



**Walter Reed Army Institute of Research
Human Subjects Protection Branch
Standard Operating Procedure**



SOP Title	EXPEDITED HUMAN SUBJECTS RESEARCH PROTOCOL REVIEW	SOP No.	UWZ-C-613
		Version	.02
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Signatures and Dates

Author:



**Please see the original
at HSPB for signatures**

Human Subjects Protection Branch(HSPB) _____
Date

21 March 2012

QA Review:

Quality Liaison _____
Date

22 March 2012

Approving Authority:

WRAIR IRB _____
Date

22 MAR 12

Review/Approval for unchanged documents

	Author/Date	QA Review/Date	Approving Authority/Date
1			
2			
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1. Purpose and Applicability

The purpose of this Standard Operating Procedure (SOP) is to specify the criteria and process for expedited review of human subjects research activities by the Walter Reed Army Institute of Research (WRAIR) Institutional Review Board (IRB).

Expedited review of human subjects research protocols is a type of review that can be conducted by the IRB Chair or other IRB members, instead of by the fully convened IRB. IRB members are designated to conduct expedited review by selection & via an official memorandum by the Chair, WRAIR IRB. Reviewers are empowered by the regulations to approve research qualifying for expedited review or to require modifications of a study to gain approval. The regulations, however, prohibit disapproval of any research reviewed using the expedited methods and require that such proposed disapprovals be referred to the full board for review and disposition. Therefore, the IRB Chair or designee may exercise all of the authority of the IRB to review research qualifying for expedited review, except that they do not have the authority to disapprove such research.

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).

Consultants may assist the IRB Chair or designee in making decisions in using expedited review.

The full IRB must be notified of all research activities ultimately approved by using the expedited review process. The IRB acknowledges receipt of the information and can request more information or can recommend full board review of any item.

This SOP applies to WRAIR IRB Chair, or designee, the WRAIR IRB, Principal Investigators or WRAIR point of contact (POC), the HSPB Staff, and the Commander, WRAIR (Institutional Official; IO).

2. Responsibilities

- a. The WRAIR IRB Chair, or designee, is responsible for fulfilling the responsibilities as outlined in this SOP.
- b. The HSPB staff is responsible for providing administrative support to the IRB and WRAIR IRB Chair.



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- c. The fully convened WRAIR IRB receives a list of protocol life-cycle actions approved by expedited review and can request more information or recommend full board review of any item listed.
- d. The WRAIR Commander is responsible for the review of the IRB recommendations of approval under expedited review and makes a final determination for implementation within the scope of his/her authority.
- e. Investigator Guidance

The Principal Investigator (PI) or WRAIR POC (if PI is not at WRAIR) is expected to:

- 1) Respond to all requests for information from the IRB or HSPB, and comply with determinations made by the IRB and WRAIR Commander regarding the research.
- 2) Fulfill their responsibilities as outlined in this SOP.

3. Materials and Equipment

Not applicable

4. Procedures for Conducting Expedited Review

- a. The HSPB staff receives, reviews, and processes documents related to human subjects research (Refer to WRAIR SOP, Submission of Human Subjects Research Protocols and Supporting Documents for Review, UWZ-C-623).
- b. Scientific review (as applicable) is conducted in accordance with WRAIR SOP, Scientific Review of Human Use Protocols, UWZ-002.
- c. Once scientific review approval is received (if applicable), the HSPB Human Subjects Protection Scientist (HSPS) performs a review of the submitted documents (Refer to WRAIR SOPs, Conducting Initial Protocol Review, UWZ-C-603 and Amendments to Human Subjects Research Protocols, UWZ-C-615) and makes a preliminary assessment as to whether or not the new protocol (or amendment) qualifies for expedited review.
- d. If clarification is needed, the HSPB HSPS drafts a pre-review report and submits the protocol through the appropriate review process. The WRAIR HSPB Director, Deputy Director (or designee) reviews all HSPB protocol evaluation forms (PEFs)



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and forwards the documentation to the WRAIR IRB Chair (or designee) for review and/or an ethical consultation, if applicable, prior to submitting the PEF to the PI.

- e. The HSPB HSPS communicates with the PI regarding any questions, additional information, clarifications or requests for revision to the submitted material that arise during the review process. This communication is documented and retained in the IRB protocol file.
- f. Once the investigator's responses to the PEF are received, or if no clarifications are requested, the HSPB HSPS provides the documents to the WRAIR IRB Chair (or designee), whom after reviewing the submitted materials, determines one of the following:
 - 1) The submission qualifies for expedited review;
 - 2) The submission does not qualify for expedited review; or
 - 3) The submission is felt to require a full board review.

Note: Steps d-f may be combined depending upon the type of protocol and/or scope of the amendment or other factors (i.e., timelines).

