1.0 Purpose

The purpose of this SOP is to describe the expedited review process for initial and continuing review.

2.0 Policy

It is the policy of the IRB that expedited review will be conducted in accordance with Health and Human Services regulations at 45 CFR §46.110. Protocols reviewed and approved by the expedited method must 1) be no more than minimal risk; 2) involve only procedures listed in one or more of the categories specified in the Federal Register (63 FR 60364-603-67, November 9, 1998); and 3) meet all the criteria specified in Health and Human Services regulations 45 CFR §46.111. Expedited review may be used to perform continuing review in accordance with HRPP Policy # 11.001. Expedited review will not be used for research involving prisoners.

Three (3) applicable criteria must be met for the initial or continuing review using the expedited continuing procedure, these include:

1. The current and future research procedures present no more than minimal risk to participants (Not required for category (8) (b)).

2. The identification of the participants or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their 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. (Not required for category (8)(b)).

3. The research is not classified.

2.1 Qualifying Categories of Research

A. Collection of blood sample by finger stick, heel stick, ear stick, or venipuncture as follows:

1. From healthy, non-pregnant adults who weigh at least 110 pounds. In studies in which more than 400 ml of blood is to be drawn within an 8 week period, the participant must have a baseline hemoglobin level of 12.0 grams. After 250 ml of blood has been drawn, the hemoglobin level must be retested; anyone whose hemoglobin has fallen below 11.0 grams must be withdrawn from the study.

2. From other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, 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 (or research sessions) per week.
Note: Health and Human Services regulations at 45 CFR 46.402(a) define children 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.”

Although according to Nebraska state statute # 43-303, “Child means an individual under nineteen years of age”, this definition is irrelevant for determining which individuals under Nebraska law meet the DHHS definition of children. To determine under Nebraska law which individuals meet the DHHS definition of children, the relevant Nebraska laws define the legal age to consent to treatment or procedures involved in some research. In some cases, individuals such as emancipated minors or minors requesting treatment for contraceptives, venereal disease, or drug abuse, have reached the legal age under Nebraska law to provide consent. These individuals are “children” under Nebraska law, but are not “children” under DHHS regulations, in that the additional protections of Subpart D are not required because these individuals have reached the legal age to consent to the treatments or procedures involved in the research.

B. Prospective collection of biological specimens for research purposes by non-invasive means.

Examples include:

1. Hair and nail clippings in a non-disfiguring manner;

2. Deciduous teeth (at time of dental 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. Supragingival 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.
C. Collection of data through non-invasive 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 or 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 include:
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 participant or an invasion of the participant’s privacy.

2. Weighing or testing sensory acuity.

3. Magnetic resonance imaging.

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 for the age, weight, and health of the individual.

D. 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).

Note: Some research in this category may be exempt from the Health and Human Services regulations for the protection of human participants. This listing refers only to research that is not exempt.

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

F. 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 Health and Human Services regulations for the protection of human participants. This listing refers only to research that is not exempt.

G. Continuing review of research previously approved by the convened IRB meets one of the following conditions:
1. Where (a) the research is permanently closed to the enrollment of new participants; (b) all participants have completed all research interventions; and (c) the research remains active only for long-term follow-up of participants, OR
2. Where no participants have been enrolled and no additional risks have been identified, **OR**

3. Where the remaining research activities are limited to data analysis.

### 2.2 Expedited review process

**A.** The IRB staff will perform a pre-review of all applications, which qualify for expedited review, using the OHRP Human Subject Regulations Decision Charts (September 24, 2004) as necessary (http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm). The IRB staff will obtain clarifications from the PI and ask for revision of submission documents, if necessary.

**B.** Once the pre-review is completed, the IRB Chair or Vice Chair will normally serve as the expedited reviewer. If warranted by the nature of the proposal, one or more experienced IRB voting members designated by the Chair will serve as an expedited reviewer(s). The IRB Administrator, in consultation with the Director and Chair, determines whether IRB members are experienced, where the minimal requirement is no less than six (6) month membership on the IRB.

If more than one (1) IRB member is designated to conduct a review, the final determination will be made by the Chair if the members do not agree.

The reviewer(s) are provided and review all submitted information, including all information required by the convened IRB.

**C.** The IRB Chair, Vice Chair, IRB Administrator or assigned IRB reviewer, retains the right to refer any protocol for review by the full IRB. However, it should be noted that the reviewers may not disapprove the research. A research activity may be disapproved only after full IRB review.

**D.** The expedited reviewer will utilize the IRB review criteria specified in HRPP Policy # 3.004. An IRB reviewer checklist is available for use by the reviewer. The reviewer using the expedited procedure evaluates and documents whether research undergoing initial or continuing review using the expedited procedure:

1. Meets the three applicability criteria.
2. Represents one or more approvable categories of research.

**E.** After a protocol or amendment is approved using the expedited review procedure, the full IRB will be notified through listing the approval in the minutes.

**F.** Any IRB member can access the complete study file via NUgrant and can make any concerns known at the full IRB meeting. Even if a protocol, or an amendment, has been approved using the expedited review procedure, the full IRB can require modification of the protocol and/or consent documents(s). Additionally, the full IRB can suspend the study or halt accrual if warranted.

### 2.3 Expedited review Actions

**A.** **Approval and full release**

No modifications or clarifications are required. All of the criteria for IRB approval specified in Health and Human Services regulations at 45 CFR §46.111 are
satisfied. The investigator will be notified of the approval in writing and is authorized to start the study.

B. **Approval with modifications, contingent upon IRB Chair/expedited reviewer or, unless otherwise specified, IRB Associate acceptance of specific modifications and/or clarifications.**

The investigator will be notified in writing as to the nature of the required modifications/clarifications. When the investigator complies, in writing, with all requirements as determined by the IRB Chair/expedited reviewer, or unless otherwise specified, IRB Associate, approval and full release will be granted.

C. **Referred for full IRB review**

The protocol is referred to the full IRB for review.

### 2.4 Documentation of Expedited continuing review

Initial review conducted under an expedited continuing review will be documented in the IRB letter to the PI. This documentation will include:

A. Identification of the specific permissible categories justifying the expedited continuing review.

B. Documentation of the review and action taken by the IRB Chair, or designated reviewer, and any findings required under the Health and Human Services regulations.

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**Administrative Approval:**

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<tr>
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<th>Title</th>
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<tr>
<td>Dan R. Hoyt, Ph.D.</td>
<td>IRB Chair</td>
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<tr>
<td>Kimberly Andrews Espy, Ph.D.</td>
<td>Associate Vice Chancellor for Research</td>
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