

## **HAC Policies and Procedures for HAC Members and OHRP Staff**

### **Expedited Review**

#### **What is the Process Followed by Reviewers to Evaluate Whether Research Undergoing Initial Review and Continuing Review Using the Expedited Procedure?**

The regulations allow expedited review procedures for certain kinds of research involving no more than minimal risks (the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [45CFR46.102(I) and 21CFR 56.102(I)]), for minor changes in approved research, and for certain categories of continuing review. These procedures are aligned with initial review of a protocol, review of amendments and continuing review.

Projects reviewed by this procedure require a complete application and are reviewed by the HAC Chairperson, or by one or more experienced reviewers who have been voting members for more than one year and have expertise in the area being considered. The HAC Chairperson will designate the individual(s). The investigator must include information in the Description of Research Proposal (DRP) as to why they feel that the submitted protocol meets the regulatory requirements for expedited review. The Principal Investigator (PI) may request expedited review but the Chairperson or his designee will make this final determination.

Research activity that presents no more than minimal risk to human subjects and involves procedures listed in one or more of the following categories may be reviewed by the HAC through the expedited review procedure. [63FR 60364-60367, November 9, 1998]

#### **What Documents are Required for Initial Expedited Review?**

The following documents are required:

- HAC Reviewers' Checklist for Expedited Review
- HAC Form 100, Clinical Study Document Cover Sheet
- HAC Form 101, Protocol Information
- Description of Research Proposal
- Complete sponsor provided protocol, if applicable
- Complete DHHS-Approved Protocol, if applicable
- Informed Consent Document and/or Children's Assent Document
- DHHS-Approved Informed Consent Document, if applicable
- Any questionnaires that may be used, if applicable
- Recruitment Plan Materials to include any advertisements or announcements that may be used, if applicable
- The entire grant application, if applicable regardless of funding source
- HAC Form 103, Human Biological Specimens for Genetic Research, if applicable
- Any letters or memoranda for all Committee members to review
- If investigator-initiated, a copy of the data capture forms

#### **What Tools are Available to the HAC Reviewer for Expedited Review?**

The HAC Chairperson or designee use the Expedited Review checklist to review the packet of information submitted by the Principal Investigator. The HAC Chairperson or designee must

## HAC Policies and Procedures for HAC Members and OHRP Staff

confirm that the protocol may be reviewed under the expedited review procedures because it involves no more than minimal risk to subjects.

The expedited review criteria are:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) Research on medical devices for which (a) an investigational device exemption application (21 CFR Part 812) is not required; or (b) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick or venipuncture as follows: from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 450 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or from other adults and children<sup>1</sup>, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects.45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance

### **Who is Responsible for Determining if the HAC Chairperson or Designee Have a Conflict of Interest Regarding the Expedited Review of a Protocol?**

The HAC Chairperson or designee must determine if they have a conflict of interest regarding the protocol as defined by the MCG Conflict of Interest Policy.

## **HAC Policies and Procedures for HAC Members and OHRP Staff**

### **Who is Responsible for Declaring a Conflict of Interest and to Whom is the Conflict Reported for an Expedited Review of a Protocol?**

If a conflict of interest is noted, then the individual must declare that conflict immediately to the OHRP Director and the Conflict of Interest panel.

### **What Must the HAC Chairperson or Designee Determine when Reviewing a Protocol for Expedited Review?**

The HAC Chairperson or designee must review the protocol to determine the following:

- Physical, psychological, social, legal, and economic risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk
- Physical, psychological, social, legal, and economic risks to participants are minimized whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes
- Physical, psychological, social, legal, and economic risks are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.
- Selection of subjects is equitable
- There are adequate provisions to protect the privacy of subjects
- There are adequate provisions to maintain the confidentiality of the data.
- Additional safeguards have been included in the study to protect the rights and welfare of participants likely to be vulnerable to coercion or undue influence

### **What must the HAC Chairperson or Designee Review for the Informed Consent Process and the Documentation of Informed Consent for Expedited Review?**

The HAC Chairperson or designee must review the informed consent process and the documentation of the informed consent for expedited review using the Expedited Review Checklist to determine the following:

Will the informed consent process will be waived (*See Checklist of Criteria to Waive or Alter the Requirement to Obtain Informed Consent*)

OR

Will the requirement for written documentation will be waived (*See Checklist of Criteria to Waive the Requirement for Written Documentation of Informed Consent*)

OR

Informed consent will be sought from each prospective subject or the subject's representative in accordance with the regulations as follows:

- The investigator will obtain the legally effective informed consent of the subject or the subject's legally authorized representative
- The circumstances of consent provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate
- The circumstances of consent minimize the possibility of coercion or undue influence
- The information that will be given to the participant or representative will be in language understandable to the subject or the representative

