Southern Utah University Institutional Review Board
REVIEWER CHECKLIST
SUU IRB Documentation for Expedited Reviews Status

This form should be downloaded and opened with Adobe Reader or Adobe Acrobat.

Reviewer

Reviewer's College

Date

Reviewer's E-mail

Reviewer's Phone Extension

Title of Proposed Research

Principle Investigator (PI)

PI's E-mail

PI's College

Expedited research proposals must meet the requirements below to qualify for expedited review:

- ☐ There is an intent to publish/present off campus
- ☐ Participants do not meet the definition for "vulnerable population"
- ☐ Research involves no more than minimal risk

Are participants part of the SUU Community?

◯ YES ◯ NO

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.
Is this condition met?

◯ YES ◯ NO

Categories eligible for expedited review (Select YES or NO for each of the following)

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.

◯ YES ◯ NO

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 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.

◯ YES ◯ NO

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.

◯ YES ◯ NO

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.

◯ YES ◯ NO

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.)

◯ YES ◯ NO

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

◯ YES ◯ NO

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.)

◯ YES ◯ NO

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.

◯ YES ◯ NO

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.

◯ YES ◯ NO

The activities listed above 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.

Checklist Items

Method of Subject Selection and Recruitment:

If there are special physiological, psychological, or social characteristics of the target population which could pose special risks for them, these characteristics have been identified and individuals possessing them will be excluded from the study?

◯ YES ◯ NO ◯ NA

Are there incentives to participate which are excessive or coercive?

◯ YES ◯ NO ◯ NA

Comments, if any, about Method of Subject Selection and Recruitment

Privacy & Confidentiality

If one or more participant's identity is known to investigator(s), adequate measures have been taken to protect their identity.

◯ YES ◯ NO ◯ NA

Does the proposed research involve observation or intrusion in situations where the subjects have a reasonable expectation of privacy?

◯ YES ◯ NO ◯ NA

Are the investigator's disclosures to subjects about anonymity/confidentiality adequate?

◯ YES ◯ NO ◯ NA

Comments, if any, about Privacy & Confidentially

Method for Obtaining Informed Consent:

Is informed consent information to be presented in a manner which is clear to participants?

◯ YES ◯ NO ◯ NA

Is there exculpatory language which appears to waive participants' rights or release SUU from negligence?

◯ YES ◯ NO ◯ NA

Comments, if any, about Method for Obtaining Informed Consent:

Required Elements for Informed Consent

Participants have been informed about *the investigator's name and position at SUU*

◯ YES ◯ NO ◯ NA

Participants have been informed about *the purposes of the research*

◯ YES ◯ NO ◯ NA

Participants have been informed about *the expected duration of the subject's participation*

◯ YES ◯ NO ◯ NA

Participants have been informed about *the procedures to be followed in the research*

◯ YES ◯ NO ◯ NA

Participants have been informed about *the type/nature of the questions, if using surveying/ interviewing methods*

◯ YES ◯ NO ◯ NA

Participants have been informed that *participation is voluntary. and that they may discontinue the study at any time for any reason without penalty, and that they may ask questions at any time.*

◯ YES ◯ NO ◯ NA

Participants have been informed that *they may skip any question they do not wish to answer, if a survey/interviewing method is being used.*

◯ YES ◯ NO ◯ NA

Participants have been informed about *any reasonable, foreseeable risks or discomforts.*

◯ YES ◯ NO ◯ NA

Participants have been informed about *any benefits to the participant which may reasonably be expected from the research*

◯ YES ◯ NO ◯ NA

Participants have been informed about *whether participation and the data collected is anonymous or confidential*

◯ YES ◯ NO ◯ NA

Participants have been informed about *who to contact for information or concerns regarding the study*

◯ YES ◯ NO ◯ NA

Participants have been informed about *whether or not compensation will be awarded and the details thereof.*

◯ YES ◯ NO ◯ NA

Comments, if any, about Required Elements of the Informed Consent

Minimal Risks:

There is no/minimal risk of breaching confidentiality

◯ YES ◯ NO ◯ NA

There is no/minimal risk of evoking emotional distress or other negative emotional response(s)

◯ YES ◯ NO ◯ NA

There is no/minimal foreseeable risk to subject's reputation and/or social status

◯ YES ◯ NO ◯ NA

There is no/minimal foreseeable legal risk to subject

◯ YES ◯ NO ◯ NA

There is no/minimal foreseeable risk to subject's employability or employment status

◯ YES ◯ NO ◯ NA

If using deception, the deception does not violate participants' rights, is unlikely to affect their decision of whether to participate, and does not involve more than minimal risk.

◯ YES ◯ NO ◯ NA

Comments, if any, on Minimal Risks

Benefits

There are immediate benefits to the individual

◯ YES ◯ NO ◯ NA

There are probable benefits to the target population

◯ YES ◯ NO ◯ NA

The research will likely contribute to the field of study/organization

◯ YES ◯ NO ◯ NA

Comments, if any, on Minimal Risks

Decision:
Based on the above materials this proposal should be:

◯ Accepted as submitted
◯ Accept contingent on minor revisions
◯ Not be accepted

If minor revision are needed list below

If the proposal should not be accepted, provide the justification for this decision

Submit