

HAC Policies and Procedures for HAC Members and OHRP Staff

Minutes Documentation

Who Prepares the HAC Meeting Minutes Documentation?

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

How is the Attendance of Members Documented?

The HAC Administrative Office prepares a spreadsheet based on the current HAC roster for each meeting. If members will be absent and an alternate will attend in their stead, this is noted in the discussion portion of the agenda and on the spreadsheet. If the member and the alternate are absent, this is noted in the discussion portion of the agenda and on the spreadsheet. The spreadsheet is also used to track members, alternates and staff as they enter and exit the room as well as any guests who may attend. This spreadsheet is attached to the minutes of the meeting and filed in the HAC Administrative Office. The current roster is also attached to the minutes of the meeting.

How are Late Arrivals or Early Departures of HAC Members Managed?

Late arrivals or early departures of HAC members are managed by the HAC Chairperson or Vice-Chairperson. The agenda lists all protocols to be reviewed as well as any absences or attendance needs of the committee members. The order of the agenda items may be shifted as needed to ensure that the primary reviewers are present. The minutes and the attendance sheet document the management of this issue.

What are the Levels of Approval for the Meeting?

Protocols may be approved, have deferred approval, tabled or disapproved. It is important that the various factors be balanced with regard to providing appropriate subject protections without unnecessarily delaying the project. The pathway followed is a judgment call by the primary reviewers and the full committee. It is based upon whether adequate information was provided by the principal investigator to the Committee to permit full evaluation of the protocol with regard to human subjects' protection issues. There may be issues that will improve the overall submission but do not directly impact on the ability of the Committee to evaluate the study. Therefore, the following guidance is provided, recognizing that these decisions are based upon the judgment of the committee and cover a wide spectrum.

What is Approved?

Protocols that receive full approval do not require any additional changes.

What is Deferred Approval?

Most protocols fall into this category. The approval is deferred pending a satisfactory response from the PI to the HAC's requests for changes or clarifications (i.e., stipulations) to address deficiencies found in the protocol submission packet. The changes or clarifications requests most frequently pertain to components of the Description of Research Proposal (DRP), Informed Consent Document (ICD), Children's Assent Document (CAD), HAC forms, and Regulatory Issues.

What are Minor Revisions?

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These involve clarifications of procedures or situations that do not involve subject safety. These revisions can permit approval following review of the responses by the Chairperson or designee.

What are Major Revisions I?

These involve significant issues relating to subject safety or study design. The responses from the Principal Investigator (PI) are sent to primary reviewers who bring the responses to the next Committee meeting for discussion. Risk-benefit determination cannot be made as these become major revisions that require committee re-review at the next convened meeting.

What are Major Revisions II?

These involve clarification of specific major issues in the protocol that involve study design or procedures. The responses from the PI will be circulated to the primary reviewers and the entire Committee. If the responses are satisfactory to the majority of the Committee, then HAC approval is granted by the Chairperson or designee and these responses are not returned to the convened meeting. The Committee is notified of the final decision by the agenda.

When are these Decisions Made?

The decision for the appropriate pathway is made by the Committee at the time of initial review.

Are There Examples of Items that May fit into the Above Categories?

Description of Research Proposal (DRP): There must be adequate information provided to permit the reviewers/Committee to understand the background/rationale for the study, the selection of the subject population and the risks and benefits. Questions as to the adequacy in these categories will be determined by the Committee and a decision rendered. The follow-up procedures may fit in any of the above categories and may, at the discretion of the Chairperson or designee, be moved to a more stringent category, depending upon the response. They will not be moved to a less stringent category.

Informed Consent (IC)/Children's Assent (CA) Document (D): The degree of deficiency will vary considerably determining the level of re-review as follows:

- The Chairperson or designee may review the revised Informed Consent (IC)/Children's Assent (CA) Document (D) or
- The primary reviewers [and IT and Privacy Officer(s) if necessary] followed by that of the Chairperson or designee with subsequent approval by that individual on behalf of the full Committee may also require review

At the discretion of the Chair/person or designee, they may be moved to a more stringent category, depending upon the response. They will not be moved to a less stringent category.

HAC Forms: Due to a lack of understanding by the research team member, these problems generally result in incorrect or incomplete information. These responses will be reviewed by the Chairperson or designee and the Privacy Officer and/or IT reviewer if appropriate and approved by the Chairperson or designee on behalf of the convened Committee.

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Regulatory Issues: These problems usually relate to missing or inadequate information regarding FDA information, Conflict of Interest, and Institutional Policies and Procedures. These will usually be resolved by the Chairperson or designee, in consultation with institutional and/or Federal Officials as necessary. They may be brought to the convened Committee if necessary.

What is a Tabled Protocol?

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

What Does the HAC Document in the Meeting Minutes?

