



**Walter Reed Army Institute of Research
Standard Operating Procedure**



SOP Title	EXPEDITED HUMAN SUBJECTS RESEARCH PROTOCOL REVIEW	SOP No.	UWS-HP-613-A-
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Appendix A - Expedited Review Categories

1. Explanation of Expedited Review:

To qualify for expedited review, an activity must (1) present no more than minimal risk to human subjects, in accordance with the categories listed below or (2) be a minor change to previously approved research, no more than one year past the IRB approval date.

For purposes of this SOP an 'activity' is defined as an initial research submission, an amendment to current approved research, a request for continuation determination (Continuing Review) or a Closeout Report.

a. Expedited Review Categories

Expedited review categories are specified in 63 Federal Register (FR) 60364-60367, 9 November 1998 (*List of Categories That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure*). Activities that may receive expedited review should not be deemed to be minimal risk simply because they are included on the list. Inclusion on the list merely means that the activity is eligible for review through the expedited review procedure when specific circumstances of the proposed research involve no more than minimal risk to human subjects. The categories are:

Category 1: Clinical studies of drugs and medical devices when condition (a) or (b) is met:

- a) Research on drugs for which an investigational new drug application (21 CFR 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) or
- b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Category 2: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:



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- a) From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
- b) From other adults and children, 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.

Category 3: Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

- a) Hair and nail clippings in a nondisfiguring manner;
- b) Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
- c) Permanent teeth if routine patient care indicates a need for extraction;
- d) Excreta and external secretions (including sweat);
- e) Uncannulated saliva collected in an unstimulated fashion or by chewing gum base or wax or by applying a dilute citric solution to the tongue;
- f) Placenta removed at delivery;
- g) Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
- h) Supra- and sub gingival 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;
- i) Mucosal and skin cells collected by buccal scraping or swab, skin swab, mouth washings; and
- j) Sputum collected after saline mist nebulization.



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Note: OHRP/FDA (HRP-313, 4 October 2010) Clarification of “noninvasive” under this category: The following procedures are considered noninvasive:

- a) Vaginal swabs that do not go beyond the cervical os;
- b) Rectal swabs that do not go beyond the rectum; and
- c) Nasal swabs that do not go beyond the nares.

Category 4: Collection of data through noninvasive procedures (not involving general anesthesia or sedation) and minimal impact 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:

- a) 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;
- b) Weighing or testing sensory acuity;
- c) Magnetic resonance imaging;
- d) Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; and
- e) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

Category 5: Research involving materials (data, documents, records, or specimens) that:

- a) Have been collected; or
- b) Will be collected solely for non-research purposes (such as medical treatment or diagnosis).



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Note: Some research in Category 5 may be exempt from the HHS regulations for the protection of human subjects (45 CFR 46.104(d)). This listing refers only to research that is not exempt.

Category 6: Collection of data from voice, video, digital or image recordings made for research purposes.

Category 7: Research on:

- a) 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
- b) 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 HHS regulations for the protection of human subjects (45 CFR 46.104(d)). This listing refers only to research that is not exempt.

Category 8: Continuing Review of research previously approved by the convened IRB as follows:

- a) 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
- b) Where no subjects have been enrolled and no additional risks have been identified; or
- c) Where the remaining research activities are limited to data analysis.

Category 9: Continuing review of research, not conducted under an investigational new drug (IND) application or investigational device exemption (IDE) where categories (2) through (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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2. In the following situations minor changes to previously approved research, during the period within one year of the date when approval was authorized, may be reviewed by expedited procedures:
 - a. Studies may be approved for implementation following the IRB Chair's administrative review of responses submitted to comply with the stipulations of the IRB (i.e. protocols approved pending receipt of specific modifications or additional information); or
 - b. Administrative amendments, minor modifications to an already approved protocol or consent form, additional versions of approved consent forms, recruitment posters or advertisements, and a change in investigator if the IRB Chair finds that the change(s) would have no significant impact on the conduct of the study or pose a detriment to the already approved plan for protection of human subjects.