

HAC Policies and Procedures

What Activities Are Involved in the Conduct of an Ongoing Protocol?

The typical activities involved in the conduct of an ongoing protocol are amendments, protocol deviations/violations, unanticipated problems, adverse events, serious adverse events, IND safety reports (for investigational drugs), continuing review and completion of the protocol and data analysis. These events must be reported to the HAC by the PI as they occur and are covered in the following sections.



Initial Submission of the Protocol:

- Review Levels
- Description of Research Proposal
- Informed Consent Documents
- Data and Safety Monitoring Plans

Ongoing Activities:

- Amendments
- Unanticipated Problems
- Adverse Events
- Serious Adverse Events
- Continuing Review
- Deviations/Violations

Termination/ Closure:

- Record storage

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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
- 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? May use track changes, bolded fonts, underlining or highlighting
Required HAC Form(s)			
HAC Form 113, Amendment Submission Form	X	X	
Personnel Changes			
Forms and Support Documentation			
HAC Form 102, Request for Personnel Change in Research Team	X	X	
HAC Form 106, Delegation of Duties	X	X	
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 or sponsor-initiated)	X	X	X
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
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 Only	
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:

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 Procedures. To ensure faster routing and approval, provide a copy of the ICD and/or CAD of 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 “clean”

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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.

Summary of Protocol Changes

To ensure faster routing and approval, provide a copy of the amendment with all changes noted from the previously approved version. 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.

This information is needed regardless if the protocol was initiated by industry, cooperative group, the investigator or another group. 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 changed to the protocol should also be submitted to the HAC.

Investigational Drug Brochures

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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 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 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.

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, bolding the font or handwriting the changes, additions or deletions. A document listing all changes is strongly encouraged and appreciated.

- [HAC Form 113](#) , Amendment Submission Form
- [HAC Form 102](#), Request for Personnel Change in Research Team, if personnel changes are made
- [HAC Form 106](#), Delegation of Duties
- 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

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.

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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.

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?

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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.

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

Contact the HAC Administrative Office at 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.

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Unanticipated Problems and Adverse Events

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Federal Regulations [45CFR46.103 (a), 45CFR46.103 (b) and 21CFR56.108R] require prompt reporting to the Human Assurance Committee (HAC) of unanticipated problems (as defined below) involving risks to subjects participating in research projects.

What Is An Adverse Event?

According to DHHS OHRP, an adverse event is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

There are two types of adverse events:

1. Internal events that involve our local subjects enrolled by our investigators.
2. External events using subjects enrolled in a clinical trial under an investigator not affiliated with our research site for this study.

When Does Participation In The Research Protocol Begin?

Participation begins when the research subject or legally authorized representative signs the informed consent document.

What is an Unanticipated Problem Involving Risks to Subjects or Others?

According to DHHS OHRP guidance, an unanticipated problem is any incident, experience, or outcome that meets all of the following criteria:

1. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol and related documents, such as the HAC approved Description of Research Proposal, the protocol and the informed consent documents; and (b) the characteristics of the subject population being studied.
2. Related or possible related to a subject's participation in the research
3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Are Unexpected Problems Only Related To Physical Events?

No. For example, an unexpected event may be any of the following:

- Stolen laptop with protected health information on it
- Digital camera or memory stick stolen with photographs or identifiable data of subjects
- Increased time off from work resulting in less pay to subjects or parents
- Increased time out of school resulting in lower grades

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- Suspected child or domestic abuse
- Errors made by pharmacy technician that gives a research subject several times the amount of the investigational drug which resulted in increased risk of toxicity to the participant, but no actual harm

Each of these examples is unexpected in nature, related to participation in the research, and resulted in new circumstances that increased the risk of harm to subjects.

What is An Unexpected Adverse Event?

Any adverse events occurring in one or more subjects, in a research protocol, the nature, severity, or frequency of which is not consistent with either of the following:

- (1) The known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) protocol and related documents, such as the HAC approved Description of Research Proposal (DRP), the protocol and the informed consent documents (ICD); and (b) other relevant sources of information, such as product labeling and package inserts; or
- (2) The expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.

How Can You Determine When an Adverse Event is an Unanticipated Problem and Must Be Reported to HAC?

If the answer to all three of the following questions is yes, then the adverse event is an unanticipated problem and must be reported to the HAC for reporting to DHHS OHRP:

- (1) Is the adverse event unexpected?
- (2) Is the adverse event related or possibly related to participation in the research?
- (3) Does the adverse event suggest that the research places subjects or others (such as parents, other students, siblings, etc.) at a greater risk of harm (physical, psychological, economic or social) than was previously known or recognized?

What If An Event Is Expected (Listed In The ICD And Protocol) But It Gets Worse Or Happens More Often?

The event does not require reporting to the HAC if the event is listed in the protocol or ICD/CAD, unless the sponsor requires reporting the event to them. However, if the event increases in frequency or duration or if any additional measures are needed, it should be reported to the HAC.

