purpose of the activity is to meet the health needs of the mother,
2. His identity or whereabouts cannot reasonably be ascertained,
3. He is not reasonably available, or
4. The pregnancy resulted from rape.

Flagging a Medical Record.

The HAC must determine if the patient's medical record (electronic or paper) must be flagged to protect the subject's safety by indicating the subject's participation in the study, and the source of more information on the study by using the HAC Reviewers Checklist for Research at the Charlie Norwood VA Medical Center. The HAC may not want to require the medical record to be flagged if:

(1) The subject's participation in the study involves:

(a) Only one encounter, (b) Only the use of a questionnaire, or (c) The use of previously collected biological specimens.

(2) The identification of the patient as a subject in a particular study (if the study is not greater than minimal risk) would place the subject at greater than minimal risk.

What Support Documents are Attached to the Minutes of each Meeting?

The OHRP staff attaches the following items as support documentation for each meeting to the corresponding minutes:

- HAC Member In/Out Spreadsheet:

- Documents the attendance of the HAC Member, consultants or special expertise
- Documents arrivals and departures of each HAC Member, consultants or special expertise
- Documents the use of an alternate member attendance for a full member attendance
- HAC Member Full Review Amendment Ballot
- HAC Member Full Review Continuing Ballot
- Any reports related to suspensions or terminations
- Any audit reports that were discussed at the meeting
- Educational topic handouts
- Current HAC Roster

Can the HAC Meeting Minutes be Altered by Anyone Including a Higher Authority Once Approved by the Members at a Convened Meeting?

No. If minutes have to be altered or revised, the convened committee must approve the alterations or revisions.

When are the HAC Meeting Minutes Available for Review?

The HAC Administrative Staff strives to make the minutes available for review within 10 business days after the meeting. The minutes are not final until approved by the convened HAC. Due to the meeting schedule, this may delay the final minutes greater than three weeks.

How are the Minutes Distributed?

Minutes are distributed via email to members, advisors, OHRP staff, the institutional officials for MCG and MCGHI as well as the Deans of Allied Health Sciences, Dentistry, Graduate Studies, Medicine, and Nursing. The Vice Dean of Research for each school is also copied on the email distribution list for minutes as well as the Office of Clinical Investigative Services Health System Review Office and the MCGHI Investigational Pharmacist. The minutes are also distributed to the media relations department for confirmation that all studies that may be featured on local news stations are approved by the HAC prior to any release.

How Does the Charlie Norwood VA Medical Center Receive the Minutes and When?

The Charlie Norwood VA Medical Center is notified of the minutes via the Administrative Officer (AO) for the Research and Development Office. The Chief of Staff is also copied on the distribution list. In an effort to increase efficiency, the AO is also provided a Word version of the minutes to assist in the preparation of documents for the R&D Committee meeting. The HAC Administrative Staff strives to make the minutes available for review within 10 business days after the meeting. The minutes are not final until approved by the convened HAC. Due to the meeting schedule, this may delay the final minutes greater than three weeks.

Whose is Responsible for the Retention of the Original Minutes?

It is the responsibility of the OHRP Assistant Director to retain the original meeting minutes and support documentation as provided by the OHRP Office Specialists assigned to the meeting.

HAC Record Storage

How Does the HAC Limit Access to their Records?

HAC file access is limited to the OHRP staff, HAC members, and advisors. Research team members and others who submit a request in writing to the HAC may be allowed to view their own records in the presence of an OHRP staff member.

How Does the HAC Store all Active Research Protocols?

All active research protocols are maintained in a keypad protected room in storage and in individual locked offices while in use. In/Out cards are used, as well as a file log in the HAC office of the OHRP suite.

How Does the HAC Store Research Protocols that are no Longer Active?

All research protocol files that are no longer active such as those protocols whose approval expired, or was cancelled without subject enrollment, or were terminated (within the past year) are maintained in a locked storage space in the OHRP suite and as space permits. All files that are no longer active (with expiration dates greater than one year ago) are maintained at a local secure data storage facility with limited access.

How Does the HAC Store HAC Records that are not Related to a Specific Research Study?

These are maintained in a locked storage space in the OHRP suite and as space permits. All files that are no longer active (with expiration dates greater than one year ago) are maintained at a local secure data storage facility with limited access.

How Long does the HAC Maintain these Records?

