

HAC Policies and Procedures

Amendments

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What Is An Amendment?

The HAC considers any changes to be made in a protocol, whether initiated by the investigator or a study sponsor, to be an amendment.

What is an Example of an Amendment?

Examples of amendments may include a change or revision to any of the following:

- Procedure
- Drug dose
- Number of participating subjects
- Length of participation
- Changes in location
- Changes in focus group interview questions
- Changes in approved research initiated without prior HAC approval to eliminate apparent immediate hazards to the participant
- Principal investigator/sub-investigator/study coordinator
- Administrative issues
- [Form FDA 1572](#)

Revisions include changes in the study team, laboratories, sites, etc. or it may be part of an amendment that requires a revised informed consent document.

How Do I Submit An Amendment For HAC Review?

Amendments must be submitted with a completed [HAC Form 113](#), Amendment Submission Form. Other forms or support documentation may be necessary.

Can I Implement The Amendment Before The HAC Approves It?

No. Amendments must be approved in writing by the HAC prior to its enactment. Conduct of the study under the revised protocol may not proceed until the HAC approval is granted.

Are There Any Exceptions?

An exception can only occur when changes to eliminate an apparent immediate hazard to subjects must be implemented for the safety of the subject.

What's the Deadline for Submitting Amendments that Require Full Committee Review?

The HAC Administrative Office (CJ-2103) must receive all amendments that require full review by 4:00 pm on the Monday prior to the HAC meeting date unless otherwise notified by the HAC Administrative Office. If this Monday falls on a holiday, then the submission must be received by 4:00 pm on the next business day. The HAC meeting date schedule can be accessed at the following link: [HAC Submission and Meeting Dates](#).

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What's the Deadline for Submitting Amendments that May Be Eligible for Expedited Review?

There are no deadlines for amendments that may be eligible for expedited review. However, if the Chairperson or designee determines that the amendment requires additional review, there may be a delay in amendment approval. The HAC must be informed of any changes that are planned in an approved study prior to their implementation unless the action is taken to reduce the risk to the subject.

Who Can Review the Amendments that May be Eligible for Expedited Review?

The Chairperson or his designee may review the amendments using expedited review. The designee must have at least one year of experience as a member of the HAC.

Do Federal Regulations Require That Protocols That Were Originally Approved as Exempt From Full Review Protocols Submit Amendments to the HAC for Review?

No. Although federal regulations do not require HAC review of amendments for studies that meet the criterion for exempt from full review, the HAC does require submission and approval of all amendments for studies that meet the criterion for exempt from full review. This action is taken to provide the maximum protections for the human subjects and/or human derived materials in the study. The HAC must be informed of any changes that are planned in an approved study prior to their implementation unless the action is taken to reduce the risk to the subject.

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What Forms and Documentation Do We Submit for Amendments?

Forms and Documentation for Amendments Table

	Expedited Review	Full Review	Summary of Changes Required? Using track changes only
Required HAC Form(s)			
HAC Form 113, Amendment Submission Form	X	X	
Personnel Changes			X
Forms and Support Documentation			
CVs/ Résumés	X		
Revised ICD/CAD	X	X	X
ICD Addendum	X	X	X
Support Documentation			
Audit Reports (from external entities such as FDA, sponsors, etc.)	X	X	
Revised Protocol (investigator and sponsor-initiated)	X	X	X <i>(Note: A summary of changes is acceptable for the sponsor's protocol. Track changes is required for revisions to the Description of Research Proposal (DRP))</i>
Data and Safety Monitoring Report			
Revised ICD/CAD	X	X	X
ICD Addendum			
Site Add – support letter from site or approval letter from other IRB	X	X	
Investigational Drug Studies Only Support Documentation			
Revised Investigational Drug Brochure/Package Insert		X	X <i>(A summary of changes is acceptable for the Investigator's Brochure)</i>
Revised Form FDA 1572	X	X	X
Investigational Device Studies Only Support Documentation			
Investigators Agreement	X	X	X

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# of copies needed	Original Only	Original plus 3 copies	
Submission Deadline	None	Third Monday of each month	

What Are Some Examples of an Amendment that Would Allow Expedited Review?