Who Reviews These Events?

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The HAC Chairperson or his designee reviews these events. These reports will be submitted to the full Committee for review. The HAC may request additional guidance from other departments or those with certain expertise to assist in the review process of these events.

What If I Have An Industry Sponsored Drug Study And The Sponsor Requires An Adverse Event To Be Reported Via The Case Report Form?

If conducting an industry sponsored drug study and the sponsor requires an adverse event to be listed in the case report form, it must also be reported to the HAC per the guidelines.

Such events must be reported in writing to the HAC within 72 hours of any member of the investigative team becoming aware of the event.

What Form is Required?

All local subjects (e.g., those followed by our investigators) expected adverse events must be reported to the HAC on HAC Form 110, Local Subject Report Expected Adverse Event (EAE) if the sponsor requires reporting to them.

All local subjects (e.g., those followed by our investigators) unexpected adverse events, unanticipated problems, or serious adverse events must be reported to the HAC on HAC Form 110 SAE, Local Subject Report Unexpected Adverse Event (UAE)/Serious Adverse Event (SAE).

The HAC File #, the protocol title, the Principal Investigator's name and the name of the person submitting the report must be included. The report must also provide the subject identification number and a statement that the PI has reviewed the information. A copy of the sponsor's adverse event or serious adverse event form(s) may be provided as supplemental information.

My Study Is an Intervention, Not A Drug or Device Study. Do I Still Have Adverse Events Or Unexpected Events?

Yes. Adverse events that occur in non-drug or device protocols must be reported as described above.

Can I Email or Fax These Reports to the HAC?

The reports may be emailed to the email address of hac@mcg.edu or faxed to the HAC at (706) 721-1479 and the original report must be mailed to the HAC Administrative Office (CJ-2103).

What If I Can't Meet the Deadline?

If the deadline cannot be met, note the cause of the reporting delay on the HAC Form 110, Local Subject Report Expected Adverse Event (EAE) or HAC Form 110 SAE, Local Subject Report Unexpected Adverse Event (UAE)/Serious Adverse Event (SAE), as applicable.

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I Can't Locate My Documentation On What I Reported – Can the HAC Help Me?

The HAC Administrative Office can provide a database report of all reported SAE, AE and IND safety reports at the request of a member of the research team. Please contact the HAC Administrative Office via email at hac@mail.mcg.edu and provide the PI name and HAC file number to request a copy which can be emailed, faxed, or hard copy can be sent. Please allow at least two business days for the report.

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

Contact the HAC Administrative Office at 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

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Serious Adverse Event

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What is a Serious Adverse Event?

Serious Adverse Events (SAE) are defined [21CFR312.32] as:

- Death due to *any cause*
- A permanent or substantial disability
- Hospitalization (inpatient admission or overnight stay) or prolongation of hospitalization
- An immediately life-threatening event
- Report of overdose (intentional or not)
- Report of congenital anomaly

Is There Any Additional Guidance For Hospitalizations?

Hospitalization is not a SAE; it is an action due to an adverse event (AE), serious adverse event (SAE) or unanticipated problem or experience. Hospitalization for an elective procedure or surgery for a pre-existing condition that has not worsened is not a serious adverse event; however, it must be reported as an adverse event (AE).

What if the SAE is Not Related to the Test Article Under Study in the Protocol?

The HAC requires reporting of all hospitalizations including elective admissions and all deaths even if unrelated to investigational drug or device.

What About SAE Reporting in Long-Term Follow-Up Studies?

Reporting of hospitalizations is not necessary for subjects enrolled in long-term follow-up studies in which the subjects are receiving no investigational therapy. Other hospitalizations that are part of the disease process do not have to be reported to the HAC unless they have increased in severity or frequency or if the sponsor requires notification. Examples of these types of studies are: Gynecologic Oncology Group (GOG), Children's Oncology Group (COG), Eastern Cooperative Oncology Group (ECOG), etc.

What About Deaths?

All deaths must be reported, regardless of relationship to study drug or device or disease progression including those in long-term follow-up studies. The research team should report any death as soon as they become aware of the event.

When Should Deaths Be Reported in Long-Term Follow-up Studies?

The research team should report these deaths to the HAC as soon as they occur or the research team member becomes aware of the death. These deaths must be reported on the HAC Form 110 SAE, Local Subject Report Unexpected Adverse Event (UAE)/Serious Adverse Event (SAE).

Do Sponsors Have the Same Reporting Requirements as the HAC?

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No. Please note that the sponsor may not have the same reporting requirements as the HAC.

Who Reviews Serious Adverse Events?

The HAC Chairperson, or his designee, and the full HAC reviews all serious adverse events.

What Form is Required?