The HAC has a letter of agreement with the FDA that records will be maintained for 25 years. FDA 21 CFR 56.115 b. The records required by this regulation shall be retained for at least 25 years after completion of the research.

HHS regulations at 45 CFR 46.115(b) require that IRB records be retained for at least 3 years, and records relating to research which is conducted be retained for at least 3 years after completion of the research. However, the HAC record will be maintained for 25 years.

Who can Access the HAC Records for Inspection and Copying?

Authorized representatives of federal agencies or departments including but not limited to, the Research and Development Committee of the Charlie Norwood VA Medical Center, United States Food and Drug Administration, and Department of Health and Human Services, can access the HAC records for inspection and copying at reasonable times and in a reasonable manner.

HAC Members Stipends

Are HAC Members Compensated?

The HAC members, Vice-Chairperson and Chairperson are not financially compensated for their time. However, due to their significant time input, the MCG OHRP provides partial funding of the salaries of the HAC Chairperson and Vice-Chairperson.

Do the HAC Members Receive a Stipend?

Yes, they do receive a small stipend to be used at their discretion to cover travel, education and/or equipment in accordance with State of Georgia regulations for state employees. Nonaffiliated members receive a check.

How Often do the HAC Members Receive their Stipend and When?

Effective July 1, 2006, the stipend will be disbursed bi-annually (\$500 for July-Dec and \$500 for Jan-June). The member will complete a Service Agreement Request (SAR), Attachment A of the SAR and a W-9 in July and again in January.

What if an Affiliated Member Leaves the Committee before Spending their Stipend?

It should be noted that service termination requires prorating the stipend amount and any remaining balance will be returned to the OHRP main sponsored project.

What is the Stipend Amount?

Stipends are allocated as follows:

1. Chairperson: \$2,000
2. Vice-Chairperson: \$1,500
3. Full Members: \$1,000
4. Alternate Members: \$ 0
5. Advisors: \$ 0

Is There a Time Limit on When Affiliated Members Have to Spend their Stipends?

These amounts must be expended in full within two years. Any remaining balance will be returned to the OHRP main sponsored project.

What's the Stipend Process for an Affiliated Member?

For MCG, MCGHI faculty and staff or Charlie Norwood VA Medical Center staff serving on the HAC:

1. An account will be established with the Department of Sponsored Program Administration (DSPA).
2. The member will be notified via an email of the account number.
3. The applicable sum as noted above will be deposited into the account semi-annually.
4. The funds in the account may be utilized for the following:
 - a. Research activity
 - b. Travel not supported by the departmental funds
 - c. University business

What's the Process for a Non-Affiliated Member?

HAC members that are not employed by the MCG, MCGHI or the Charlie Norwood VA Medical Center:

1. A professional services agreement must be completed.
2. Upon receipt of the complete professional services agreement, a check will be issued in the amount as noted above.

Who do I Contact if I Have Questions about the Stipends?

Contact the OHRP Business Manager at OHRP@mcg.edu or 706.721.9346.

HAC Administrative Office Staff

Who Provides Funding For The HAC Administrative Office Staff?

The staff members of the HAC Administrative Office are employees of the MCG Office of Human Research Protection and therefore, MCG OHRP funds their positions.

Who Receives The HAC Mail Each Day?

The MCG OHRP Office Assistant receives and date stamps all HAC mail each day. In case of an absence, the duties are assumed by the HAC Administrative Office Staff or the MCG OHRP Assistant Director.

Are All HAC Submissions Logged In?

Yes. All HAC submissions from new protocols, amendments, continuing review, adverse event reports, serious adverse reports, IND safety reports, protocol deviations/violations, data safety monitoring reports, Research Self-Assessment Checklists, terminations, general information and letters to the HAC are logged in on a daily basis by the MCG OHRP Office Assistant.

What Internal Tools Does the HAC Administrative Office Staff Use To Route Paperwork Through The Process?

