

## **HAC Policies and Procedures**

### **HAC Members**

#### **What Is The Purpose Of This Section?**

This section provides information regarding HAC membership requirements, responsibilities, education and training, regulations, and the information received by the Committee members and alternates.

#### **When Are the Meetings?**

The full Committee meets on the fourth Monday of each month, unless otherwise changed by the HAC Chairperson. 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 Does The Meeting Start?**

The HAC meetings begin promptly at 12:00 p.m.

#### **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 about 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 his designee, prior to the meeting, must approve each visitor’s request to attend.

## **HAC Policies and Procedures**

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

If requesting to attend a meeting, please contact the HAC Administrative Office 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 are available
- The potential for any conflicts of interest is determined

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.

Contact the HAC Administrative Office at the contact information listed below.

### **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.

### **Am I Required to Complete a Non-Disclosure Statement to Attend the Meeting?**

Yes. The non-disclosure statement is required of all visitors and guests.

### **Am I Allowed To Stay In The Room During The Discussion And Vote?**

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

### **What about Confidentiality?**

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.

### **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 full Committee. The investigator or research team will be given approximately five minutes to

## **HAC Policies and Procedures**

answer questions related to the study, whereas, the 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.

### **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/or non-affiliated member.

### **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, we have lost a quorum twice.

### **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 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 or scholarly) or a consultant will be required for the HAC to adequately review a protocol. The use of special expertise is at the

## **HAC Policies and Procedures**

discretion of the HAC Chairperson or his designee. Additional expertise is sought from leaders in the field. This expertise is usually presented in writing to the Committee members. The expert is not allowed to vote on the protocol.

### **If Additional or Special Expertise or Consultants Have a Conflict of Interest, Can They Participate in the Vote?**

No. They 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.

### **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 for scientific merit.

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

Yes. Members are also required to attend scheduled training and education sessions.

### **How Are Exempt and Expedited Projects Reviewed?**

Projects reviewed by the expedited or 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.

### **How Does the HAC Administrative Office and OHRP Communicate to the HAC Members of 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.

### **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 numbers of terms that a member may serve.

### **Can an HAC Member's Service Be Terminated?**

## **HAC Policies and Procedures**

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.

### **Who Appoints the HAC Chairperson?**

The President of the Medical College of Georgia (MCG) appoints the HAC Chairperson on a three year basis. The President reviews the performance of the HAC Chairperson, Vice-Chairperson and the members.

### **Is There A Term Limit for the HAC Chairperson?**

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

### **Can The HAC Chairperson Approve Research Protocols If They Qualify For Exempt From Full Review Or Expedited Review?**

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

### **Who Appoints the HAC Vice-Chairperson?**

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

### **Is There A Term Limit for the HAC Vice-Chairperson?**

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

### **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?**

## **HAC Policies and Procedures**

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

### **Who Appoints the HAC Members?**

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

### **Is There A Term Limit for the HAC Members?**

There is no expiration limit on this term.

### **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 to be submitted at the time of initial appointment and then at each re-appointment.

### **How are Members Selected from MCG, MCGHI and the Augusta VAMC?**

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.

For Augusta VAMC 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 Augusta VAMC members as voting members and no votes are taken on protocols that involve the Augusta VAMC unless at least one of these members is present.

### **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.

### **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.

## **HAC Policies and Procedures**

### **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.

### **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?**

The conflicts may be any of the following:

Financial – owning stock or receiving payments, gifts, etc., from an individual or sponsor

Professional – bias, whether positive or negative, toward an individual, section, department, and population

### **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.

## **HAC Policies and Procedures**

### **What Should A HAC Member Do If They Feel That A Conflict Of Interest Exists For Them Personally Or Professionally?**

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

### **If The HAC Member Does Have A Conflict Of Interest, Can They Vote On The Protocol?**

No. HAC members who may have a conflict of interest are required to recuse themselves from discussing and voting on these protocols.

### **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.

### **Can Any HAC Member Vote On Any Protocol Where Their Vote May Represent A Conflict Of Interest?**

No individual shall vote on any protocol where such a vote may represent a conflict of interest.