All local subjects (e.g., those followed by our investigators) unexpected adverse events, unanticipated problems, or serious adverse events must be reported to the HAC on HAC Form 110 SAE, Local Subject Report Unexpected Adverse Event (UAE)/Serious Adverse Event (SAE).

The HAC File #, the protocol title, the Principal Investigator's name and the name of the person submitting the report must be included. The report must also provide the subject identification number and a statement that the PI has reviewed the information. A copy of the sponsor's adverse event or serious adverse event form(s) may be provided as supplemental information.

When Are The Deadlines?

Such events must be reported in writing to the HAC within 24 hours of any member of the investigative team becoming aware of the event.

Can I Email or Fax These Reports to the HAC?

All events may be sent via email to the hac@mail.mcg.edu or faxed to the HAC at (706)721-1479. The original must be sent via campus mail; US mail or be hand-delivered to CJ-2103 within 10 business days. These events must also be reported to the sponsor as described in the study protocol or agreement.

What If I Can't Meet the Deadline?

If the deadline cannot be met, note the cause of the reporting delay on the HAC Form 110 SAE, Local Subject Report Unexpected Adverse Event (UAE)/Serious Adverse Event (SAE), as applicable.

I Can't Locate My Documentation On What I Reported – Can the HAC Help Me?

The HAC Administrative Office can provide a database report of all reported AE and SAE at the request of a member of the research team. Please contact the HAC Administrative Office to request a copy via email at hac@mail.mcg.edu and provide the PI name and HAC file number. Allow at least two business days for the report, which may be e-mailed, faxed or hard copy mailed.

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IND Safety Reports For Industry Sponsored Studies

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What is an Investigational New Drug (IND) Safety Report?

Serious Adverse Events (SAEs) occurring at sites other than MCG or VAMC that are reported to the investigator by a sponsor are usually referred to as Investigational New Drug (IND) Safety Reports.

What Should the Investigator Do With IND Safety Reports?

IND safety reports should be carefully reviewed to determine if any changes are needed to the HAC approved Informed Consent Document (ICD) and/or Children's Assent Document (CAD). Investigators are responsible for changing the conduct of the trial and/or updating the consent form as soon as any information is received about increased risks to subjects. This action should not wait until the next study continuation review for any information that increases risks to subjects.

Do I Submit These to the HAC?

The individual reports are not required to be submitted to the HAC but must be kept on file by the investigator. If submitted, IND safety reports will be returned to the research team. However, a summary must be submitted to the HAC at the time of initial and continuing review.

How Should Investigators Report IND Safety Reports to the HAC Before the Study Starts?

Have the PI prepare a report at the time of initial submission that includes the following information:

- The number of IND reports received from the sponsor, if any
- A summary synopsis of the types of reports and their effect (example, cancer drug with deaths - deaths only related to disease progression, not the drug)
- The number of reports related to the drug and the system(s) impacted

What if I Receive IND Safety Reports between the Time I Submitted to the HAC and the Time of HAC Approval?

Submit at the time of continuing review if the protocol is approved. The investigator is responsible for changing the conduct of the trial and/or updating the informed consent document as soon as any information is received about increased risks to subjects.

How Should Investigators Report IND Safety Reports to the HAC After the Study Starts?

Have the PI prepare a report at the time of continuing review that includes the following information:

- The number of IND reports received from the sponsor (if "None" or "Not Applicable" so indicate. If the question is not addressed then the report will be returned as incomplete.)
- A summary synopsis of the types of reports and their effect (example, cancer drug with deaths - deaths only related to disease progression, not the drug)

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- The number of reports related to the drug and the system(s) impacted

Can These Summaries Be Faxed Or Emailed?

The forms may be emailed to HAC@mcg.edu or faxed to the HAC at (706) 721-1479. The original must follow in campus or US mail or be hand-delivered within three (3) business days.

Who Reviews IND Safety Report Summaries?

Initial IND Safety Report Summaries are reviewed by the HAC primary reviewer system. Refer to the section on Continuing Review for more information. Additional information may be requested.

What If The Sponsor Continues To Send Our Site IND Safety Reports After We Have Completed The Study And Terminated The Approval With The HAC?

If the protocol was terminated and the sponsor continues to provide Investigational New Drug (IND) safety reports to the research team, the research team must submit summaries of those reports to the HAC in compliance with institutional policy. However, if the study was terminated prior to any local subjects enrolling, then the summary reports are not required.

I Can't Locate My Documentation On What I Reported – Can the HAC Help Me?

The HAC Administrative Office can provide a database report of all reported SAE, AE and IND safety reports at the request of a member of the research team. Please contact the HAC Administrative Office via email hac@mail.mcg.edu and provide the PI name and the HAC file number to request a copy. Allow at least two business days for the report, which may be e-mailed, faxed or hard copy mailed.

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Protocol Deviations/Violations

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Protocol Deviations/Violations

What Is A Protocol Deviation?