The following examples are amendments that would allow expedited review:

- Central lab changes
- Study coordinator changes
- Performance sites
- Advertisements
- Administrative changes such as phone numbers, mailing addresses, etc.
- Typographical error corrections
- FDA approval and renaming of a drug

What Are Some Examples of an Amendment that Would Require Full Review?

The following are some examples of amendments that would require Full Review by the convened HAC:

- Changes of PI or sub-investigator if the individual will be obtaining consent
- Changes in the dosing regime (i.e., amount, number of times, etc.)
- Any increased risk to subject whether the risks involve physical, psychological, social, economic, confidentiality risks, etc. (i.e., increased number of blood draws, more procedures, adverse events, etc.)
- Protocols involving vulnerable subjects (adding pediatric subjects to an approved protocol is a major change and requires full Committee review)

What Other Types of Documents May Be Required?

Completion of the HAC Form 113, Amendment Submission Form, may also require the completion of additional forms such as:

- A revised Description of Research Proposal (DRP) is required for any amendment which involves a revision to the sponsor's protocol.

Revised Informed Consent Document/Children's Assent Documents

A protocol amendment may require a revision to the Informed Consent Document (ICD) and/or Children's Assent Document (CAD). The revised ICD and/or CAD must be submitted to the HAC and must be in compliance with current HAC Policies and

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Procedures. To ensure faster routing and approval, provide a copy of the ICD and/or CAD of all changes noted. Changes must be noted by using the track changes feature in Microsoft Word or other software. A “clean” unstamped copy of the revised ICD and/or CAD must also be submitted. A document listing all changes is strongly encouraged and appreciated.

A “clean” copy is required so that it may be stamped on each page with the HAC approval stamp and a copy returned to the investigator. The stamped copy must be used for all informed consent processes.

ICD Addendum

Sometimes an amendment may only require an ICD and/or CAD addendum. All revisions must be in compliance with current HAC policies and procedures and should follow the same formatting procedures as the original ICD and /or CAD. A listing of all changes is also encouraged. These are only to be used if the protocol has enrolled subjects who must be informed of small changes to the conduct of the protocol.

Subject Information Letters

Occasionally, the HAC may request a “Subject Information Letter”. This letter may be requested in situations where the study is no longer in the enrollment phase and new subjects will not be added. The purpose of this type of letter would be to provide current subjects with information regarding personnel changes. A listing of all changes is also encouraged.

Investigator’s Agreements

To ensure faster routing and approval, provide a copy of the Investigator’s Agreements with all changes noted. Changes may be noted by using the track changes feature in Microsoft Word or other software, or by highlighting, bolding the font or handwriting the changes, additions or deletions. A document listing all changes is strongly encouraged and appreciated.

Protocol Amendments and Revisions

To ensure faster routing and approval, provide a copy of the amendment with all changes noted from the previously approved version. If the protocol was initiated by industry or a cooperative group, it is highly recommended that investigators date stamp the amendments with the date the amendment was received from the sponsor and submit this stamped copy along with the required HAC forms. The sponsor’s memo indicating the changes to the protocol or a document listing all changes is strongly encouraged.

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A revised Description of Research Proposal (DRP) is required for all protocol amendments that involve a revised sponsor's protocol. Changes to the DRP may be noted by using the track changes feature in Microsoft Word or other software.

Investigational Drug Brochures

To ensure faster routing and approval, provide a copy of the amendment and/or revisions made to the Investigational Drug Brochure (IDB) and note all changes from the previously approved version. Changes may be noted by using the track changes feature in Microsoft Word or submitting a summary of changes. A document listing all changes is strongly encouraged and appreciated.

Protocol Title Changes

Often protocols are submitted to more than one funding source and the HAC has allowed the use of a single HAC protocol with appropriate amendments to include additional data sets or title changes. Effective immediately, protocols that have greater than two title changes related to different funding sources must submit a new protocol. If an addition of a protocol title relates to a grant submission, a copy of the entire grant must be submitted with the amendment.

