

## **HAC Policies and Procedures**

### **Full Review**

Protocols that require full committee review are those that have a probability for greater than minimal risk. These types of protocols frequently use investigational drugs or devices or may be cooperative group studies such as oncology (pediatric, adult, prevention and gynecologic). Full review protocols may also specifically recruit vulnerable subjects.

**Please refer to the Table for information on deadlines, forms, support documentation and examples.**

### **What Are the Criteria For Full Review?**

If the protocol involves greater than minimal risk as defined in the Expedited Review Section, then the protocol must be reviewed by the Full Committee.

### **What Materials Are Required For Full Committee Review?**

See the **Initial Review and Approval Table** for required forms, support documents, number of copies and deadlines that are required for submission to the HAC.

### **We Are Conducting A Study That Has Investigators Off-Site Who Are Not MCG, MCGHI Or the Charlie Norwood VA Medical Center Personnel. Do We Need To Submit A Copy Of Their or Résumé To The HAC?**

Yes. Please provide a bio-sketch for off-site investigators who are not affiliated with MCG, MCGHI, or the Charlie Norwood VA Medical Center.

### **I Submitted A Protocol Last Month For My Investigator With Five Copies Of the CV or Résumé. Do I Have To Submit This Again This Month?**

No. The investigator's CV or résumé must be updated and forwarded to the HAC on an annual basis. The CV or résumé must be dated and preferably signed by the individual. Only one copy is required for submission, as applicable. Contact the HAC Administrative Office Staff to confirm if they have a CV/ résumé on file.

### **Can the HAC Administrative Office Pre-Review My Submission for Full Review?**

Yes. Contact the HAC Administrative Office with the information listed below.

### **Why Do We Have To Submit So Many Copies (Original Plus Four And Then An Additional 27 Copies) For Full Committee Review?**

In order to remain compliant with current Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) and the United States Food and

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Drug Administration (FDA) rules and regulations, the proposed research must be available for review by each member of the institutional review board (IRB).

### **Are There Any Special Requirements For The HAC When Reviewing FDA Regulated Test Articles?**

A licensed clinician must be one of the voting members for research involving a FDA-regulated test article.

### **What Should I Expect After I Submit to the HAC?**

The HAC Administrative Office Staff communicates with the research team members at the time of each submission. The following information will provide additional guidance.

#### **Communication**

You will receive an email from the HAC Administrative Office when they accept the protocol for processing which will provide the HAC file for your protocol. You may receive emails requesting additional information or clarification.

#### **HAC File Number**

Each new protocol is assigned a distinct HAC file number (year, month, number of protocols received in the fiscal year). This number, along with the last name of the PI, is used to track all documents and actions related to the study. When requesting information or action for a study, always refer to the HAC file number and the last name of the PI.

### **How Can I Find Out More Information About the HAC Meetings?**

Refer to the HAC Members section for more information on the HAC meetings such as meeting dates, times, attendance policy, etc.

### **How Are Results Communicated To The PI?**

The decisions by the Committee are sent to the investigator or designee initially by email which is then followed by a hard copy letter signed by the HAC Chairperson or Vice Chairperson.

### **Will The Committee Tell Me The Status Of My Protocol Prior To The Written Or Emailed Answer?**

No.

### **What's the Average Turnaround Time for Full Review Studies?**

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The average turnaround time for HAC Full Review from HAC receipt to HAC approval is approximately 50 days. Please contact the HAC Administrative Office at the contact information listed below if you do not receive an email providing the names of the primary reviewers assigned to your full review protocol from the HAC Administrative Office within 3 business days after your submission.

### **Can I Start My Study Before I Receive HAC Approval?**

No.

### **HAC Responses**

The study will be assigned one of the following statuses after the protocol is initially reviewed by the full Committee:

#### *Approval is Deferred (Stipulation request/Changes and clarifications required)*

Most protocols fall under this category status indicating that approval is deferred pending a response from the PI to the HAC stipulations (i.e., changes, clarifications) request. The stipulation request will generally pertain to the Description of Research Proposal (DRP), Protocol, Informed Consent Document (ICD), Childrens' Assent Document (CAD), HAC forms, etc. The stipulations request is initially sent via e-mail usually within three (3) business days after the meeting date followed by the hard copy letter signed by the HAC Chairperson or Vice Chairperson. This letter is generally mailed (via campus or United States mail) to the PI within five (5) to seven (7) business days after the HAC meeting date.

The PI must address each stipulation request promptly in writing as the HAC must receive a response to the stipulations from the PI within 30 days from the date of the letter. The protocol will be administratively withdrawn by the HAC if no response is received by that date. If this occurs, the investigator must resubmit the full review package prior to reconsideration of the protocol.