Deviations generally do not have a major impact on subject's welfare or data integrity. Examples of deviations are scheduling a required procedure outside of the time frame specified in the protocol because the subject was on vacation when the procedure should have occurred or subject use of a prohibited concomitant medication.

Is an Enrollment Exception to the Inclusion/Exclusion Criteria of an Approved Protocol a Protocol Deviation?

Yes. The Principal Investigator should submit a written request for a one-time, one-patient enrollment exception as a modification request to the HAC to allow treatment of a single patient who does not meet the entry criteria of the HAC approved protocol.

These requests, which should be rare, must be justified in terms of serving the best interests of the one-time, one-patient only. The HAC Chairperson or his designee will evaluate the level of review required.

If the protocol receives external funding, the PI should attach a copy of the sponsor's written approval of this one-time event.

HAC approval is required before this type of exception to the inclusion/exclusion criteria of an approved protocol can be done. Contact the HAC Administrative Office at the numbers below to facilitate the request.

What Is A Protocol Violation?

Violations affect a subject's rights, safety or well-being or data integrity. It may also affect primary safety or efficacy endpoints of the study. Examples are:

- Enrolling subjects who did not meet entry criteria without prior permission of the sponsor/CRO
- Failing to obtain informed consent prior to any study-related procedures
- Failure to treat subjects according to protocol procedures that specifically relate to primary safety or efficacy endpoints

When Is The Reporting Deadline?

All protocol deviations and violations must be reported to the Human Assurance Committee (HAC) within five (5) business days.

What Form Must Be Submitted?

A completed [HAC Form 120PDV](#), Protocol Deviation/Violation, must be submitted.

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Who Do I Contact if I Have Any Questions About How to Complete the HAC Form 120PDV, Protocol Deviation/Violation?

If there are any questions, please contact the HAC Administrative Office at 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.

Is There Any Other Additional Guidance Regarding Protocol Deviations/Violations?

Elisabeth Clark, Research Ethics Officer/Human Protections Administrator of McGill University Health Center provides the following clarification:

"Protocol Violation - A term broadly used in clinical research to describe any study event whereby the current HAC approved research protocol was not followed, i.e. a change in a research activity. There is a general acceptance in the biopharmaceutical industry for two categories of protocol violation, protocol exception and protocol deviation."

"Protocol Deviation - A divergence or departure from the expected conduct of an approved study that is not consistent with the current research protocol, consent document or study addenda that had not been anticipated. All protocol deviations must be reported in writing to the HAC immediately upon discovery.

Urgent action to eliminate an immediate hazard to a subject is the only acceptable protocol deviation, and the event must be explained in writing to the sponsor, and to the HAC, as soon as possible."

"Protocol Exception - A divergence or departure from expected conduct of an approved study that is not consistent with the current research protocol, consent document or addenda, that had been anticipated by the investigator, and for which HAC grants acceptance."

Why Is a Prevention Plan Required?

The prevention plan is necessary so that the HAC can determine what will be done to prevent future occurrences. They will review the plan to determine if it is appropriate. Additional information may be requested.

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Continuing Review

HAC Policies and Procedures

What is Continuing Review?

Continuing review is a report to the HAC on the progress of the study. Again, it is the responsibility of the investigator to request continuing review by the HAC.

Are All Studies Required To Undergo Continuing Review?

The request for continuing review applies to all studies (e.g., medical record reviews, sample processing or other) regardless of the initial review level. Please note that studies initially meeting the criteria for exempt and expedited review are eligible for expedited review for their continuation request. Although federal regulations don't require continuing review for those studies initially approved as exempt from full review, the HAC does require an annual submission for exempt studies in order to provide the maximum protection for human subjects and/or human derived materials.

It is the investigator's responsibility to seek continuing review. However, as a courtesy, the HAC Administrative Office will mail the [HAC Form 107, Clinical Study Status Report](#), to the PI or designee approximately 60 days prior to the approval expiration date.

Why Do We Have to Complete the HAC Form 107, Clinical Study Status Report?

FDA, DHHS OHRP and institutional policies require that all research be reviewed at least annually or more frequently depending on the risk assessment.

What Information is Provided to Me on the HAC Form 107 From the HAC?

The HAC uses the HAC Form 107, Clinical Study Status Report, to confirm the information submitted by the Principal Investigator or his designee during the course of the study with all actions related to the study. This report contains information about the:

- Research team members and their educational status, demographic information, ability to obtain informed consent
- Number of subjects approved for inclusion in the study
- If the PI submits Adverse Events or Serious Adverse Events and a summary of IND Safety Reports, to the HAC for review during the approval period, this information will be included in the report.
- If the PI submits protocol deviations/violations, to the HAC for review during the approval period, this information will be included in the report.
- If the PI submits amendments, to the HAC for review during the approval period, this information will be included in the report.

All of this information should be reviewed by the Investigator for accuracy. If any mistakes or omissions are discovered please report to the HAC office.