Action	Intake/Internal Routing Forms	Color	Publicly Available
New protocols	HAC Submission Checklist	White	Yes
Exempt Protocols	Exempt Routing Form	Salmon	No
Expedited Protocols	Expedited Routing Form	Dark turquoise blue	No
Full Review Protocols	HAC Submission Checklist	White	Yes
Stipulation Response	Action Item	Dark Rose	No
Continuing Review	HAC Staff & Reviewers Checklist Internal Routing Form	Yellow	No
Protocol Deviations/ Violations	Protocol Deviation/Violation Internal Routing Form	Purple	No
Unanticipated	Unanticipated Problems, Related and	Red	No

Problems, Related and Unexpected Adverse Events or Serious Adverse Events	Unexpected Adverse Event and/or Serious Adverse Event Notification Internal Routing Form		
Final Protocol Approvals	Final Protocol Approval	White	No
HAC Approval Expiration, Suspension or Termination	HAC Approval Expiration, Suspension or Termination Internal Routing Form	White	No

When are the HAC Members Packets Distributed?

The Reviewer’s Packets are generally mailed or hand-delivered by the Friday following the second Monday. This allows roughly 10 days for the reviewers to review their packets since the HAC meetings are held on the fourth Monday unless that day is a holiday.

How Is Quality Assurance/Quality Improvement Measured?

The MCG OHRP auditors conduct an internal audit of each HAC file in preparation for the site audit. For more information on the MCG OHRP auditing program, please view their web site. These findings are communicated to the MCG OHRP Assistant Director who assigns these to the appropriate staff member for correction. Education and training or re-training may be necessary and is implemented.

How Is The Workload Distributed?

The workload is currently distributed by the last name of the PI. Each of the three HAC Administrative Office Specialists is assigned a specific letter group (A-G, H-P, and R-Z) as their primary responsibility, although they are cross-trained and share information.

The Office Specialists use a calendar to keep track of meeting assignments, agenda and minutes preparation as well as continuing review report generation. All OHRP office staff assist with meeting set-up/take down. Catering needs are coordinated by the ORHP Office Assistant.

Is There A Database?

Yes. The current database uses an Access front end on Sequel Server with Visual Basic Program and is not web-enabled at this time. The new system, eProtocol, is web-enabled and should be implemented soon.

How Much Space Does The HAC Have?

The HAC is administratively supported by the MCG OHRP whose total square footage is 1782 square feet. Dedicated HAC space occupies the following:

HAC Administrative Office	258.10
HAC Chairperson/Vice-Chairperson office	73.64
HAC Active File Room #1	114.22
HAC Active File Room #2	73.64
HAC Terminated File Room	146.75
Total square footage	666.35

Meeting space is a shared conference room with wireless internet access and is approximately 500 square feet.

What Is The Hard Copy Filing System?

Active files are stored in Lektriever filing systems to facilitate easy identification and ergonomics. Files are assembled and are created as needed. For more information, please see the HAC Administrative Office Staff Operations Manual.

Routine study closures files are placed alphabetically by year in standard vertical filing cabinets. Files that have been closed for more than one year are archived off-site with a local storage provider. A log is kept on site for easy retrieval.

What is in the Hard Copy HAC file?

The hard copy HAC file is the definitive record for each study. The contents of the file will vary based on the type of research conducted but generally includes the following:

- The original protocol and Description of Research Proposal
- Draft Informed Consent Document (ICD)/Children’s Assent Document (CAD)
- Questionnaire/Surveys (if applicable)
- All applicable HAC Forms
- Stipulation Response from PI
- Amendments
- Clinical Study Status Reports (Continuations)
- Research materials (advertisements, brochures, pamphlets, newsletters, etc.)
- HAC approval letters
- The original HAC approved ICD/CAD and Questionnaire (if applicable)
- All correspondence regarding the study (emails, memos, letters, etc.)
- Audit reports of the HAC file
- All other institutional approvals (MCGHI, IBC, RSC, Charlie Norwood VA Medical Center IBC, Charlie Norwood VA Medical Center RSC, educational requirements met, MCG IT, MCGHI IT, other sites, etc.)
- FDA Form 1572, package inserts, investigational drug brochure
- Investigator’s agreement, device manual, technical information
- Unanticipated problems
- Adverse Events/Serious Adverse Events
- Data safety monitoring reports, interim analyses, etc.
- Intake forms/internal checklist
- Protocol Deviations/Violations

- HAC Reviewer's Checklist and comments

NOTE: Minutes of each meeting where an action took place regarding this protocol are maintained in separate files that may be retrieved upon request for purposes related to auditing or accreditation.

What about Communication?

The HAC Administrative Officer serves as the primary contact points for both the investigator and the HAC members.