### **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.

### **Who Assigns The Reviewers To A Protocol?**

Once a protocol is deemed to undergo full review, the Chairperson or designee assign 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.

## **HAC Policies and Procedures**

### **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.

### **What Are The Primary Reviewers Responsible For?**

The primary reviewers are responsible for reviewing the submitted information 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.

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

The reviewers are to conduct the following for initial and 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.

### **Can The Primary Reviewers Contact The Research Team Prior To The Meeting To Determine If Any Issues Can Be Resolved Prior To The Meeting?**

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 Documents Do The Primary Reviewers Receive For 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)
- Sponsor provided protocol, if applicable
- Informed Consent Document and/or Children's Assent Document
- 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

## **HAC Policies and Procedures**

- 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?**

The remaining Committee 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

### **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. This document is available at <http://www.mcg.edu/research/OHRP/hac/HAC%20Reviewers%20ChecklistDec2005.pdf>

This signed form should be submitted with the reviewer's notes and/or typed summaries. These are forwarded to the HAC Administrative Office after the committee meeting.

### **Who Prepares The HAC Meeting Minutes Documentation?**

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

### **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?**

## **HAC Policies and Procedures**

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 Is The Attendance Of Members Documented?**

The HAC Administrative Office prepares a roster for each meeting. If members will be absent, this is usually noted in the discussion portion of the agenda. The roster is also used to track members entering and exiting the room as well as any guests who may attend.

### **How Are Late Arrivals Or Early Departures Of HAC Members Handled?**

The agenda lists all protocols to be reviewed and is a guide for the HAC Chairperson or Vice-Chairperson. The agenda items may be shifted as needed to ensure compliance with regulations.

## **HAC Policies and Procedures**

### **HAC Member Education and Training**

#### **Are New Members (Regular And Alternate) Required To Complete CITI?**

Yes.

#### **Are New Members (Regular And Alternate) Required To Complete An Orientation Session Prior To Serving?**

Yes. Each new member is required to complete an orientation session as conducted by the Office of Human Research Protection prior to serving.

#### **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.

#### **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

## **HAC Policies and Procedures**

### **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. Non-affiliated 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

#### **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 Augusta VAMC 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.

## HAC Policies and Procedures

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 Augusta VAMC:

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.

### Deferred Approval

Most protocols fall into this category, indicating that approval is deferred pending a satisfactory response from the PI to the HAC requests for changes or clarifications (i.e., stipulations) to address deficiencies found in the protocol submission. 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. The possible results of these deliberations include:

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

Major Revisions I (involving 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.

Major Revisions II (involving 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, with approval being granted by the Chairperson or designee if responses are satisfactory to the majority of the Committee.

Minor Revisions (involving 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.

It is important that the various factors be balanced with regard to providing appropriate subject protections without unnecessarily delaying the project. The decision as to the appropriate pathway is made by the Committee at the time of initial review.

## HAC Policies and Procedures

Which pathway is to be followed is, of necessity, a judgment call by the primary reviewers and the full committee, based upon whether adequate information was provided to permit full evaluation of the protocol with regard to human subjects protection issues versus issues that will improve the overall document 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.

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. These can most often be dealt with by Chairperson or designee re-review or re-review by 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. 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: These problems generally relate to incorrect or incomplete information, often related to a lack of understanding by the research team member, information technology (IT) issues or privacy issues. 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 full 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 full Committee if necessary.

### **Who Do I Contact if I Have Any Questions?**

Contact the HAC Administrative Office at [HAC@mcg.edu](mailto:HAC@mcg.edu) or call the following extensions:

(706) 721-8397 for PIs whose last names begin with A-G

(706) 721-3110 for PIs whose last names begin with H-P

(706) 721-1482 for PIs whose last names begin with Q-Z

## **HAC Policies and Procedures**

Although the above listing indicates the staff's primary PI assignments, all HAC Administrative Office staff can answer your questions. There may be situations when your questions may require consultation with the HAC or OHRP leadership.