Do I Need To Submit The Yellow Copy Of The HAC Form 107, Clinical Study Status Report, Or Can I Print Out A Copy From The HAC Forms?

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The HAC Administrative Office prefers that the original yellow HAC Form 107, Clinical Study Status Report, sent to the Investigator, be used when submitting the report. This report contains additional information that the Investigator is responsible for checking for accuracy before submitting the report. If you misplace the original you can print out a HAC Form 107, Clinical Study Status Report, from the HAC web site and submit it instead of the original.

What Are The Deadlines For Submission?

The Due Dates are noted on the HAC Form 107, Clinical Study Status Report.

My Approval Doesn't Expire Until The 25th Of Next Month. Why Do I Have To Turn In The Completed HAC Form 107, Clinical Study Status Report, So Early?

The HAC requires that the completed HAC Form 107, Clinical Study Status Report, must be approved at the monthly meeting for protocols that were initially reviewed as full review. Protocols that were initially reviewed as exempt from full review or expedited review must be reported to the full Committee at the next convened meeting. HAC requires that the completed HAC Form 107, Clinical Study Status Report, must be submitted by the due date noted on the form in an effort to avoid unnecessary termination.

What If I Can't Get The Completed HAC Form 107, Clinical Study Status Report, To the HAC Administrative Office, On Or Before The Due Date?

If the form is not returned to the HAC Administrative Office by the due date noted on the form, the protocol approval **terminates**. Data and/or samples collected after the approval expiration date may not be used. If the project is funded and the HAC approval expires, the funding may also be withheld. If the HAC protocol approval lapses, then the protocol must be resubmitted in its entirety as if it were a new protocol. If the study has not been approved for continuation by the approval expiration date, all research activity must cease immediately. Subject accrual and data collection must be suspended pending re-approval of the research by the HAC. The protocol **must** be re-submitted as a new review.

What Happens if I Don't Submit the HAC Form 107, Clinical Study Status Report, by the Due Date and I Have Subjects Receiving Active Test Articles?

Research approval that expires because the HAC did not grant continuing review, either because the HAC did not receive the required materials from the investigator or because the HAC received the materials but did not grant continuing review requires additional procedures by the HAC, the sponsor and the investigator.

Subjects receiving test articles should be withdrawn in an orderly manner appropriate to the research medication. A plan for this procedure should be submitted in writing to the HAC for review as soon as possible per the Food and Drug Administration (FDA) regulations. The investigator must submit a list of research participants for whom stopping research procedures would cause harm. The HAC may allow continuation of the research intervention or interactions in already enrolled participants only when the convened HAC or HAC Chairperson finds that it

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is in the best interest of the individual participants to do so. The Chief of Staff at the Augusta VAMC must be consulted for all protocols that list the Augusta VAMC as a performance site.

The HAC will also notify the sponsor of the termination.

Can I Enroll New Subjects After the HAC Approval Expires?

No. Enrollment of new subjects cannot occur after HAC approval expires and the data collected on subjects after HAC approval expires cannot be included in the research analysis. Enrolling subjects after HAC approval expires is considered to be a protocol violation which requires the completion and submission of the HAC Form 120PDV, Protocol Violation, to the HAC.

What if I Don't Receive the HAC Form 107, Clinical Study Status Report, from the HAC Administrative Office?

If the PI does not receive the HAC Form 107, Clinical Study Status Report, it may be accessed on the HAC Forms web site or you may contact the HAC Administrative Office to obtain an additional form. **It is the investigator's responsibility to seek continuing review.**

What if I Am Out of the Country or On Leave?

These issues should be addressed with the HAC prior to extended leave. The form may be emailed to HAC@mcg.edu or faxed to the HAC Administrative Office at (706) 721-1479, if necessary.

What Am I Responsible for in Reviewing this Report?

It is the responsibility of the PI to review the HAC Form 107, Clinical Study Status Report, for accuracy, completeness, and study progress. The form must be completed in its entirety, **including a progress report regarding study activity and returned to the HAC by the requested due date.** In the case of multi-center studies, study progress occurring at the MCG or MCGHI site only is required. If a progress report is submitted to a granting agency, a copy of that report should be submitted with the continuation request. All information on the form should be typed or printed and correction fluid should not be used. The report should be a cumulative progress report beginning from the original approval date of the study.

What are the Directions for the Proper Completion of the HAC Form 107, Clinical Study Status Reports?

Page One

Confirm that all information regarding the PI and the SC is correct. If any information is incorrect, please submit a completed HAC Form 113, Amendment Submission Form, to modify the incorrect information. Do not make modifications on the HAC Form 107, Clinical Study Status Report.

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Study Status

If the study was not funded and therefore not initiated, check the space next to “Completed” and note the reason(s) on page two under “Study Progress.” If the study is finished, check “Completed”. The HAC Form 107, Clinical Study Status Report, must be completed, especially the report section on page two. If the data is still being analyzed then, the study must remain active. If all data have been analyzed and publication is in process, the study may be completed and terminated.

