



Office of Research Integrity-
Human Subjects

SOP #:

ORI(HS)

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| UNLV Office of Research Integrity- Human Subjects and Institutional Review Board Standard Operating Procedures | | |
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4. Procedures
Submission Intake

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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 standards requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review or fully convened utilized by the IRB.
- F. Categories one (1) through seven (7) pertain to both initial and continuing IRB review procedures for reviewing previously approved studies during continuing review are discussed in SOP 5.10.

Allowable 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 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.
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 gum base 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;

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4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving microwaves. Where medical devices are employed, they must be cleared 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 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 and 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 research 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.)

Review Outcomes

The reviewer(s) makes one of the following three determinations:

1. **Approved** The submission meets the requirements for approval. The reviewer(s) sends their review to ORI-HS staff. ORI-HS staff sends the PI an approval letter noting the date of the approval issued by the reviewer(s) and the study expiration date.
2. **Revisions or Additional Information Required** The submission requires revision or additional information in order for the reviewer(s) to make an approval. The reviewer(s) sends their review to ORI-HS staff outlining the requested revisions or information. ORI-HS staff sends the PI letter with the requested revisions or information.
3. **Full Board Review Required** The reviewer(s) determines that the submission requires review by the FB. The reviewer sends their determination along with any requested revisions or requests for information to ORI-HS staff. ORI-HS staff sends the PI a letter indicating that the submission will be reviewed by the FB along with any requested revisions or requests for information as dictated by the expedited reviewer(s). The letter includes the date of the FB meeting where the submission will be reviewed along with a deadline date (prior to meeting) for submitting any requested revisions or additional information.

Reporting Expedited Approvals to the Full Board

The FB is notified of all research approved using the expedited review process via reports contained within a FB meeting agenda. Actions approved using the Expedited review process are tracked (within

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IRBNet) and placed on a meeting agenda that is published and viewable by all members of the appropriate IRB. Agendas are created/published prior to predetermined board meeting date

5. References

45 CFR 46.101
45 CFR 46.110
21 CFR Part 312
21 CFR 56.110

Institutional Review Board Management and Function, Bankert & ACO Chapter 4-2
List of Expedited review categories <http://www.hhs.gov/ohrp/policy/expedited98.html>