## HAC Policies and Procedures for HAC Members and OHRP Staff

- No information will be provided to the subject or the representative that waives or appears to waive any of the subject's legal rights, or that releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence
- All required and appropriate additional disclosures will be provided to the subject or the subject's representative. *(See Elements of Informed Consent Disclosure)*
- Informed consent will be documented in writing in accordance with the regulations
  - The consent document embodies the basic and appropriate additional elements of disclosure. *(See Elements of Informed Consent Disclosure)*
  - The participant or the participant's legally authorized representative will sign the consent document.
  - If the research is FDA-regulated, the participant or the participant's legally authorized representative will sign and date the consent document.
  - A copy of the consent document will be given to the person signing the consent document.
  - For VA research, a copy of the signed and dated consent document will be given to the person signing the consent document.
  - The investigator will give either the participant or the representative adequate opportunity to read the consent document before it is signed.

### **What Are the Elements of Informed Consent Disclosure?**

The elements of informed consent disclosure are:

- A statement that the study involves research.
- An explanation of the purposes of the research.
- An explanation of why the subject is invited to participate in the research.
- An explanation of the expected duration of the participant's participation.
- A description of the procedures to be followed.
- The approximate number of participants involved in the study.
- Identification of any experimental procedures. *(May be omitted if there are none.)*
- A description of any reasonably foreseeable risks or discomforts to the participant. *(May be omitted if there are none.)*
- A statement that the particular treatment or procedure may involve risks to the participant, which are currently unforeseeable.
- A statement that if the participant is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable. *(Look for when the research involves pregnant women or women of childbearing potential, and the effect of the procedures have not been evaluated in pregnancy or a goal of the research is to define safety in pregnancy.)*
- A description of any benefits to the participant or to others, which may reasonably be expected from the research.
- A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant. *(Look for this on long-term clinical trials.)*
- An explanation of whom to contact for answers to pertinent questions about the research.
- An explanation of whom to contact about concerns or complaints about the research study.
- An explanation of whom to contact for answers to pertinent questions about the research participants' rights (George S. Schuster, DDS, PhD at 706-721-2991).

## HAC Policies and Procedures for HAC Members and OHRP Staff

- An explanation of whom to contact in the event of a research-related emergency.
- A statement that participation is voluntary.
- A statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled.
- A statement that the participant can discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.
- Any additional costs to the participant that may result from participation in the research. *(Look for when additional costs are expected.)*
- An explanation of whether the subject will be paid/reimbursed for their participation in the research.
- Inclusion of Statement of Privacy Notice
- An explanation as to whether compensation is available when injury occurs, an explanation as to what it consists of or where further information may be obtained. *(May be omitted if the research involves no more than minimal risk.)*
- An explanation as to whether any medical treatments are available if injury occurs and what it consists of or where further information may be obtained *(May be omitted if the research involves no more than minimal risk.)*
- A statement that notes the possibility that the Food and Drug Administration may inspect the records. *(May be omitted for research that is not subject to FDA regulations.)*
- A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained. *(May be omitted if confidentiality will not be maintained.)*
- Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent. *(Look for when the protocol mentions this as a possibility.)*
- The consequences of a participant's decision to withdraw from the research. *(Look for when withdrawal from the research will have adverse consequence.)*
- Procedures for orderly termination of participation by the participant. *(Look for when such procedures are part of the protocol.)*
- Is there a description of the protected health information (PHI) to be used or disclosed, identifying the information in a specific and meaningful manner?
- Are the names or other specific identification of the person or persons (or class of persons) authorized to make the requested use or disclosure clearly designated?
- Are the names or other specific identification of the person or persons (or class of persons) clearly designated, indicating to whom MCG Health Systems may make the requested use or disclosure?
- Is there a description of each purpose of the requested use or disclosure?
- Is there an Authorization expiration date or expiration event for the duration that relates to the individual or to the purpose of the use or disclosure? (Note: "end of the research study" or "none" are permissible for research, including for the creation and maintenance of a research database or repository.)
- Is there a signature and date line for the individual or their legally authorized representative to sign and date?

