Office for Human Research Protections (OHRP) - Categories of Research

Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure[1]

Applicability

A. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this 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.

B. The categories in this list apply regardless of the age of subjects, except as noted.

C. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects= financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

D. The expedited review procedure may not be used for classified research involving human subjects.

E. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

F. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

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

   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.)

   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.

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

   a. (a) from healthy, nonpregnant 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[2], 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.

   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 gumbase 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 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; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) 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: (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; (e) 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 nonresearch 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 HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

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.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (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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[1] An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

[2] Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a).

Source: 63 FR 60364-60367, November 9, 1998.

IRB EXPEDITED REVIEW TEMPLATE

MSU IRB	Date and Time of Review:
Principal Investigator:	Lack of Financial CoI Has Been Verified ☐
Protocol Title:	Materials Reviewed:

Decision:	Approval Period:	Review Type:
☐ Approve with required changes ☐ Approve with Administrative changes ☐ Approve as presented ☐ Defer to Full Board	☐ Annual ☐ Six Months ☐ Until next Continuing Review ☐ Other:	☐ Initial ☐ Re-Review ☐ Unanticipated Problem ☐ Continuing Review ☐ Modification, reason(s):

1) **Review:**

Scientific Hypothesis and Design *(Required)*		
45 CFR 46.111.1-2 *For Overall Study*	Risks to Subjects are Minimized and Risk/Benefit Ratio is acceptable.	☐ Acceptable ☐ Needs Changes/Clarifications:
45 CFR 46.111.1-2 *Devices: separate vote on SR vs. NSR*	Risks to Subjects are Minimized and Risk/Benefit Ratio is acceptable.	☐ N/A ☐ Non Significant Risk Device ☐ Significant Risk Device ☐ Needs Changes/Clarifications:
45 CFR 46.111.6	An Adequate Data & Safety Monitoring Plan is in Place	☐ Acceptable ☐ Needs Changes/Clarifications:
	An Adequate Monitoring Entity has been designated.	☐ Acceptable ☐ Needs Changes/Clarifications:
Subject Population *(Required)*		
45 CFR 46.111.3	Selection of Subjects is Equitable	☐ Acceptable ☐ Needs Changes/Clarifications:
45 CFR 46.111.7	Privacy of Subjects is Adequately Protected	☐ Acceptable ☐ Needs Changes/Clarifications:
	Other:	☐ Acceptable ☐ Needs Changes/Clarifications:

Informed Consent *(Required)*		
45 CFR 46.111.4-5	Informed Consent will be Sought/ Documented	☐ Acceptable ☐ Waiver/Alteration of Consent/Documentation is Requested ☐ Reconsent? If so, when/how: ☐ Needs Clarifications:
45 CFR 46.116(a)(b)	Elements of Informed Consent are Included in Consent Form *(complete checklist below)*	☐ N/A ☐ Acceptable ☐ Needs Changes/Clarifications:
Waiver/Alteration of Consent:		
45 CFR 46.116(d)	All of the following criteria must be met to satisfy a Waiver of Consent: ☐ The research involves no more than minimal risk to subjects ☐ The Waiver or Alteration will not adversely affect the rights and welfare of subjects ☐ The research could not practicably be carried out without the waiver or alteration ☐ Whenever appropriate, subjects will be provided with additional pertinent information after participation	☐ N/A ☐ Alteration Acceptable: ☐ Complete Waiver Acceptable: ☐ Needs Changes/Clarifications:
Waiver of Documentation of Consent:		
45 CFR 46.117(c)	One of the following must be met to satisfy Waiver of Documentation: ☐ That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. OR… ☐ That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.	☐ N/A ☐ Acceptable: ☐ Needs Changes/Clarifications:
Waiver/Alteration of Authorization:		
45 CFR 160 & 164	All of the following must be met to satisfy Waiver of Authorization: 1. ☐ The use and disclosure of the PHI involves no more than minimal risk to the privacy of individuals based on, at least, the presence of the following elements: ☐ An adequate plan to protect health information identifiers from improper use and disclosure. ☐ An adequate plan to destroy identifiers at the earliest opportunity consistent with conduct of the research (absent a health or research justification for retaining them or a legal requirement to do so). ☐ Adequate written assurances that the PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule. 2. ☐ The research could not practicably be conducted without the waiver or alteration. 3. ☐ The research could not practicably be conducted without access to and use of the PHI.	☐ N/A ☐ Partial Waiver Acceptable, Terms: ☐ Complete Waiver Acceptable: ☐ Needs Changes/Clarifications:

Additional Issues & Resolutions (not addressed above):	
Issue	**Resolution** *(Include protocol-specific basis for each finding, if applicable)*

Vulnerable Population(s) Determinations:

Vulnerable Populations:
☐ None
☐ Pregnant Women, Fetuses
☐ Children
☐ Prisoners
☐ Placenta, Dead Fetus/Fetal Material
☐ Neonates
☐ Other:

Description of Vulnerable Population Determinations	
Determination *(cite each specific regulation separately)*	**Justification** *(Must include study-specific basis for decision)*

Issues Documented in Reviewer(s) Notes:	
Issue	**Resolution** *(Include protocol-specific basis if applicable)*

ELEMENTS OF INFORMED CONSENT CHECKLIST		
45 CFR 46.116(a)	Basic Elements of Informed Consent are Included in Consent Form	
116(a)(1)	Statement of **Purpose, Duration, Procedures**	☐ Acceptable ☐ Needs Changes/Clarifications:
116(a)(2)	Description of **Foreseeable Risks/Discomforts**	☐ Acceptable ☐ Needs Changes/Clarifications:
116(a)(3)	Description of **Benefits**	☐ Acceptable ☐ Needs Changes/Clarifications:
116(a)(4)	Disclosure of Appropriate **Alternatives**	☐ Acceptable ☐ Needs Changes/Clarifications:
116(a)(5)	Description of **Confidentiality** Practices	☐ Acceptable ☐ Needs Changes/Clarifications:
116(a)(6)	Description of **Costs/ Compensation**	☐ Acceptable ☐ Needs Changes/Clarifications:
116(a)(7)	Description of **Liability** and **Whom to Contact** with Questions or if Injury Occurs	☐ Acceptable ☐ Needs Changes/Clarifications:
116(a)(8)	Statement that **Participation is Voluntary**	☐ Acceptable ☐ Needs Changes/Clarifications:
45 CFR 46.116(b)	Additional Elements of Informed Consent, when Applicable, must be Included in Consent Form	
116(b)(1)	Statement that Study may Involve Unforeseeable Risks	☐ N/A ☐ Acceptable ☐ Needs Changes/Clarifications:
116(b)(2)	Circumstances Under Which Participation may be Terminated	☐ N/A ☐ Acceptable ☐ Needs Changes/Clarifications:
116(b)(3)	Additional Costs to Subject Resulting from Participation	☐ N/A ☐ Acceptable ☐ Needs Changes/Clarifications:
116(b)(4)	Consequences of Subject Withdrawal	☐ N/A ☐ Acceptable ☐ Needs Changes/Clarifications:
116(b)(5)	Statement that Significant New Findings that may Affect Willingness to Participate will be Provided	☐ N/A ☐ Acceptable ☐ Needs Changes/Clarifications:
116(b)(6)	Approximate # of Subjects in Study	☐ N/A ☐ Acceptable ☐ Needs Changes/Clarifications:
	Other:	