What Should I Do If I Have Not Started the Study?

If a research study has not commenced (i.e., no subjects enrolled, no samples received, no data collected, etc.) and it has been three years since the original study approval date, the PI should submit a completed HAC Form 107, Clinical Study Status Report, or HAC Form 111, Final Report, to officially close the study.

If a study terminates before the HAC Form 107, Clinical Study Status Report, is received, the research team may submit a completed HAC Form 111, Final Report, to terminate the study.

Performance Sites:

Confirm that each site where the study is being conducted is included as a performance site. A copy of approval letter from sites (other than MCGHI or the Augusta VAMC) and/or their IRB or equivalent is required. Please refer to the section on Performance Sites for additional guidance.

Sponsor Information:

Confirm that the sponsor’s name is correct. This should be the financial sponsor of the study. For example, a federal sponsor under the National Institutes of Health (NIH) may sponsor a study but the institution may serve as a sub-contract via a different university. For this case, the different university would be the sponsor.

PeopleSoft Account Number:

This number is required in order that study information may be shared with different areas within Research Administration. This information is also required for financial auditing purposes.

What is meant by the Protocol Prior/New and Extension Prior/New?

If this is the first Clinical Study Status Report form completed for the study, leave the Protocol Prior section blank and enter the numbers on the Protocol New section.

If an annual report was submitted to the HAC after 10/97, the Protocol Prior section will show the numbers previously submitted that were entered into the HAC database.

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If this is a multiple extension protocol and there is not enough room to include all of the information, attach a report with the numbers.

Cumulative Number of Subjects

The tables should indicate the cumulative number of subjects from the original approval date of the study.

Specified by protocol/contract: This is the maximum number of subjects approved by the HAC that the site can enroll. The protocol should state how many subjects were to be enrolled in the study. If the study receives external funding, then the grant or contract paperwork should state how many subjects would be enrolled. For example, if the study was initially approved to enroll 15 subjects, then the protocol prior column should indicate 15 under “Specified by Protocol/Contract”. If an amendment was submitted and approved to increase the number of subjects to 20, then indicate 20 under the “Specified by Protocol/Contract” for the new column.

We Often Conduct Studies That Don’t Have A Specified Number In The Protocol Or Contract, So What Should I Put In The Box?

Put an asterisk in the box and explain in the comments section on page two.

Screened: The number of subjects screened for inclusion/exclusion criteria. This number may exceed the number specified by the protocol/contract. If the number does exceed, then this information should be relayed to the Committee in the Brief Report section on page 2. This number should not exceed the number consented.

We Don’t Keep A Screening Log Of Patients. What Do We Enter in the Screened Section?

It is highly recommended that a screening log of subjects be used since the log can track whether a patient being screened may qualify or not qualify for the study, and can be used as documentation that subjects were actually screened, etc.

Consented: Enter the number of signed informed consent documents (ICD) and/or children assent documents (CAD).

Dropped/Withdrawn/Screen Failures: Enter the number of subjects who were dropped from the study by the PI, the number of subjects who withdrew from the study, and the number of subjects that were screening failures after signing the informed consent document. **NOTE: Each of these must be explained in the brief report section on page two for each year of the study.**

How Should Subjects That Are Lost To Follow-Up Be Reported On The HAC Form 107, Clinical Study Status Report?

These subjects should be counted as dropped/withdrawn/screen failure. Please indicate lost to follow up in the comments section on page two.

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Completed: The cumulative number of subjects who fulfilled their obligations as study participants and have completed all required visits.

Continuing: The cumulative number of subjects who are continuing their participation in the study because they have not completed all required visits.

Additional Examples:

Year One of the Protocol

	Prior	New
Specified by Protocol/Contract	15	15
Screened	0	20
Consented	0	20
Dropped/Withdrawn/Screen Failures	0	7
Completed	0	0
Continuing	0	13

Year Two of the Protocol

	Prior	New
Specified by Protocol/Contract	15	15
Screened	20	22
Consented	20	22
Dropped/Withdrawn/Screen Failures	7	7
Completed	0	0
Continuing	13	15

Year Three of the Protocol

	Prior	New
Specified by Protocol/Contract	15	15
Screened	22	0
Consented	22	0
Dropped/Withdrawn/Screen Failures	7	7
Completed	0	15
Continuing	13	0

Only complete the extension column if the HAC approved a protocol extension. Continuing review of the protocol is not an extension of the original approval.

Why is the Gender and Minority Status Required?

The HAC is required to confirm that research is distributed fairly and equally across gender and minority lines, as appropriate. The VHA 1200.5 requires this information as well.

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What if I Have Not Enrolled on the Study After Three Years?