## HAC Policies and Procedures for HAC Members and OHRP Staff

- Is there also a line to indicate a description of the representative's authority to act for the individual?
- Required Statements:
- Is there a statement indicating the individual's right to revoke the Authorization and how to do so?
- Is there a statement that indicates whether treatment, payment, enrollment, or eligibility can be conditioned upon signing the Authorization and consequences of refusing to sign the Authorization (i.e., may not participate in the research)?
- Is there a disclaimer statement of the potential risk that PHI may be re-disclosed by the recipient and thus may no longer be protected the Privacy Rule?
- Is there a statement indicating whether the individual's access to his/her health record is suspended during participation in the clinical trial and, if so, that it will be restored upon conclusion of the clinical trial?
- An explanation about who to contact concerning the privacy of the subject's information: MCG Privacy Officer, Christine Adams at (706) 721-5631, or the Toll Free Hotline, 1-800-576-6623.
- Does the advertisement state or imply a certainty of favorable outcome or other benefits beyond what was outlined in the consent document and the protocol?
- Does the advertisement include exculpatory language?
- Does the advertisement emphasize the payment or the amount to be paid, by such means as larger or bold type?
- Does the advertisement promise "free treatment" when the intent was only to say participants would not be charged for taking part in the investigation
  - Does the advertisement make claims, either explicitly or implicitly, about the drug, biologic or device under investigation that were inconsistent with FDA labeling?
  - Does the advertisement use terms, such as "new treatment," "new medication" or "new drug" without explaining that the test article was investigational?
  - Does the advertisement allow compensation for participation in a trial offered by a sponsor to include a coupon good for a discount on the purchase price of the product once it had been approved for marketing?

### **How is it Determined how Often Review should be Obtained more than Annually and how Often for Expedited Protocols?**

This decision is based on the degree of risk assigned to the protocol.

### **How is the Risk Determination made for Expedited Protocols?**

The risk determination is made by the HAC Chairperson or designee as minimal risk or greater than minimal risk.

### **What about the Considerations for Continuing Review for Expedited Protocols?**

The HAC Chairperson or designee 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

## **HAC Policies and Procedures for HAC Members and OHRP Staff**

- 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 about the Considerations for Review of Amendments for Protocols that Undergo Expedited Review?**

The HAC Chairperson or designee must determine if:

- Information has arisen that might affect the willingness of participants to continue to take part in the research?
- Is there indication that a change was made without prior HAC approval to eliminate apparent immediate hazards to participant?
  - If yes, is the change consistent with ensuring the subject's continued welfare?

### **Are There any Special Requirements for Expedited Reviews that may be Conducted at the Charlie Norwood Veterans Affairs Medical Center?**

Yes. The HAC Chairperson or designee must review each protocol that will be conducted at the Charlie Norwood Veteran Affairs Medical Center to determine the following:

- Is tissue banking involved?
  - If tissue banking is involved, does the DRP indicate that tissue will be stored in a VA approved tissue bank?
- Are there data mining/warehousing issues?
- Is there assurance that non-veteran subjects will be enrolled in the research **only** when there are insufficient veterans to participate in the research?
- Payment of Research Subjects (The HAC may not approve paying subjects to participate in research when the research is integrated with a patient's medical care and when it made no special demands on the patient beyond those of usual medical care)
  - Payment of subjects is permissible according to one of the following criteria which apply to the research:
    - The research is not directly intended to enhance the diagnosis or treatment of the medical condition for which the participant was being treated, and when the standard of practice in affiliated non-VA organizations was to pay participants in this situation.
    - The research was a multi-institutional study and participants at collaborating non-VA organizations were paid for the same participation in the same study at the same rate proposed;
    - Payment of participants would be appropriate in other comparable situations;
    - The participant incurred transportation expenses that would not be incurred in the normal course of receiving treatment and were not reimbursed by another mechanism.
- Should the medical record for each subject be flagged to indicate participation in the study and the source of any more information for the study?
- Is there indication that a copy of the signed and dated consent document will be given to the person signing the consent document?

## **HAC Policies and Procedures for HAC Members and OHRP Staff**

### **Are There any Special Requirements for Expedited Reviews Involving an Informed Consent Document that may be Conducted at the Charlie Norwood Veterans Affairs Medical Center?**

Yes. The HAC Chairperson or designee must review each protocol that will be conducted at the Charlie Norwood Veteran Affairs Medical Center to determine the following:

- Will consent be obtained using the VA Form 10-86?
- Is there a signature and date line for the subject or the subject's legally authorized representative?
- For the witness signature: is there a note under the signature line explaining the role of the witness to the consenting process and subject's signature?
- Does the ICD include a statement that in the event of a research-related injury the VA will provide necessary medical treatment to a participant injured by participation?
- Does the ICD include a statement that a veteran-participant will not be required to pay for care received as a participant in a VA research project except in accordance with federal law and that certain veterans were required to pay co-payments for medical care and services provided by VA?

### **What do the HAC Members Review the Description of Research Proposal (DRP) to Determine if the Study is a Multi-Center Trial in which the Principal Investigator is the Lead Investigator?**

The HAC reviews the DRP to determine if there is an assurance which adequately describes how the following information from sites will be managed.

### **Can the HAC Chairperson Disapprove a Protocol Regardless of Level of Review?**

No. The HAC Chairperson may not disapprove a protocol. All disapprovals, regardless of level of review, must be determined by the full committee.