

HAC Policies and Procedures for HAC Members and OHRP Staff

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

HAC Policies and Procedures for HAC Members and OHRP Staff

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:

HAC Policies and Procedures for HAC Members and OHRP Staff

- 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*)

HAC Policies and Procedures for HAC Members and OHRP Staff

- 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.

HAC Policies and Procedures for HAC Members and OHRP Staff

- 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?

HAC Policies and Procedures for HAC Members and OHRP Staff

- 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

HAC Policies and Procedures for HAC Members and OHRP Staff

- 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?

HAC Policies and Procedures for HAC Members and OHRP Staff

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

HAC Policies and Procedures for HAC Members and OHRP Staff

- 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.

HAC Policies and Procedures for HAC Members and OHRP Staff

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?

HAC Policies and Procedures for HAC Members and OHRP Staff

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.

HAC Policies and Procedures for HAC Members and OHRP Staff

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?

HAC Policies and Procedures for HAC Members and OHRP Staff

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.