HAC meeting minutes document the following:

- Education and training topic for the meeting
 - Guests who attended the meeting
 - Reminders about confidentiality of the HAC meetings
 - Information only items
 - Absence of an HAC member
 - An alternate member serving instead of the regular member
 - Any suspension and terminations by the HAC Chairperson
 - Serious and continuing non-compliance and the management plan of those incidents, as appropriate
 - Votes for each protocol as numbers for, against, or abstaining.
 - Actions taken by the HAC
 - Separate deliberations for each action
 - The basis for requiring changes in research if applicable
 - The basis for disapproving research if applicable
 - A written summary of the discussion of controverted issues and their resolution
 - Justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document
 - The names of HAC members, consultants or special expertise that left the meeting because of a conflicting interest, along with the fact that a conflicting interest was the reason for the absence.
 - For initial and continuing review, the approval period.
 - Determinations required by the regulations and protocol-specific findings justifying:
 - Waiver or alteration of the consent process
 - Research involving pregnant women, fetuses, and neonates.
 - Research involving prisoners
 - Research involving children
 - For VA research:
 - The approval of research contingent on specific minor conditions by the HAC Chairperson or designee, to be documented in the minutes of the first HAC meeting that took place after the date of the approval.
 - The determination of the level of risk.
- (1) Activities related to pregnant women must not be undertaken unless:
- (a) Except if appropriate studies on animals and non-pregnant individuals have been completed, and data for assessing potential risks to pregnant women and fetuses is provided.

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(b) The purpose of the activity is to meet the health needs of the mother or the particular fetus, the risk to the fetus is minimal, and, in all cases, is the least possible risk for achieving the objectives of the activity.

(c) Individuals engaged in the activity will have no part in:

1. Any decisions as to the timing, method, and procedures used to terminate the pregnancy; or
2. Determining the viability of the fetus at the termination of the pregnancy.
3. Introducing any procedural changes, for research purposes, into the procedures for terminating the pregnancy.

(2) No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of research activity

(3) No pregnant woman may be involved as a subject in a research activity unless:

(a) The purpose of the activity is to meet the health needs of the mother, and the fetus will be placed at risk only to the minimum extent necessary to meet such needs; or

(b) The risk to the fetus is minimal.

(c) The mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if:

1. The purpose of the activity is to meet the health needs of the mother,
2. His identity or whereabouts cannot reasonably be ascertained,
3. He is not reasonably available, or
4. The pregnancy resulted from rape.

Flagging a Medical Record.

The HAC must determine if the patient's medical record (electronic or paper) must be flagged to protect the subject's safety by indicating the subject's participation in the study, and the source of more information on the study by using the HAC Reviewers Checklist for Research at the Charlie Norwood VA Medical Center. The HAC may not want to require the medical record to be flagged if:

(1) The subject's participation in the study involves:

(a) Only one encounter, (b) Only the use of a questionnaire, or (c) The use of previously collected biological specimens.

(2) The identification of the patient as a subject in a particular study (if the study is not greater than minimal risk) would place the subject at greater than minimal risk.

What Support Documents are Attached to the Minutes of each Meeting?

The OHRP staff attaches the following items as support documentation for each meeting to the corresponding minutes:

- HAC Member In/Out Spreadsheet:

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- Documents the attendance of the HAC Member, consultants or special expertise
- Documents arrivals and departures of each HAC Member, consultants or special expertise
- Documents the use of an alternate member attendance for a full member attendance
- HAC Member Full Review Amendment Ballot
- HAC Member Full Review Continuing Ballot
- Any reports related to suspensions or terminations
- Any audit reports that were discussed at the meeting
- Educational topic handouts
- Current HAC Roster

Can the HAC Meeting Minutes be Altered by Anyone Including a Higher Authority Once Approved by the Members at a Convened Meeting?

No. If minutes have to be altered or revised, the convened committee must approve the alterations or revisions.

When are the HAC Meeting Minutes Available for Review?

The HAC Administrative Staff strives to make the minutes available for review within 10 business days after the meeting. The minutes are not final until approved by the convened HAC. Due to the meeting schedule, this may delay the final minutes greater than three weeks.

How are the Minutes Distributed?

Minutes are distributed via email to members, advisors, OHRP staff, the institutional officials for MCG and MCGHI as well as the Deans of Allied Health Sciences, Dentistry, Graduate Studies, Medicine, and Nursing. The Vice Dean of Research for each school is also copied on the email distribution list for minutes as well as the Office of Clinical Investigative Services Health System Review Office and the MCGHI Investigational Pharmacist. The minutes are also distributed to the media relations department for confirmation that all studies that may be featured on local news stations are approved by the HAC prior to any release.

How Does the Charlie Norwood VA Medical Center Receive the Minutes and When?

The Charlie Norwood VA Medical Center is notified of the minutes via the Administrative Officer (AO) for the Research and Development Office. The Chief of Staff is also copied on the distribution list. In an effort to increase efficiency, the AO is also provided a Word version of the minutes to assist in the preparation of documents for the R&D Committee meeting. The HAC Administrative Staff strives to make the minutes available for review within 10 business days after the meeting. The minutes are not final until approved by the convened HAC. Due to the meeting schedule, this may delay the final minutes greater than three weeks.

Whose is Responsible for the Retention of the Original Minutes?

It is the responsibility of the OHRP Assistant Director to retain the original meeting minutes and support documentation as provided by the OHRP Office Specialists assigned to the meeting.