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## Conflict of Interest (CoI) Disclosure

- Yes  
 No Do you have a conflict of interest (personal, financial, academic or other interest) in reviewing this protocol that would prevent you from conducting a fair and objective review?

[Clear](#)

If No, please continue with your review by completing all areas of the checklist.

If Yes, please contact your IRB Coordinator immediately. You will be provided with specific instructions should your conflict of interest be valid. Please complete this COI section only and save this checklist in the appropriate study within the ERICA system.

- *Example of personal COI – your spouse, an immediate family member, your advisor*
- *Example of academic COI – your student, my research partner/colleague*
- *Example of financial COI – income from stock in etc. the Sponsor or company whose business is substantially related to the subject matter of the research.*

### Reviewer Description of Conflict of Interest:

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## Reviewer Description

### Reviewer Description of Study/Study Progress/Amendment:

*Please provide, in your own words, a description of the study here. You can read this at the meeting in order to summarize the study.*

Yes  No [Clear](#) **Does the IRB have the appropriate expertise to review this research?**

*If no, please contact your IRB coordinator immediately to arrange appropriate consultation (i.e. ad-hoc consultant reviewer).*

**For new studies:** A risk category (e.g. minimal, moderate) has preliminarily been assigned to this study by the IRB staff. Document the risk category for the study.

**For continuing reviews and amendments:** The risk assessment has been assigned. Continue to the next page. Consideration of changes in the risk assessment will be addressed in a separate portion of the checklist for continuing reviews and amendments.

- The study is minimal risk.
- Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*
- The study is greater than minimal risk.

[Clear](#)

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## Criteria for IRB Approval

- Check here if you are assigned as the second reviewer and may not be able to assess some of the criteria below (e.g. using procedures which are consistent with sound research design). Review of the criteria which you are unable to assess will be deferred to the primary reviewer.

### Instructions:

Mark the appropriate box.

- If you answer "yes", the required criterion is satisfied.
- If you answer "no", the required criterion is not satisfied. You may request modifications in the "Specific Concerns" section.
- If instructed, one option must be selected in order to satisfy a required criterion.

In order to approve research, the IRB shall determine that all the following requirements are satisfied.

### Risks

- Yes  
 No  
Clear
- Are risks to participants minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk?
- Yes  
 No  
Clear
- Are risks to participants minimized whenever appropriate by using procedures already being performed on the participants for diagnostic or treatment purposes?
- Yes  
 No  
Clear
- Are risks to participants reasonable in relation to anticipated benefits, if any, and the importance of knowledge that may reasonably be expected to result?

### Equitable Selection of Subjects

Is the selection of participants equitable?

- Yes  
 No  
Clear
- *Appropriate inclusion and exclusion criteria for research participants are essential in order to ethically justify human subject research. This may be in regard to race, ethnicity, sex, relevant demographic data, or medical criteria.*
  - *Inclusion and exclusion criteria should be clearly stated and reasonable. Poorly specified inclusion/exclusion criteria may result in inadvertent exclusion of eligible research subjects and an imbalance of or inappropriate enrollment of research subjects.*
  - *If for some extenuating reason, inclusion criteria are not equitable, the investigator must provide justification.*
  - *Recruitment methods do not adversely affect the equitable selection of participants.*

### Will Informed Consent be obtained?

**At least one option must be selected to meet this approval criterion. Select the process the investigator will use to obtain informed consent:**

- N/A** The study is closed to enrollment, so informed consent will no longer be obtained.

**Informed consent will be obtained:** The investigator will obtain informed consent from prospective participants or the participant's representative (i.e. parent or legally authorized representative).

*The "Informed Consent Requirements" portion of the checklist will be required.*

- 
- *Studies involving deception should also meet the criteria for Waiver or Alteration of Informed Consent. If deception is involved in the proposed study, please check "obtaining informed consent" and "requesting informed consent be waived or altered".*

**Informed consent will not be obtained or some consent elements will be left out:** The investigator requests that informed consent be waived or altered for part or all of the study.

*The "Waiver or Alteration of Informed Consent" portion of the checklist will be required.*

- 
- *A Waiver of Informed Consent may be used to request that all elements of informed consent will be waived. An example is a retrospective chart or record review where there will be no contact with participants and no documentation of consent.*
  - *A Waiver of Informed Consent may also be used to request that one or more required elements of consent be removed. An example is when the investigator has asked that the requirement to explain the purpose of the research be waived.*

- An Alteration of Informed Consent means requesting that one or more required elements of consent be altered. An example is when incorrect information is disclosed, as might occur in a study using deception.