- g. Submissions that qualify for expedited review and have been reviewed to assess whether the activity meets the approval criteria defined in the regulations receive one of the following recommendations by the reviewer:
 - 1) Approval, identifying the specific expedited category it meets, or
 - 2) Approval, as a minor amendment to already approved research [32 CFR 219.110 (b) (2), 45 CFR 46.110 (b) (2), and 21 CFR 56.110 (b) (2)] (if submission is an amendment) or
 - 3) Referral to the fully convened IRB for review and determination.
- h. Submissions that do not qualify for expedited review or that could qualify for expedited review but received a referral recommendation by the reviewer, are placed on the agenda of the next available convened IRB committee meeting for full review and deliberation once PEF items have been addressed. The PI is informed of this action and is requested to be available to the committee should they have questions.



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- i. When the IRB Chair (or designee) recommends approval of a submission that qualifies for expedited review, an official signed memorandum recommending this approval is submitted to the WRAIR IO. The specific expedited review category under which it falls is identified in the memorandum.
- j. The WRAIR Commander reviews the IRB recommendation and makes a final determination. Research activity may begin only when the IO, WRAIR, gives final written authorization approval based on the recommendations of the IRB. An exception to this is when the activity is a request for continuation determination or a final report, wherein the IRB Chair (or designee) is the final authority.
- k. The official IRB recommendation and IO's Authorization approval letters are generated by the HSPB.
- l. Correspondence and communication regarding the IRB review is prepared and sent to the PI or WRAIR POC with assistance by the HSPB. Copies of the IRB Chair recommendation memo and the WRAIR IO Authorization Approval memo, when applicable, are provided to the PI or WRAIR POC.
- m. Activities approved through expedited review are reported to the full IRB.
- n. A copy of the documents submitted by the PI, the official memoranda, documentation of any communication with those involved with the review and, as applicable, a copy the IRB meeting minutes relating to the protocol are filed in the HSPB.

5. Explanation of Abbreviations, Acronyms, and Terms

DHHS	Department of Health and Human Services
FDA	U.S. Food and Drug Administration
HSPB	Human Subjects Protection Branch, WRAIR, is the administrative support of the IRB. (Formerly known as the Division of Human Subjects Protection (DHSP))
HSPS	Human Subjects Protection Scientist
IRB	Institutional Review Board
OHRP	Office of Human Research Protections, HHS



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PI	Principal Investigator
Approval Authorization	WRAIR Commander's final determination of implementation of a protocol based on the recommendation of the IRB, within the scope of his/her authority.
Consultant	One who gives professional advice to the IRB regarding matters in the field of his/her special knowledge or training but is not a member of the IRB.
Expedited Review	An expedited review is a procedure permitted by 32 CFR 219.110, 21 CFR 56.110, and 45 CFR 46.110, by which a protocol, amendment or continuing review/final report receives IRB review and approved for human subjects research activities without being reviewed at a fully convened meeting of an IRB.
Human subjects research	Research involving humans as research subjects, or involving biological specimens, specimens or data from repositories or anatomical substances of human origin. This includes the administration of questionnaires or surveys, as well as research done in an educational setting
Minimal Risk	The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves those than ordinarily encountered in daily life or during performance of routine physical or psychological examination or tests (DHHS and FDA definition) OHRP further interprets this to be relative to the daily life of a normal, healthy person.
Research	Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
WRAIR IRB	WRAIR Institutional Review Board, the ethical review committee for research involving human subjects at WRAIR its CONUS detachments or OCONUS Laboratories, or when WRAIR funding, facilities or personnel are involved in any way (investigator, consultant, collaborator, etc.). This includes protocols for which recruitment of subjects is being



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performed at WRAIR.



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6. References

Reference Number or Authors	Document Title
32 Code of Federal Regulations (CFR) 219	Protection of Human Subjects, 1 July 1999.
45 Code of Federal Regulations (CFR) 46	Protection of Human Subjects, updated 23 June 2005.
21 Code of Federal Regulations (CFR) 56	Institutional review Boards, updated 1 April 2008.
21 Code of Federal Regulations (CFR) 50	Protection of Human Subjects, updated 1 April 2008.
DOD Instruction 3216.02	Protection of Human Subjects and Adherence to Ethical Standards in DOD-Supported Research, 8 November 2012.
AR 70-25	Use of Volunteers as Subjects of Research, Appendix D, 25 January 1990
Amdur, R.J. and Bankert, E.A.	Institutional Review Board Management and Function. Boston: Jones and Bartlett Publishers, 2006.
63 Federal register (FR) 60364-60367	National Institutes of Health. Protection of Human Subjects: Categories that May Be reviewed by the Institutional Review Board (IRB) through an Expedited review Procedure, 9 November 1998.
WRAIR SOP UWZ-C-603	Conducting Initial Protocol Review
WRAIR SOP UWZ-C-615	Amendments to Human Subjects Research Protocols

7. Appendices and Attachments

Appendix or Attachment Number	Title
UWZ-C-613-A-A	Expedited Review Categories
UWZ-C-613-A-B	Checklist for Expedited Review Eligibility



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8. Document Revision History

Version Number	Brief Description of Changes	Effective Date
.00	New	9 March 2007
.01	Biennial Review, including organization name updates, updates to reflect current policies and procedures, and minor editorial clarifications	12 August 2009
.02	Biennial Review, including organization name updates, updates to reflect current policies and procedures, and minor editorial clarifications	<i>APR 11 2012</i>



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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, and be found in the categories listed or (2) be a minor change in previously approved research during the period of 1 year or less for which approval is authorized by the IRB.

