

## Human Subject and Research Category Checklist For OUSD(P&R) Institutions

### Are human subjects involved?

- \_\_\_\_\_ 1. The activity involves collecting data about living people through an interaction or intervention with people. For example, an intervention can involve physical procedures or a manipulation of the subject's environment. An interaction includes surveys, interviews, focus groups, etc.
- \_\_\_\_\_ 2. The activity involves identifiable, private information. Private information is information provided for specific purposes which the individual can reasonably expect will not be made public (e.g., medical, personnel, and student records), or information about behavior that occurs in a context in which the individual can reasonably expect no recording or observation is taking place. Identifiable information includes both direct identifiers and indirect identifiers. Direct identifiers include name, address, SSN, registration numbers, etc. Indirect identifiers include general demographic information when combinations of specific non-identifiable data can lead to individual identification (e.g., female, marine officer, limited geographic area).

If yes to 1 **or** 2, the activity involves human subjects; otherwise, it is not subject to the human subjects regulation.

If yes to 2, and the information is protected health information (PHI), then privacy review is required in addition to any human subjects review.

### Is it research?

- \_\_\_\_\_ 3. The activity is a systematic investigation. For example, if the activity includes a hypothesis or clearly stated research question, utilizes research methodology, and has a plan for data analysis, then it is probably research.
- \_\_\_\_\_ 4. The activity is designed to contribute to generalizable knowledge. Generalizable knowledge means new information that has relevance beyond the population or program from which it was collected, or information that is added to the scientific literature.

If yes to both 3 **and** 4, it is human subjects research subject to regulation. If no to **either** 3 **or** 4, the human subject regulation doesn't apply; however, P&R requires that the activity be conducted in a manner consistent with the ethical and professional standards embodied in the regulations and policies.

If a project has multiple components and at least one of those components is research, the entire project is classified as research unless the components are separable.

### Is it exempt?

To be exempt, the research must not involve (target) prisoners\*. Exemption 2, except for procedures only involving observation of public behavior, may not be used with children.

\*Prisoners of war may not be used as human subjects in research.

\_\_\_\_\_ This research does NOT involve (target) prisoners.

#### Category 1 Exemption (see attachment 1):

\_\_\_\_\_ The research is in an educational setting, involving normal educational practices.

#### Category 2 Exemption (see attachment 1): **Subjects must be adult except as noted above.**

\_\_\_\_\_ The research procedures **only** involve educational tests, survey or interview procedures, or observation of public behavior. **AND**

\_\_\_\_\_ The data are non-identifiable [either directly, indirectly, or by a coding procedure linked to subjects' identity] **OR**

\_\_\_\_\_ Disclosure poses no risk of criminal or civil liability, or will not be damaging to subjects' financial standing, employability or reputation.

#### Category 3 Exemption (see attachment 1):

\_\_\_\_\_ The research procedures only involve educational tests, survey or interview procedures, or observation of public behavior (that is not exempt under Category 2). **AND**

\_\_\_\_\_ The subjects are elected or appointed officials or candidates for public office. **OR**

\_\_\_\_\_ Federal statutes require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

#### Category 4 Exemption (see attachment 1):

\_\_\_\_\_ The research involves the collection or study of existing [operational data that would exist regardless of the research] data, documents, records, or pathological or diagnostic specimens. **AND**

\_\_\_\_\_ The sources are publicly available **OR**

\_\_\_\_\_ The information is recorded in such a manner that subjects can't be [readily] identified [either directly, indirectly, or by a coding procedure linked to subjects' identity].

#### Category 5 Exemption (see attachment 1):

\_\_\_\_\_ The research is a federal demonstration project. **AND**

\_\_\_\_\_ The research is studying the cost and utilization of a particular benefit change [but **NOT** assessing clinical outcomes in comparison to the clinical outcomes of the standard covered therapies].

#### Category 6 Exemption (see attachment 1):

\_\_\_\_\_ Taste and food quality evaluation of wholesome foods without additives **OR**

\_\_\_\_\_ Taste and food quality evaluations of foods with ingredients at or below the level found to be safe by FDA, EPA or USDA.

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[text] = guidance

If it is not exempt, then it requires IRB review.

## Can it be reviewed by expedited review?

To qualify for expedited review, the research must present no more than minimal risk to human subjects 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.

### Category 1 Expedited Review (see attachment 2):

\_\_\_\_\_ Clinical studies of drugs and medical devices only when an IND or IDE is not required.

### Category 2 Expedited Review (see attachment 2):

\_\_\_\_\_ Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from:

\_\_\_\_\_ healthy, nonpregnant adults who weigh at least 110 pounds. Amount drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; **OR**

\_\_\_\_\_ 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. 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.

### Category 3 Expedited Review (see attachment 2):

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

### Category 4 Expedited Review (see attachment 2):

\_\_\_\_\_ 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.)

### Category 5 Expedited Review (see attachment 2):

\_\_\_\_\_ 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)

### Category 6 Expedited Review (see attachment 2):

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

Category 7 Expedited Review (see attachment 2):

\_\_\_\_\_ 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.

Category 8 Expedited Review (see attachment 2):

\_\_\_\_\_ 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.

Category 9 Expedited Review (see attachment 2):

\_\_\_\_\_ 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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[text] = guidance

If it does not qualify for expedited review, then review at a fully convened IRB meeting is required.

**Attachment 1: Exempt Categories**

Reference	Description
§219.101(b)(1)	Research conducted in established or commonly accepted educational settings, involving normal educational practices, <b>such as</b> (i) research on regular and special education instructional strategies, <b>or</b> (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
§219.101(b)(2)	Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, <b>unless:</b> (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; <b>and</b> (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
§219.101(b)(3)	Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, <b>if</b> (i) the human subjects are elected or appointed public officials or candidates for public office; <b>or</b> (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and hereafter.
§219.101(b)(4)	Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, <b>if</b> these sources are publicly available <b>or if</b> the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
§219.101(b)(5)	Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, <b>and</b> which are designated to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; <b>or</b> (iv) possible changes in methods or levels of payment for benefits or services under those programs.
§219.101(b)(6)	Taste and food quality evaluation and consumer acceptance studies, (i) <b>if</b> wholesome foods without additives are consumed <b>or</b> (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, <b>or</b> agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration <b>or</b> approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

## Attachment 2: Expedited Categories

### 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<sup>1</sup> procedure authorized by 32 CFR 219. 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.

**Comment [m1]:** Remember to see if 10 USC 980 applies

(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) 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) 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<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.

(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. 32 CFR 219.101(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. 32 CFR 219.101(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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<sup>1</sup>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 32 CFR 219.110.