Form FDA 1572

To ensure faster routing and approval, provide a copy of the revised Form FDA 1572 with all changes noted. Changes may be noted by using the track changes feature in Microsoft Word or other software, or by highlighting. A document listing all changes is strongly encouraged and appreciated.

- [HAC Form 113](#) , Amendment Submission Form
- CV or résumé

CVs/Résumés

At times, submission of a dated and preferably signed CV or résumé may be required if they are MCG, MCGHI or the Augusta VAMC personnel. Only one copy is required of the dated CV or résumé.

What Are Changes in the Research Team?

Changes in the research team may include the following:

- Principal Investigator (PI)
- Sub-Investigator (Sub-I)
- Study Coordinator (SC)
- Name changes due to marriage or divorce

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What About the Required Education Program?

When adding new members to the research team, please confirm that they have completed the required web-based education program initially or the recertification part of the CITI program prior to HAC submission.

What About Research Team Members That Are Not at MCG, MCGHI or the Augusta VAMC?

Individuals who are not affiliated with MCG, MCGHI or the VAMC should submit documentation of the clinical research education required by their institution.

Who is Responsible for Notifying Other MCG, MCGHI or Augusta VAMC Departments of These Changes in Personnel?

For MCG and/or MCGHI research, the PI is responsible for notifying the MCGHI Investigational Pharmacy and the Division of Sponsored Program Administration (DSPA) of these changes.

For research conducted at the Augusta VAMC, the PI is responsible for notifying the Augusta VAMC Pharmacy and the Augusta Biomedical Research Center (ABRC).

What Do We Do If We Need to Change the PI for a Sponsored Study?

Obtain approval from the external sponsor first. This may require a revision to contract and/or budget.

What Information Is Required To Change A Study Title?

Submit a completed [HAC Form 113](#), Amendment Submission Form, indicate the protocol title change and provide a reason for requesting the title change. If the study is actively recruiting subjects, a revised ICD and/or CAD may be required as well as a revised [FDA Form 1572](#). If funded, the contract may also require revision. Please contact the Division of Sponsored Programs Administration (DSPA) or the ABRC for Augusta VAMC protocols for additional guidance.

Are Any Other Approvals Necessary?

A protocol amendment may affect the budget for the study. If the protocol will utilize MCG Health, Inc. (MCGHI) resources (e.g., patients, personnel, equipment, space, supplies or records) and will have an impact on the budget, the amendment must be submitted to OCIS HRSO for their review. For more information on their submission requirements, please view their web page.

Please contact the DSPA at (706) 721-2592 for MCG or MCGHI to determine if a revised budget should be completed.

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Please contact the ABRC for the Augusta VAMC projects to determine if a revised budget should be completed.

What Do We Do If We Have An Approved Study And One Of The Subjects Becomes A Prisoner?

If a subject is participating in a study and becomes a prisoner, then all study related activities must stop until a protocol amendment to include prisoners as research subjects is submitted and approved in writing by the HAC as well as by the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP).

Our Study Has Terminated With The HAC But The Sponsor Recently Sent An Administrative Amendment. Do We Need To Submit That Information To The HAC?

Yes.

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

Request this specific wording in writing with the amendment submission.

Should I Keep Copies of this Submission to the HAC?

Retain a copy of the completed form and any support documentation (such as informed consent documents, children's assent documents, publications, study reports to funding agency, etc.) with the regulatory files or binders as maintained by the Principal Investigator.

How Soon Should I Expect Approval of the Amendment?

Expedited Amendments- the processing and approval time for expedited amendments is 5 to 7 business days.

Full Review Amendments- the processing and approval time for amendments that require review and discussion at the fully convened IRB meeting is dependent upon the submission date and the date of fully convened HAC meeting.

What Should I Do if the Approval Letter Needs to be Revised?

All special requests for revised letters will be processed in the order received. The HAC Administrative team processes special requests on Thursdays only. The request must be submitted by Wednesday Tuesday at 5:00 pm to be processed on Thursday.

Who Do I Contact if I Have Any Questions About How to Complete the Form?

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Contact the HAC Administrative Office at 1-9346, 1-8397, or 1-3110.