

HAC Policies and Procedures for HAC Members and OHRP Staff

Continuing Review

What about the Considerations for Continuing Review?

The HAC must determine if:

- Verification is to be obtained from sources other than the investigator that no material changes have taken place since prior HAC review
- Has information arisen that might affect the willingness of participants to continue to take part in the research?
 - If yes, will the information be provided to those subjects?

What Documents do the Primary Reviewers Receive for Continuing Expedited Review?

The HAC Chairperson or designee serves as the primary reviewer and receives the following information for review:

- HAC Reviewers' Checklist
- HAC Form 107, Clinical Study Status Report:
 - Research team personnel to include their demographic and education information
 - Amendment description and approval dates
 - Continuation history (if applicable)
 - Protocol deviation/violation history
 - Adverse event/serious adverse event listing
 - IND safety report summary, if applicable
 - Unanticipated problems, if applicable
 - Relevant recent literature
 - Interim findings
 - Relevant multi-center trial reports
 - Summary of any subject withdrawals and the reasons for those withdrawals
 - Summary of any complaints about the research
 - Number of subjects to include the minority status
 - Number of subjects to include the members of the vulnerable populations
 - A current version of the Description of Research Proposal that has been reviewed by the PI to ensure it is an up-to-date description of the conduct of the protocol from a human subjects protection perspective.
 - Informed Consent Document and/or Children's Assent Document currently in use by the Principal Investigator
 - Informed Consent Document and/or Children's Assent Documents that are newly proposed, if applicable
 - Recruitment Plan Materials to include any advertisements or announcements that may be used, if applicable
 - The grant annual status report, if applicable, regardless of funding source
 - Any letters or memoranda for all Committee members to review
 - If investigator-initiated, a copy of the data capture forms if not submitted at the time of initial review or if the forms were changed

What Documents do the HAC Members Receive for Continuing Full Review?

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The following documents are scanned and placed on a common computer drive for review. HAC members that do not have access to the common computer drive receive the following information in their submission packets:

- HAC Reviewers' Checklist
- HAC Form 107, Clinical Study Status Report:
 - Research team personnel to include their demographic and education information
 - Amendment description and approval dates
 - Continuation history (if applicable)
 - Protocol deviation/violation history
 - Adverse event/serious adverse event listing
 - IND safety report summary, if applicable
 - Unanticipated problems, if applicable
 - Relevant recent literature
 - Interim findings
 - Relevant multi-center trial reports
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 - The grant annual status report, if applicable, regardless of funding source
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What Documents are Available if Needed?

The following documents are available for review at the meeting if needed:

- Full sponsor's protocol
- Amendments and support documentation
- Continuing review and support documentation
- Reports of serious or continuing non-compliance
- Audit reports
- Protocol files

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What Tool Does the HAC use when HAC Approval Expires without Request for Continuing Review?

The HAC uses the “HAC Approval Expiration, Suspension or Termination Internal Routing Form” to document that necessary steps are taken when a principal investigator has not submitted a request for continuing review.

What Actions Are Taken if an Investigator did not Provide Continuing Review Information to the HAC or the HAC has not Approved a Protocol by the Expiration Date?

If the HAC does not receive the completed HAC Form 107, Clinical Study Status Report, by the due date noted on the form, then the protocol approval is allowed to expire. The Principal Investigator is notified by the HAC Administrative Office staff that:

- All activities must stop, including recruitment, advertisement, screening, enrollment, consent, interventions, interactions, and collection of private identifiable information.
- A list of subjects for whom stopping research activities would cause harm must be submitted immediately to the HAC Chairperson or designee via the HAC@mcg.edu email address for all researchers including those who conduct research at the Charlie Norwood VA Medical Center.

The HAC Chairperson or designee review the protocol and the list of subjects to determine if the interventions and interactions on current subjects continue only when the HAC finds and determines an over-riding safety concern or ethical issue involved such that it was in the best interests of individual subjects. If the protocol is allowed to continue, then the PI must submit a protocol submission packet in compliance with the submission processes.

If there are issues related to continuing review and the HAC has not approved a protocol by the expiration date, then the protocol approval expires and the protocol approval is allowed to expire. The Principal Investigator is notified by the HAC Administrative Office staff that:

- All activities must stop, including recruitment, advertisement, screening, enrollment, consent, interventions, interactions, and collection of private identifiable information.
- A list of subjects for whom stopping research activities would cause harm must be submitted immediately to the HAC Chairperson or designee via the HAC@mcg.edu email address for all researchers including those who conduct research at the Charlie Norwood VA Medical Center.

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