The HAC will not approve the renewal of a project that lacks the appropriate resources if subjects have not been enrolled after three years. The only exceptions are oncology cooperative studies.

Page Two

Adverse Events, Serious Adverse Events, and IND Safety Reports

A listing of all received reports will be included with the [HAC Form 107](#), Clinical Study Status Report, if adverse events (AE), serious adverse events (SAE) or a summary of investigational new drug (IND) safety reports were submitted. Please review the listing carefully to determine if all reports were submitted to the HAC. It is the investigator's responsibility to compare this listing with all documents located at the study site. If a discrepancy is found, it must be promptly addressed with the HAC via the HAC Form 113, Amendment Submission Form, and indicate by marking the box labeled "Other". Additional forms may be required.

Amendments

A listing of all received amendments will be included with the [HAC Form 107](#), Clinical Study Status Report, if amendments were requested. Please review the listing carefully to determine if all amendments were submitted to the HAC. It is the investigator's responsibility to compare this listing with all documents located at the study site. If a discrepancy is found, it must be promptly addressed with the HAC with the HAC via the HAC Form 113, Amendment Submission Form, and indicate by marking the box labeled "Other". Additional forms may be required.

Protocol Deviations/Violations

A listing of protocol deviations/violations will be included with the [HAC Form 107](#), Clinical Study Status Report, if protocol deviations/violations were reported. Please review the listing carefully to determine if all protocol deviations/violations were submitted to the HAC. It is the investigator's responsibility to compare this listing with all documents located at the study site. If a discrepancy is found, it must be promptly addressed with the HAC with the HAC via the HAC Form 113, Amendment Submission Form, and indicate by marking the box labeled "Other". Additional forms may be required.

Brief Report on Study Progress

Please note that the statement **"Study is proceeding as planned"** is ***not*** an adequate report regarding the study progress. If there were any unanticipated problems with recruitment, retention, lab tests, supplies, the protocol itself or if there were unanticipated benefits, this information must be provided. If a progress report was made to the sponsoring agency, a copy should be submitted with this HAC Form 107, Clinical Study Status Report. If an article was published on data collected, a copy should be submitted with this HAC Form 107, Clinical Study Status Report. Reasons for subject withdrawal and/or termination should be stated. **The HAC**

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Form 107, Clinical Study Status Report, will be returned to the PI and may be allowed to expire if a brief study report is not completed as requested.

Are There Any Examples of Guidance Statements for the Brief Report Section?

"The study was not begun at the desired start date. Therefore, our enrollment goals were not met. We enrolled 12 of the projected 50. One subject was dropped from the study since the subject relocated to another area. Ten subjects have completed the study and one subject is nearing completion. There have been no unexpected adverse events or problems with this study."

Or:

"Twelve medical records were reviewed. The data were gathered and protected per the Description of Research Proposal. The poster presentation was made at the July meeting of National Principal Investigators. The study is now complete."

NOTE: The above examples are suggestions to assist the investigators. Please be as informative as possible when completing the report section. Use of these guides does **not** guarantee that the HAC will approve the continuation request.

Are Other Approvals Required?

If the study involves the use of MCGHI resources (equipment, personnel, patients, space, supplies and/or records) and has a new impact on the budget that was originally approved by MCGHI via the OCIS HSRO, the [HAC Form 107](#), Clinical Study Status Report, and all supporting documentation must be submitted to the OCIS HSRO for their review prior to HAC approval.

What About the Education Program?

Members of the research team who have not successfully completed the appropriate tiers of the required web-based education program or the recertification program must complete the program prior to the HAC Form 107 due date or the continuation request will not be processed. Individuals who fail to cooperate with the education program requirements must be removed from the study via the HAC Form 113, Amendment Submission Form, and may not conduct any research-related procedures after that time.

Are There Any Other Documents That Should Be Submitted with the Completed HAC Form 107, Clinical Study Status Report?

Informed Consent Document (ICD)/Children's Assent Document (CAD)

A "clean" unstamped version of the ICD and/or CAD must be submitted with the [HAC Form 107](#), Clinical Study Status Report, for those studies that are still actively enrolling subjects. A "clean" version means without the HAC approval stamp. This clean copy is required so that the

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HAC can stamp it approved. The HAC Administrative Office will maintain the original and a copy will be returned to the PI or designee if approved for continuation. In compliance with federal regulations, each ICD and/or CAD will be reviewed and stamped approved as necessary. It is strongly recommended that the version date should be revised to reflect the current submission date.

Advertisements/Recruitment Plans

If a study has an approved advertisement and will continue to recruit subjects, then a “clean” unstamped copy of the advertisement must be submitted with the HAC Form 107, Clinical Study Status Report. A “clean” version means without the HAC approval stamp. This clean copy is required so that the HAC can stamp it approved. The HAC Administrative Office will maintain the original and a copy will be returned to the PI or designee if approved for continuation. In compliance with federal regulations, each advertisement will be reviewed and stamped approved as necessary. This includes brochures and pamphlets that may be given to the study subjects.

