Valencia College - IRB- Categories of Research Review Checklist (Revised Common Rule) revised 12-10-2019

Certain studies meeting exempt criteria are still determined to be expedited. Please see Valencia College's IRB Written Procedures and Frequently Asked Questions (FAQ)

To qualify for exemption, the research must fit into one or more of the following categories and involve only minimal-risk[1] to subjects.

Exempt Cat	Exemption	Conditions/Limitations
1	☐ Research in established or commonly accepted education settings that involves normal educational practices that are: ☐ Not likely to adversely impact students' opportunity to learn or assessment of educators	
2	☐ Research only includes educational tests, surveys, interviews, observation of public behavior: **ONE of the following criteria are met:**	**…and ALL of the following are met:**
	☐ i) Recorded information cannot readily identify the subject (directly or indirectly/linked) ☐ ii) Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation)	☐ Data collection only; ☐ Surveys & interviews do not involve children; ☐ Educational tests or observation of public behavior: only include children when investigators do not participate in activities being observed
3	☐ (i) Research involving benign behavioral interventions through verbal, written responses, (including data entry or audiovisual recording) **from adult subjects who prospectively agree:** **ONE of following criteria are met**:	**…and ALL of the following are met:**
	☐ A. Recorded information cannot readily identify the subject (directly or indirectly/linked) ☐ B. Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation)	☐ No children; ☐ No medical interventions; ☐ Unlikely that subjects will find interventions offensive or embarrassing

[1] Minimal risk is defined by the federal regulations (45 CFR 46) as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

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Exempt Cat	Exemption	Conditions/Limitations
		☐ Subjects prospective agreement will be obtained; ☐ Deception: subjects prospective agreement will be obtained ☐ Benign behavioral interventions will be: • Brief in duration • Painless/Harmless • Not physically invasive • Not likely to have a significant adverse lasting impact on subjects
4	☐ Secondary research use of identifiable Information or identifiable biospecimen that have been or will be collected for some other 'primary' or 'initial' activity, and **ONE of following criteria met:**	
	☐ i) Biospecimens or information is publically available	
	☐ ii) Information recorded so subject cannot readily be identified (directly or indirectly/linked); and →→→	☐ Investigator does not contact subjects and will not re-identify the subjects
	☐ iii) Collection and analysis involving Investigators Use of identifiable health information when use is regulated by HIPAA "health care operations" or "research" or "public health activities and purposes" and →→→	☐ Investigator obtains HIPAA authorization or HIPAA waiver
	☐ iv) Research information collected by or on behalf of federal government using government generated or collected information obtained for non-research activities	If research generates identifiable private information it is subject to specified federal privacy laws (Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.)
5	☐ Taste and Food Quality evaluation Research Demonstration projects with the approval of a department or agency such as the Department of Housing and Urban Development (HUD). A project that seeks to document the benefit of a public service program would fall into this category.	
6	☐ Taste and Food Quality evaluation and consumer acceptance studies if **ONE of the following**:	
	☐ A wholesome foods without additives are consumed.	
	☐ A food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.	

Vulnerable populations in exempt research			
Subpart B	Research Involving Pregnant Women, Fetuses & Neonates	–	eligible for exempt under all exempt categories
Subpart C	Research Involving Prisoners	–	eligible for exempt under all exempt categories when research is aimed at involving a broader subject population that only incidentally includes prisoners
Subpart D	Research Involving Children	–	Children allowed in exemption categories 1,4,5, Limitations/exclusion of children in category 2 & 3

Expedited Research

To qualify for an expedited review, research must fall into nine (9) federally-defined expedited categories. These categories involve collection of samples and data in a manner that is not anonymous and that involves no more than minimal risk to subjects. Some examples of expedited research are:

- studies involving collection of hair, saliva or dental plaque samples,
- studies of blood samples from healthy volunteers,
- analyses of voice recordings
- studies of existing pathological specimens with patient identifiers.

Expedited review as defined by federal regulations allows the IRB chairperson or one or more experienced reviewers designated by the chairperson from among members of the IRB to evaluate and approve specific types of research. Reviewers conducting an expedited review may exercise all of the authority of the IRB except that they may not disapprove a study. When a subcommittee cannot approve the research under expedited review, the study is referred to the full Committee for review.

Certain studies meeting exempt criteria are still determined to be expedited. Please see Valencia College's IRB Written Procedures and Frequently Asked Questions (FAQ)

Expedited Review Categories List

https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-expedited-review-procedures/index.html

Applicability of Expedited Review

- 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.
- 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.
- IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review utilized by the IRB (i.e., expedited or full committee review).
- Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Full Committee Review

Proposed human subject research which does not fall into either the exempt or expedited review categories must be submitted for full committee review.

typically exempt categories 1, 2, 3

EXEMPT REVIEW - CATEGORIES AND EXAMPLES

OHRP EXEMPT CATEGORIES 45 CFR 46.101(B) - (WORKSHEET: HRP-312)

CATEGORY 1

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Examples:

- Evaluating the use of accepted or revised standardized tests
- Testing or comparing a curriculum or lesson
- A program evaluation of pharmacy continuing education

CATEGORY 2

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (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.

Note: The section of this category pertaining to standardized educational tests may be applied to research involving children. This category may also apply to research with children when the investigator observes public behavior but does not participate in that behavior or activity. This section is not applicable to survey or interview research involving children.

Examples:

- Surveying teachers, nurses, or doctors about a technique or an outcome
- Interviewing managers about a management style or best practice
- Conducting a focus group about an experience or an opinion of a community program

CATEGORY 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 (2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Example:

- Interviewing public officials about a local or global issue.

CATEGORY 4

Research involving the collection or study of existing* data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

***Note:** "Existing" means existing before the research is proposed to the institutional review board to determine whether the research is exempt.

Example:

- Analyzing existing tissue samples or data set which are recorded by the investigator without identifiers

CATEGORY 5

Research and demonstration projects which are conducted by or subject to the approval of department or agency

heads, and which are designed 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; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

See OHRP's guidance regarding this category (http://www.hhs.gov/ohrp/policy/exmpt-pb.html)

CATEGORY 6

(See also FDA's Exempt Category (#FDA)) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

FDA EXEMPT CATEGORIES 21 CFR 56.104

a. Any investigation which commenced before July 27, 1981 and was subject to requirements for IRB review under FDA regulations before that date, provided that the investigation remains subject to review of an IRB which meets the FDA requirements in effect before July 27, 1981.
b. Any investigation commenced before July 27, 1981 and was not otherwise subject to requirements for IRB review under Food and Drug Administration regulations before that date.
c. Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at the institution is subject to IRB review.
d. Taste and food quality evaluations and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical, or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture

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Categories 6 + 7 typically for dissertations

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.