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Levels of Review

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Minimal Risk Tip Sheet ^[1]

The Level of Review and Minimal Risk

If your study needs IRB review ^[2], the next step is to identify the level of review required ? full committee review, expedited review ^[3] or exempt certification.

The level of review reflects the level of risk to the subject. The risk level is compared to ?minimal risk? as defined by the federal regulations:

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45.CFR.46.102(j))(Common Rule).

Greater than minimal risk studies require full committee review, while minimal risk studies *may* be eligible for expedited review or exempt certification. Call the IRB Analyst of the Day at 415-476-1814 if you are unsure about which level of review is needed.

Full Committee Review

These studies are reviewed by the IRB committee at a convened meeting. Full committee review is required for:

- Greater than minimal risk studies **OR**
- Studies that are minimal risk, but do not fit in an expedited review category.

Examples of studies requiring full committee review

- Randomized treatment studies
- Studies using investigational drugs and/or devices
- Behavioral studies involving risky interventions, observations of illegal behavior or very sensitive data/questions

Expedited Review

Expedited review studies typically are reviewed by a small number of IRB reviewers. Expedited review is appropriate for studies that according to 45 CFR 46.110 and 21 CFR 56.110:

- Involve no greater than minimal risk **AND**
- Fit into one (or more) of the following nine specific expedited review categories.

Additional restrictions and conditions

- If subjects will be randomized to a treatment group as part of the study, then the study does not qualify for expedited review.
- 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.
- The categories in this list apply regardless of the age of subjects, except as noted.
- 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.
- The expedited review procedure may not be used for classified research involving human subjects.
- The standard requirements for informed consent ^[4] apply.
- Categories one through seven pertain to both initial and continuing IRB review. See the Modification

[5] page to learn what kind of changes/amendments can be reviewed under expedited review procedures.

Expedited Review Categories

In addition to the information below, see the Minimal Risk Tip Sheet [1] for examples of research activities that may be considered minimal risk.

Category 1: Approved drug or device being used for its approved indication

(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.

Comments: The drug or device must be approved and used exactly according to its labeling. All study procedures other than use of the drug or device must themselves be of minimal risk for the study to qualify for expedited review. Few studies fit this category.

Example: A study examines how well standard doses of ibuprofen relieve headache pain in adults.

Category 2: Blood sampling (limited amounts)

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 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 [6] 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).

Category 3: Noninvasive specimen collection

Prospective collection of biological specimens for research purposes by noninvasive means.

Examples:

1. Hair and nail clippings in a non-disfiguring manner
2. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction
3. Permanent teeth if routine patient care indicates a need for extraction
4. Excreta and external secretions (including sweat)
5. 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
6. Placenta removed at delivery
7. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor
8. 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
9. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings
10. Sputum collected after saline mist nebulization

Category 4: Noninvasive, routine clinical procedures, such as MRI or EKG (no sedation, general anesthesia, x-rays or microwaves)

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:

1. 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
2. Weighing or testing sensory acuity
3. Magnetic resonance imaging (**FDA-approved scanners of 3 Tesla or under**)
4. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow and echocardiography
5. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

Category 5: Use of data or specimens collected for non-research or research purposes (e.g. chart reviews)

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).

Comments:

(a) This category refers to materials collected for "non-research purposes," but can be used to cover research materials if the investigator's role is simply to analyze them. That is, if an investigator is receiving materials from colleagues who have separate approval to collect them, and the materials are handled with protections for confidentiality, the investigator may apply for expedited review for the analysis.

(b) Under limited circumstances, research involving private information or specimens may be exempt or may not qualify as human subjects research [7]. If the project is not human subjects research, IRB review is not required.

Examples:

1. Retrospective chart review
2. Analysis of specimens that contain identifiable information (e.g. name or medical record number)

Category 6: Collection of data from voice, video, digital, or image recordings

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

Example: Using video recordings to examine communication styles between educators and students

Reminder: 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.

Category 7: Low-risk behavioral research

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 qualify for exempt certification, most commonly under exempt category 2.

Example: Interviewing teenagers about the influence of social media on body image.

Reminder: 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.