For purposes of this SOP an 'activity' is defined as an initial research submission, an amendments to current approved research, a request for continuation determination (continuing review) and a final report.

a. Expedited Review Categories

The 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*). The categories listed should not be deemed to be of 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 the 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 (21 CFR 812) 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 from:

Healthy non-pregnant adults, 18 years old or older, who weigh at least 110 pounds and are in good health. For these subjects, the amounts drawn may not



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exceed 450 ml 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 include the following:

- a) Hair and nail clippings in a nondisfiguring manner;
- b) Deciduous teeth at exfoliation, or if routine care indicated a need for extraction;
- c) Permanent teeth if routine 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 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 and the process is accomplished in accordance with accepted prophylactic techniques;
- i) Mucosal and skin cells from buccal scraping/swab, skin swab, mouth washing; and
- j) Sputum collected after saline mist nebulizer.

Category 4: Collection of data through noninvasive and minimal impact procedures (not involving general anesthesia or sedation), routinely employed in clinical practice, excluding procedures involving the significant use of potentially harmful inputs such as X-rays, contrast dyes or microwave irradiation. Where medical devices are employed, they must be cleared/approved for marketing. Examples:

- a) Physical sensors applied to the surface of the body or at a distance and not involving input of significant amounts of energy or an invasion of privacy;
- b) Weighing or testing sensory acuity;



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- c) Magnetic resonance imaging without gadolinium or similar contrast agent;
- 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 appropriate for the subject's age, weight and health.
- f) Note: 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.

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).

Note: Such research may be exempt under some conditions.

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: Such research may be exempt under some conditions.

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,



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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 application or investigational device exemption where categories (2) through (8) do not apply.

Therefore, for research not conducted under and IND or IDE, category 9 specifically permits continuing review to be conducted by expedited review, subsequent to a full IRB initial review, where the following three conditions are met:

- a) Categories (2) - (8) on the list do not apply;
 - b) No additional risks have been identified in the research since the initial approval period; and
 - c) The IRB determines that the research is not greater than minimal risk.
2. In the following situations minor changes to previously approved research, during the period of one year or less for which the 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 detriment to the already approved plan for protection of human subjects.



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Checklist for WRAIR IRB Determination of Expedited Review Eligibility and Expedited Review Category Selection

Instructions: Use this checklist as an optional supplementary tool when making the determination of whether a protocol qualifies for expedited review.

Expedited Review: Expedited review of human subjects research protocols is a type of review that can be conducted by the IRB Chair or other 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 research risks 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, mentally 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. **Protocol Title:**
2. **Principal Investigator:**
3. **Name of IRB member performing this review:**
4. **Expedited Review Eligibility Considerations:**

Section 1: Minimal Risk

Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	Does any part 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: Identifiability Risks and Protections

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, reputation, or be stigmatizing?
<input type="checkbox"/>	<input type="checkbox"/>	b. Will reasonable and appropriate protections be implemented so that risks related to 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

Yes	No	
		Does this protocol involve any of the below:
<input type="checkbox"/>	<input type="checkbox"/>	Children?
<input type="checkbox"/>	<input type="checkbox"/>	Pregnant women, fetuses, or human in vitro fertilization?
<input type="checkbox"/>	<input type="checkbox"/>	Mentally disabled or cognitively impaired persons?
<input type="checkbox"/>	<input type="checkbox"/>	Economically or educationally disadvantaged persons?
<input type="checkbox"/>	<input type="checkbox"/>	DNA testing
<input type="checkbox"/>	<input type="checkbox"/>	Prisoners? (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.

5. Expedited Review Categories:

CATEGORY 1
Clinical studies of drugs and medical devices only when conditions (a) and (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (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.
<input type="checkbox"/> Check if any part of this protocol falls within Category 1

CATEGORY 2
Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (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 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.
<input type="checkbox"/> Check if any part of this protocol falls within Category 2



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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 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

OHRP/FDA 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

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:

- (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, infrared imaging, Doppler blood flow, and echocardiography;
- (e) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

Check if any part of this protocol falls within Category 4



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CATEGORY 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).

Check if any part of this protocol falls within Category 5

CATEGORY 6

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

Check if any part of this protocol falls within Category 6

CATEGORY 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.

Check if any part of this protocol falls within Category 7

6. 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 no eligibility considerations* are identified, this project is eligible for expedited review. <u>Identify all of the expedited review categories that apply.</u>
		No: this protocol requires a full-board review.

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

Reviewer Notes: