



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



SOP Title	EXPEDITED HUMAN SUBJECTS RESEARCH PROTOCOL REVIEW	SOP No.	UWS-HP-613-A- B
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Appendix B - Checklist for WRAIR IRB Determination of Expedited Review Eligibility and Expedited Review Category Selection

Instructions: Use this checklist when making the determination of whether a protocol or protocol action (e.g., amendment) qualifies for expedited review. Please note that this checklist is to be used to draw a distinction between expedited and full-board review. For Limited IRB review, please consult SOP UWS-HP-603-A6.

Expedited Review: Expedited review of human subjects research protocols and protocol actions can be conducted by the IRB Chair or other designated IRB members, instead of by the fully convened IRB.

DHHS and FDA regulations refer to two general categories that can qualify for expedited review: (1) research activities that present no more than minimal risk and are listed in a National Institutes of Health guidance document as an adjunct to the DHHS and FDA regulations (see Appendix A) and (2) “minor changes in previously approved research during the period (of one year or less) for which approval is granted”.

Research qualifying for expedited review must also meet the approval criteria defined by the Department of Health and Human Services (45 CFR 46), the Department of Defense (32 CFR 219 and DoD Instruction 3216.02) and the U.S. Food and Drug Administration (21 CFR 56), briefly summarized here:

1. Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design, and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research.) The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those criteria that fall within the purview of its responsibility.
3. Subject selection must be equitable. In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, developmentally-disabled persons, or economically or educationally disadvantaged persons.
4. Informed consent should be sought and appropriately documented unless a waiver of consent and/or documentation of consent has met the waiver criteria at 45 CFR 46. If a waiver of informed consent is granted, IRBs that also serve as privacy boards must consider the HIPAA Act or Privacy Rules as they relate to human subjects research at 45 CFR 164.512.
5. When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure subject safety.
6. The privacy of subjects and maintenance of confidentiality of data are protected.
7. When necessary, additional safeguards have been included to protect vulnerable subjects.



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1. **WRAIR #:**
2. **Protocol Title:**
3. **WRAIR Principal Investigator/POC and Branch:**
4. **Name of IRB member performing this review:**
5. **Review Type (please check):**

Initial Review Amendment Other: _____

6. **Expedited Review Eligibility Considerations:**

Section 1: Minimal Risk

Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	Does <u>any part</u> of this protocol present MORE than *minimal risk to human subjects?
		*Minimal risk means that 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.
		If you answered:
		No: this protocol meets the minimal risk requirement
		Yes: this protocol is <u>not eligible</u> for expedited review. A full board review is required.

Section 2: Risks and Protections of Identifying Participants

Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	a. Could identification of the subjects and/or their responses reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, or reputation, or be stigmatizing?
<input type="checkbox"/>	<input type="checkbox"/>	b. Will reasonable and appropriate protections be implemented so that the risk of invasion of privacy or breach of confidentiality is no greater than minimal?
		If you answered:
		No to (a) or Yes to (b) this protocol can move forward for expedited review category selection.
		Yes to (a) AND No to (b) this protocol is not eligible for expedited review. A full board review is required.



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Section 3: Vulnerable Populations N/A (if checked N/A, proceed to Item #7)

Yes	No	
		Does this protocol involve any of the below ...
<input type="checkbox"/>	<input type="checkbox"/>	Children? (complete Section 3a)
<input type="checkbox"/>	<input type="checkbox"/>	Pregnant women, fetuses, or human <i>in vitro</i> fertilization?
<input type="checkbox"/>	<input type="checkbox"/>	Developmentally-disabled or cognitively impaired persons? (complete Section 3c)
<input type="checkbox"/>	<input type="checkbox"/>	Economically or educationally disadvantaged persons?
<input type="checkbox"/>	<input type="checkbox"/>	Military Personnel? (complete Section 3d)
<input type="checkbox"/>	<input type="checkbox"/>	Other Vulnerable Adults (e.g., socially or economically disadvantaged)? (complete Section 3e)
<input type="checkbox"/>	<input type="checkbox"/>	Prisoners? (Note: Expedited Review is not allowed for this population)
		If you answered yes to any of these questions, additional considerations will need to be assessed to determine if the protocol can be reviewed by expedited review.

Section 3a: (Research Involving Children): N/A

Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	Information specifying the legal age for consent to treatments or procedures involved in the research under the applicable jurisdiction has been provided?
<input type="checkbox"/>	<input type="checkbox"/>	Overall protections for children in this research are adequate?

Comments or Concerns:

Section 3b. Child Category Determinations N/A

Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	<p>Category 1 – 45 CFR 46.404 – Research not involving greater than minimal risk with the prospect of direct benefit:</p> <p>The research is not greater than minimal risk; AND:</p> <ul style="list-style-type: none"> ▪ Permission of at least one parent will be obtained; and ▪ Assent of child will be obtained.
<input type="checkbox"/>	<input type="checkbox"/>	<p>Category 2 – 45 CFR 46.405 – Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects:</p> <p>The research involves greater than minimal risk, but presents the prospect of direct benefit to individual subjects, AND:</p> <ul style="list-style-type: none"> ▪ Risk is justified by anticipated benefit to subject; and



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		<ul style="list-style-type: none"> ▪ Benefit to risk ratio is at least as favorable as that presented by alternative approaches; and ▪ Permission of at least one parent will be obtained; and ▪ Assent will be obtained unless the benefit is not available outside the research.
<input type="checkbox"/>	<input type="checkbox"/>	<p>Category 3 – 45 CFR 46.406 – Research involving greater than minimal risk but presenting NO prospect of direct benefit to the individual subjects:</p> <p>The research involves greater than minimal risk and no prospect of direct benefit to individual subjects, but will likely yield vitally important generalizable knowledge about the subjects’ disorder or condition, AND:</p> <ul style="list-style-type: none"> ▪ Risk represents a minor increase over minimal risk; ▪ The research presents experiences reasonably commensurate with those inherent in subjects’ actual or expected medical, dental, psychological, social, or educational situations; ▪ Permission of both parents will be obtained unless either parent is not reasonably available; ▪ Assent will be obtained.
<input type="checkbox"/>	<input type="checkbox"/>	<p>Category 4 – 45 CFR 46.407 – Research not otherwise approvable:</p> <p>The research is not otherwise approvable but would help understand, alleviate, or prevent a serious child health problem and should be forwarded to the HHS Secretary or the FDA Commissioner for review.</p>

Comments or Concerns:

Section 3c (*Research Involving Subjects with Impaired Capacity for Decision-Making*):
N/A

Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	Procedures to assess subjects’ decisional capacity and understanding of the research are adequate?
<input type="checkbox"/>	<input type="checkbox"/>	Procedures for obtaining consent from legally authorized representative are adequate?
<input type="checkbox"/>	<input type="checkbox"/>	Protections for subjects with impaired decision-making are adequate?

Comments or Concerns:



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Section 3d (*Research Involving Military Personnel*): N/A

Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	Deployment of military personnel has been considered and contingency planning is appropriate?
<input type="checkbox"/>	<input type="checkbox"/>	Approval from appropriate supervisors has been obtained?
<input type="checkbox"/>	<input type="checkbox"/>	When a percentage of the unit is being recruited to participate as a group, an ombudsman (independent from the research and unit) will be present to monitor the recruitment briefings?

Comments or Concerns:

Section 3e (*Research Involving Other Vulnerable Subjects*): N/A

Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	Procedures to address subjects' vulnerabilities are included, appropriate, and adequate (e.g., provisions for coercion and operational commitments)?

Comments or Concerns:

7. Expedited Review Categories: Research that Presents No More Than Minimal Risk

CATEGORY 1	
Cat. 1	Clinical studies of drugs and medical devices only when conditions (a) or (b) are met:
<input type="checkbox"/> (a)	(a) 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) OR
or	
<input type="checkbox"/> (b)	(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR 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.
	Check if any part of this protocol falls within Category 1

CATEGORY 2	
Cat. 2	Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
<input type="checkbox"/> (a)	(a) From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 mls in an
or	



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<input type="checkbox"/> (b)	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 subject, the collection procedure, the amount of blood collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 mls or 3 mls per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
	Check if any part of this protocol falls within Category 2