What Should I Do if Research Team Members Are No Longer on this Protocol?

Submit a completed HAC Form 113, Amendment Submission Form, to remove the research team members from the study. Please follow all policies and note that other forms or documentation may be necessary.

What Should I Do to Add New Research Team Members to the Protocol?

Submit a completed HAC Form 113, Amendment Submission Form, HAC Form 102, Request for Personnel Change in Research Team, and HAC Form 106, Delegation of Duties, to add new research team members to the study. Please follow all policies. Other forms may be necessary.

CVs/Résumés

Submit a currently dated and preferably signed CV or résumé must also be on file with the HAC Form 107, Clinical Study Status Report, if one is not on file with the HAC for all approved members of the research team.

We Are Conducting a Study That Will Use Investigators Off-Site (that is, not MCG or MCGHI, etc). Do we need to submit a copy of their CV to the HAC?

No. Only those investigators with MCG or MCGHI affiliations must submit their dated and preferably signed CV or résumé.

I Submitted A Protocol Last Month For My Investigator With Five Copies Of the CV/ Résumés. Do I Have To Submit This Again This Month?

No. One copy of the dated and preferably signed CV or résumé should be submitted on an annual basis.

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Should I Keep Copies of this Submission Packet to the HAC?

Retain a copy of the completed HAC Form 107, Clinical Study Status Report, and any support documentation (e.g., 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 PI.

Who Reviews the HAC Form 107, Clinical Study Status Report?

The HAC Administrative Office performs the initial review of the HAC Form 107 and the investigator will be contacted if the form is incomplete.

If the form is complete, the HAC Administrative office will forward the HAC Form 107 to the Chairperson or his designee to review.

Can Continuing Review Fall Under the Expedited Criterion?

Yes. If the protocol was originally reviewed as exempt or expedited and continues to qualify as such, then the Chairperson or designee will review the HAC Form 107 and/or attachments (e.g., advertisement, informed consent document, etc.). If approved, these results are reported to the full Committee at the next HAC meeting via the agenda.

If the protocol was originally reviewed as full review and may now be reviewed via the expedited method, the Chairperson or designee will review the submission. If approved, these results are reported to the full Committee at the next HAC meeting via the agenda.

8. Continuing review of research previously approved by the convened IRB as follows where:
 - (i) The research is permanently closed to the enrollment of new subjects;
 - (ii) All subjects have completed all research-related interventions; and
 - (iii) The research remains active only for long-term follow-up of subjects; or
 - (iv) Where no subjects have been enrolled and no additional risks have been identified; or
 - (v) Where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

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¹ *Children are defined in the DHHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a).*

What Will Determine if the Continuing Review Should be Conducted as a Full Review?

If the protocol was originally reviewed as full review and continues to require full review, the Chairperson and an additional HAC member will review the submission and will then forward the HAC Form 107 and/or attachments to the full Committee for review.

What if the HAC Needs Additional Information After Reviewing My Completed HAC Form 107?

The HAC will approve the protocol for continuing review on contingent basis pending the satisfactory response by the investigator. The approval will be held until the requested items are received. This approval will be for a defined time period and may be extended upon receipt of the requested items. If the requested items are not received in a timely manner, the convened HAC may disapprove the protocol.

When Can I Expect the HAC Determination Letter For The Continuation?

The HAC meetings are held on the fourth Monday of each month, unless otherwise designated. Therefore, the letters should go out via campus mail, no later than the Monday following the meeting.

Why Do We Have To Have The Informed Consent Document And/Or Children's Assent Document Reviewed And Approved During The Continuing Review Time?

If the protocol is still recruiting subjects, then the ICD and/or CAD must be reviewed and approved. As part of the continuing review each protocol must be reviewed and approved by the IRB as outlined by the Food and Drug Administration and the Office for Human Research Protections. Each informed consent document (ICD) and/or children's assent document (CAD) will be reviewed and stamped approved, as appropriate.

What If The HAC Requires Changes To The Protocol As A Result Of Continuing Review?

The investigator must ensure that the sponsor and/or the FDA and the NIH are informed of actions, if any, taken by the HAC as a result of its continuing review. The HAC may set conditions under which a protocol can be approved for continuing review. If the conditions are substantive regarding the protocol or informed consent process/documents then the approval must be deferred until the next convened HAC meeting. If the conditions are not substantive

Are There Any General Tips And Hints For The Continuing Review Process And HAC Form 107?

HAC Policies and Procedures

- Start the process early and ask questions!
- Prepare a reminder on your calendar indicating the HAC approval expiration date.
- Keep a copy of the submitted materials.
- Request a list of studies from the HAC Administrative Office, if needed.

Who Do I Contact if I Have Any Questions?

Contact the HAC Administrative Office at 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.