



## Human Research Protection Expedited Application Checklist IRB-2F

Applicant(s) Name:

Project Name:

Please answer the following questions about your research protocol to determine if your study can be considered for expedited review, and if so, for which review category. Once completed, submit to the Human Protections Administrator.

### SECTION ONE: Applicability

Please read the following guidelines carefully before requesting an expedited review of your protocol. Do not request **expedited review** for studies that meet the criteria for **exempt review** (see [45 CFR 46.101\(b\)](#) for a description of the exempt criteria).

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 procedures 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, or 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. 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 both to initial and continuing IRB review.

**\*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.**

## SECTION TWO: Research Categories

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

- (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.

*Justification:*

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

- (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, 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.

*Children are “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.”*

*Justification:*

### (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.

*Justification:*

- (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.

*Justification:*

- (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. 45CFR 46.101(b)(4). This listing refers only to research that is not exempt).**

*Justification:*

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

*Justification:*

- (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 HHS regulations for protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)**

*Justification:*

**(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.**

*Justification:*

**(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.**

*Justification:*

**SECTION THREE: Additional Materials**

Be sure to follow all of the instructions for the full submission and submit any supplemental materials such as:

- the grant application or sponsor’s protocol;
- consent or assent document(s);
- recruitment materials;
- other supporting materials

If your study qualifies for expedited review, it will not require review at an IRB meeting. You will be notified when the materials have been reviewed, and either a full approval will be given or you will be asked to respond to contingencies.

Note that the study should not be commenced (i.e. potential subjects should not be solicited or entered onto this protocol) until you have complied with any contingencies and you have received a full approval letter from the IRB.

*This worksheet should be used by the designated IRB member or the chair to document his/her review of protocols via Expedited or Convened IRB review.*

Data Initial Review Complete:

Deadline:

Review Category:  
(1-9, see attached list)

FDA Regulated                      YES                      NO

<b>Approval Criteria</b>	<u>Check appropriate boxes. Summarize controverted issues in Discussion box and list required changes in Modifications box below.</u>	
Sound Design / Risks Minimized	Satisfactory	Controverted, needs changes or needs full review
Risks Reasonable / Anticipated Benefits	Satisfactory	Controverted, needs changes or needs full review
Subject Selection Equitable	Satisfactory	Controverted, needs changes or needs full review
Informed Consent Process/Documentation	Satisfactory	Controverted, needs changes or needs full review <u>If waiver of consent process or documentation involved, document criteria and justification in discussion box below.</u>
Safety Monitoring	Satisfactory	Controverted, needs changes or needs full review
Privacy / Confidentiality	Satisfactory	Controverted, needs changes or needs full review
Safeguards for Vulnerable Subjects	Satisfactory	Controverted, needs changes or needs full review

If Children, Prisoners, Pregnant Women, or Fetuses, document category and rationale in discussion box below.

**Discussion:**

Summarize substantive issues discussed by the applicant. Describe controverted issues and their resolution. If children, prisoners, pregnant women, or fetuses are involved, document category and rationale. If waiver of informed consent process or documentation is involved, document criteria and justification.

**Required Modifications or Reasons for Requesting Full Review**

List Required Modifications or Reasons for Requesting Full Review. Number each item separately. Required modifications must be stipulated with specificity sufficient to permit objective verification by the IRB.

1.

2.

3.

**Review Decisions (check IRB determinations):**

Level of Risk:       Minimal risk                               Greater than minimal risk

Approval Status:    Approved as Submitted               Request Full Review

Approved When Required Modifications Verified by Chair/Member\*      \* See above

**Conflict of Interest as a Reviewer**

I do not have a conflict of interest in reviewing this research application.

I do have a conflict of interest and therefore I will report this to the IRB Chair so that another reviewer can be assigned to conduct the review

\_\_\_\_\_  
(IRB Chair or Designee Signature)

\_\_\_\_\_  
(Date)

\_\_\_\_\_  
Date of IRB Meeting Where Decision Announced

## Research Categories

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(b) from other adults and children<sup>2</sup>, 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.

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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.

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