Category 8: Continuing review of inactive research or studies that are essentially complete

Continuing review of research previously approved by the convened IRB as follows:

1. 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
2. Where no subjects have been enrolled and no additional risks have been identified; or
3. Where the remaining research activities are limited to data analysis.

Category 9: Continuing review of other minimal risk research studies

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.

Exempt Certification

DHHS regulations in 45 CFR 46.104 (Common Rule) identify several different categories of minimal risk research as being exempt from federal policy for the protection of human subjects. Federal HIPAA regulations, California state law and UCSF institutional policies further limit exempt research categories.

Exempt research involves human subjects [2], and undergoes limited IRB approval is not required. However, **you must submit the study to the IRB.** The IRB will review the application and certify that the study qualifies for the exemption. You will receive an exempt certification letter, not a letter of approval.

The IRB will **NOT** certify the following types of research as exempt at UCSF:

FDA regulated

Involves the collection of Protected Health Information (PHI) [8]

Involves inpatients or prisoners [9] as subjects

Demonstration projects and taste tests

Other notes about exempt studies:

Unique exempt consent templates and guidance are available

If your research involves interaction with subjects, there usually should be a process to ask subjects to participate and confirm their agreement. The IRB has created special consent templates and guidance [10] for exempt studies.

For exempt research only, you can make minor changes to your study without notifying the IRB. Significant changes must be submitted to the IRB. See the Modification page [11] for examples.

Exempt studies have no expiration date and do not require continuing review. Submit a Study Closeout Report [12] when the study is finished.

You cannot certify your own study as exempt

At this time, funding agencies do not allow investigators to make an exempt determination on their own, nor does the University. You must submit the study [13] to the IRB, which will make this determination.

?Exempt research must be minimal risk **AND** fit into one (or more) of the following categories:

Category 1: Research, conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content and does not adversely impact the assessment of educators who provide instruction. This includes:

- Most research on regular and special education instructional strategies, and
- Research on:
 - The effectiveness of instructional techniques, curricula, or classroom management methods
 - The comparison among instructional techniques, curricula, or classroom management methods.

Category 2: (Common Rule): **Research the only includes: interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:**

- a. The information obtained is recorded by the investigator in a way that the identity of the human subjects **cannot** be established, directly or through identifiers linked to the subjects;
- b. Any disclosure of the human subjects' responses outside the research would not

reasonably place the subjects at risk or criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

c. The information obtained is recorded by the investigator in a way that the identity of the human subjects **can** be established, directly or through identifiers linked to the subjects, and the IRB conducts a **limited IRB** review to make the determination. The IRB will determine whether there are adequate plans to protect the privacy of subjects and to maintain the confidentiality of the data as required by 46.111(a)(7).

Category 3: (Common Rule): Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and collection of the information and at least one of the following criteria is met:

a. The information obtained is recorded by the investigator in a way that the identity of the human subjects cannot be established, directly or through identifiers linked to the subjects;

b. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk or criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

c. The information obtained is recorded by the investigator in a way that the identity of the human subjects **can** be established, directly or through identifiers linked to the subjects, and the IRB conducts a **limited IRB** review to make the determination of whether there are adequate plans to protect subject privacy and confidentiality as required by 46.111(a)(7).

Benign behavioral interventions means:

Brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

- If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement (consent) to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Category 4: (Common Rule) Secondary research for which consent is not required

Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

- a. The identifiable private information or identifiable biospecimens are publicly available.
- b. Information, which may include information about biospecimens, is recorded by the investigator in a way that the identity of the human subjects cannot be established directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
- c. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
- d. The research is conducted by, or on behalf of a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

Limited IRB Review (Common Rule)

Categories 2 and 3 have provisions for exempt research that require limited IRB review. Which means, when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data 45 CFR 46.1111(a)(7).

Investigators submitting exempt research that requires limited IRB review will be prompted to complete the appropriate confidentiality sections.

Limited IRB review will be conducted on all exempt studies.

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Links

- [1] <http://hrpp.ucsf.edu/sites/hrpp.ucsf.edu/files/tip-sheet-minimal-risk.pdf>
- [2] <https://irb.ucsf.edu/research-needing-irb-review>
- [3] <https://irb.ucsf.edu/#expedited>
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