To submit a response, complete [HAC Form 100](#), Clinical Study Document Cover Sheet, and include a memo listing each of the HAC requested changes/modifications/clarifications as well as the response from the research team. For example:

1. The HAC Stipulation Request: Reread for typographical errors.  
The PI Response: All typographical errors were corrected.

The PI must sign all stipulation responses and the SC may co-sign.

#### *Approved*

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The approval period is for a maximum of one year from the original meeting date. This may result in an approval period of less than one full year. The Committee may approve a study for less than one year depending on their assessment of the risk to benefit ratio. As an example, the protocol is reviewed at the January 22<sup>nd</sup> meeting. The PI adequately addresses all stipulations request and the Chairperson then approves the protocol on March 1<sup>st</sup>. The approval period for this protocol will be from March 1<sup>st</sup> until January 21<sup>st</sup>. The approval expiration date is noted in the approval letter that is mailed to the PI or his/her designee. The expiration date is the last date that the protocol is approved. If the study has not received continuing approval before the expiration date, all study-related activities must cease after the expiration date (see HAC Policies and Procedures, Section 3, Continuing Review for more information).

### Disapproved

Protocols are disapproved if the Committee feels that the risks outweigh the benefits. Only the full convened Committee can disapprove a protocol. Follow submission procedures for new, full review protocols if the research protocol will be submitted once the issues are addressed.

### Tabled

Protocols may be tabled because the protocol itself was poorly written, the requested/required information was not submitted to the HAC, the submitted protocol was inadequate to address the reviewer's concerns or if the HAC convened meeting fails to maintain a quorum as defined in the HAC Members Section.

The PI must sign all written responses to a tabled protocol and the SC may co-sign. Follow submission procedures for new, full review protocols if the research protocol will be submitted once the changes are addressed. Please note that HAC forms are not required to be revised unless the HAC requires changes on the forms.

The protocol will be reviewed at the next HAC meeting if required changes are received by the HAC submission date for that meeting. These deadlines are available on the HAC web site at <http://www.mcg.edu/research/OHRP/news/hacsubdead.pdf>. Submissions of tabled protocols require the 32 copies of the revised materials.

Tabled protocols require a response within 30 days of the date of the letter. The protocol is administratively withdrawn by the HAC if no response is received by that date. If the protocol is administratively withdrawn, the investigator must submit the full review package prior to reconsideration of the protocol.

### **How Are The Stipulation Responses Reviewed?**

The stipulation responses from the PI will be reviewed by the:

- a) Chairperson or his designee if appropriate

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- b) Primary reviewers per their request
- c) Full Committee if requested

An approval letter is generated only if the stipulation responses are adequate. If the responses are not adequate, another request for further clarification may be sent to the PI. The approval by the HAC Chairperson or designee is noted in the agenda and minutes of the next HAC meeting.

### **HAC Correspondence**

All correspondence will be mailed to the PI unless the PI has requested in writing that correspondence be sent to a designee, such as the SC. Some information may be emailed if appropriate.

### **Can HAC Decisions Be Appealed?**

Yes. The PI should initially contact the HAC Chairperson at (706) 721-2991 to discuss the issue. If after speaking with the HAC Chairperson, the end result is not satisfactory, the PI may appeal the final decision of the HAC to the President of MCG (NOTE: This authority may be delegated to the Vice President for Research). This process applies to all investigators at MCG, MCGHI, and the Augusta VAMC.

### **What Are The Grounds For An Appeal?**

Grounds for an appeal shall include the failure of the HAC to follow its published procedures in reviewing the study or that the decision by the HAC was arbitrary and capricious. A mere disagreement with the decision by the HAC shall not constitute valid grounds for an appeal.

### **What's The Deadline for Appealing a Decision?**

All appeals must be made in writing to the President within five (5) working days of the PI's receipt of the HAC decision.

### **Can Anyone Overturn The HAC Decision?**

Only the HAC can reverse an earlier decision. The President or his designee may not overturn the decision of the HAC per 21CFR56.112 and 45CFR46. They may refer the matter back to the HAC and the PI for further discussion and subsequent re-review.

### **What Should I Do if the Sponsor Requires Certain Wording in the HAC Approval Letter?**

A written request for specific wording should be included with the initial submission.

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### When Can I Start My Study?

The protocol may be initiated once all approvals are in place. Additional approvals (e.g., Institutional Biosafety Committee, Information Technology Support Services, etc.) may be necessary prior to initiation.

Protocols that are funded will require the approval of the Division of Sponsored Programs Administration (DSPA) (i.e., a fully executed contract or agreement) if MCG and/or MCGHI will be a performance site. Augusta Biomedical Research Corporation (ABRC) approval is required if the VA is a performance site and the protocol is funded. Do not begin the study until a fully executed agreement is in place, if applicable.

### What Is the Contact Information for the HAC Administrative Office Staff?

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

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.