

HAC Policies and Procedures

Expedited Review

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.

Approval may be granted, but the Chairperson or his designee may not disapprove the research; only the fully convened Committee can exercise disapproval.

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]

Criteria for expedited review:

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 children¹, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with

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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. Examples include:
 - a) Hair and nail clippings in a non-disfiguring manner;
 - (b) Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; permanent teeth if routine patient care indicates a need for extraction;
 - (c) Excreta and external secretions (including sweat);
 - (d) Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
 - (e) Placenta removed at delivery;
 - (f) Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
 - (g) Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
 - (h) Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
 - (i) Sputum collected after saline mist nebulization.
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.)

Examples:

Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;

Weighing or testing sensory acuity;

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Magnetic resonance imaging (MRI);

Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography;

Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual

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 methodologies.

(NOTE: Some research in this category may be exempt from the DHHS regulations for the protection of human subjects [45 CFR 46.101(b) (2) and (b) (3)] but are not exempt from HAC review. This listing refers only to research that is not exempt.)

Who Decides If The Protocol Is Eligible For Expedited Review?

The investigator may request expedited status but the final decision lies with the HAC. If appropriate, the HAC will send the investigator a letter stating that the study was examined and found to be appropriate for expedited review. No studies may be conducted without the letter signed by the HAC Chairperson or his designee. Occasionally a protocol that is submitted for expedited review must be reviewed via the full Committee review procedure. If this occurs, the PI and/or research team is notified by an email from the HAC Administrative Office.

When Are The Protocols Approved By The Expedited Procedure Reported To The Full HAC?

Protocols approved by the expedited review procedure are reported to the full Committee at the earliest regularly scheduled Committee meeting via the meeting agenda. Please be aware that the Committee may request additional forms, information and copies.

What Do I Submit For Expedited Review Protocols?

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For protocols that meet the Expedited Review Criteria, please see the table for required forms, support documents, number of copies and submission deadlines.

We Are Conducting A Study That Will Use Investigators Off-Site (That Is, Not MCG, VAMC, Etc). Do We Need To Submit A Copy Of Their CV or Résumé To The HAC?

No. Only those investigators with MCG, MCGHI or the Augusta VAMC 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. The investigator's CV or résumé must be updated and forwarded to the HAC on an annual basis. The CV or résumé must be dated and preferably signed by the individual. Only one copy of the CV or résumé should be submitted.

Can the HAC Administrative Office Pre-Review My Submission for Expedited Review?

Yes. Contact the HAC Administrative Office staff as listed below.

What Should I Expect After I Submit to the HAC?

Communication

Initially, you will receive an email from the HAC Administrative Office indicating the HAC file number for your protocol once the protocol is accepted for processing. You may then receive emails requesting additional information or clarification. And lastly, you will receive a letter with the HAC approval information if the protocol is approved.

HAC File Number

Each new protocol is assigned a distinct HAC file number (year, month, number of protocols received in the fiscal year). This number, along with the last name of the PI, is used to track all documents and actions related to the study. When requesting information or action for a study, always refer to the HAC file number and the last name of the PI.

What's the Average Turnaround Time for Expedited Review Studies?

The average turnaround time for expedited review studies from HAC receipt to HAC approval is approximately 10 days.

Can I Start My Study Before I Receive HAC Approval?

No. Other approvals may be necessary prior to initiation.

What Is the Contact Information for the HAC Administrative Office Staff?

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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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