	CATEGORY 3
Cat. 3	Prospective collection of biological specimens for research purposes by noninvasive means.
<input type="checkbox"/>	Examples: (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; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated 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 delivery; (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. OHRP/FDA (HRP-313, 4 October 2010) Clarification of “noninvasive” under this category: The following procedures are considered noninvasive: Vaginal swabs that do not go beyond the cervical os; Rectal swabs that do not go beyond the rectum; and Nasal swabs that do not go beyond the nares.
	Check if any part of this protocol falls within Category 3

	CATEGORY 4
Cat. 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.)
<input type="checkbox"/>	Examples:



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	<ul style="list-style-type: none"> (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 sensor 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/ flexibility testing, and body composition assessment where appropriate given the age, weight, and health of the individual.
	Check if any part of this protocol falls within Category 4

	CATEGORY 5
Cat. 5	Research involving materials (data, documents, records, or specimens) that:
<input type="checkbox"/> (a)	(a) Have been collected for some other purpose, OR
or	(b) Will be collected solely for non-research purposes (such as medical treatment of diagnosis). 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.
<input type="checkbox"/> (b)	
	Check if any part of this protocol falls within Category 5

	CATEGORY 6
Cat. 6	Collection of data from voice, video, digital, or image recordings made for research purposes.
<input type="checkbox"/>	
	Check if any part of this protocol falls within Category 6

	CATEGORY 7
Cat. 7	Research on:
<input type="checkbox"/>	<ul style="list-style-type: none"> (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.



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<input type="checkbox"/>	Check if any part of this protocol falls within Category 7
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	CATEGORY 8 – FOR GUIDANCE ONLY. SEE CRR SOP
Cat. 8	Continuing Review of research previously approved by the convened IRB as follows:
<input type="checkbox"/> (a)	(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
<input type="checkbox"/> (b)	
or	
<input type="checkbox"/> (c)	(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
	Check if any part of this protocol falls within Category 8

	CATEGORY 9 – FOR GUIDANCE ONLY. SEE CRR SOP
Cat. 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
<input type="checkbox"/>	
	Check if any part of this protocol falls within Category 9

8. For Studies Requesting a Waiver of Consent or Documentation of Consent (Verify that the following criteria have been satisfied) N/A

Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	The research involves no more than minimal risk; AND
<input type="checkbox"/>	<input type="checkbox"/>	Waiver/alteration will not adversely affect the rights and welfare of subjects; AND
<input type="checkbox"/>	<input type="checkbox"/>	The research could not practicably be conducted without waiver/alteration; AND
<input type="checkbox"/>	<input type="checkbox"/>	Whenever appropriate, subjects will be provided additional pertinent information after participation.

Note: Waiver of informed consent, waiver of parental permission, and waiver of documentation are **NOT permitted under FDA regulations** or for the involvement in research of nonviable neonates. Pursuant to 10 USC 980, waiver of informed consent is **NOT permitted for “research involving experimental subjects.”** DoDI 3216.2 defines “research involving human beings as experimental subjects” as activities where there is an



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intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction.”

Comments or Concerns:

9. Expedited Review Categories: Minor Changes to Previously Approved Research

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.

10. Determination of Qualification for Expedited Review

Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	Does all of the human subjects research within this protocol fall into one or more of the expedited review categories?
		If you answered:
		Yes and there are no *eligibility considerations are identified, this project is eligible for expedited review. <u>Identify all</u> of the expedited review categories that apply.
		No: this protocol requires a full-board review.

*If eligibility considerations are identified, please discuss these with the HSPB.

Reviewer Notes:

8. For Initial Review:

Level of Risk (please check one):



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- Minimal Risk
- Greater than minimal risk

9. For Amendment or Other Review (please check all that applies):

- Remains.... or Has Changed to....

- Minimal Risk
- Greater than minimal risk

10. IRB Reviewer Action (check one):

- Approve as submitted; No further action required
- Modifications required to secure approval (comments below)
- Request for More Information (comments below)
- Forward to the Full WRAIR IRB for Review
- Forward to the Full WRAIR IRB for Information Only
- No action required; File Only

Comments:

Signature of Reviewer

Date