### How will Informed Consent be documented?

**At least one option must be selected to meet this approval criterion. Select the process the investigator will use to obtain informed consent:**

**N/A** The study is closed to enrollment, so informed consent will no longer be documented.

**N/A** The informed consent process will be waived, so informed consent cannot be documented.

**A Consent Document will be signed:** The investigator will document informed consent in writing.

*The "Written Documentation of Informed Consent" portion of the checklist will be required.*

- 
- Documentation of Consent can be obtained by using an informed consent document, parental permission document or short form.

**A Consent Document will not be signed:** The investigator requests that the documentation of informed consent be waived.

*The "Waiver of Documentation of Consent" portion of the checklist will be required.*

- 
- A Waiver of Documentation of Consent may be used to request that the requirement to obtain written documentation of consent be waived. Examples are questionnaire cover letters, web-based consents, and consent without obtaining signature, etc. Therefore, a consent process is still in place, but there is no documentation.

### Monitoring Data to Ensure the Safety of Subjects

**One option must be selected to meet this approval criterion.**

The study is minimal risk and a data safety and monitoring plan is not required by the University of Utah IRB.

Adequate provisions are made for monitoring the data collected to ensure the safety of participants

Clear

### Provisions to Protect Privacy

Privacy refers to **persons and to their interest in controlling access of others to themselves**. Privacy can be defined in terms of having control over the extent, timing and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

Are adequate provisions in place to protect the privacy interests of the participants?

- In research, privacy typically refers to whether the participant considers it the researcher's business to delve into the participant's life concerning whatever matter is the topic of the research. Whether a subject wishes to give a researcher access to such information depends on the background of the participant, who is sponsoring the research, the context in which the data are to be gathered, and such factors as whether the participant finds the researcher likeable.
- Points to Consider:
  - Will participants be comfortable in the research setting? A protocol involves normal volunteers in an HIV vaccine study. Having participants show up to the general medical clinic may be more comfortable for the volunteers than showing up to the AIDS clinic, because if they show up to the AIDS clinic, they may be worried that other people will incorrectly assume that they have AIDS.
  - Do procedures for identifying participants minimize any invasion of privacy? Your privacy has been invaded when someone accesses your information who you did not want to access your information. Has the researcher considered and minimized the invasion of privacy?
- Ways to respect privacy in research:
  - Informed consent
  - Knowledge of a participant's culture
  - Rapport and sensitivity to individuals
  - Research associates from that culture
  - Consultation with appropriate professionals and peers of participants

Yes

No

Clear

### Provisions to Protect Confidentiality

Confidentiality is about **data** (not people), **and about agreements and procedures for limiting the access of others to data**. Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission.

Has the investigator adequately described provisions in place to protect the confidentiality of the participants?

- The investigator must outline measures to protect confidentiality. However, a promise to maintain confidentiality is not required by regulation.
- Examples of outlining measures to protect confidentiality without promising confidentiality:
  - In a focus group, the investigator does not promise confidentiality but outline measures intended to protect confidentiality to the extent possible. In addition, the investigator informs participants that other members of the focus group may disclose information. Therefore, the investigator has adequately described provisions in place to protect the confidentiality of participants.
  - The investigator states that confidentiality will not be promised. There are no legal or ethical requirements to maintain confidentiality and data release will not cause risk of harm. Therefore, the investigator has adequately described provisions in place to protect the confidentiality of participants.

Yes

No

Clear

- *Ways to protect confidentiality:*
  - *Locked cabinets accessed only by the PI and study personnel*
  - *Procedures eliminating linkage of data to unique identifiers*
  - *Statistical strategies*
  - *Certificate of confidentiality*
  - *Ethical editing of qualitative descriptions*
  - *Restricted access*

### Vulnerable Populations

#### One option must be selected to meet this approval criterion:

- None of the participants are likely to be vulnerable to coercion or undue influence.

Additional safeguards been included in the study to protect the rights and welfare of participants likely to be vulnerable to coercion or undue influence.

- *Select the vulnerable population involved in the research below. Not all vulnerable populations are listed below. You may identify another vulnerable population and consider whether additional safeguards have been included to protect their rights and welfare.*
- *You may refer to the Vulnerable Population page of the application to view the investigator's justification for inclusion of such participants.*
- *Points to Consider:*
  - *The PI has provided sufficient information to describe any processes that might be necessary to protect vulnerable populations. Each population and protocol has different issues, but things to consider are privacy, confidentiality, and the procedures proposed by the PI.*
  - *Will any special physiological, psychological, or social characteristics of the subject group pose special risks for them?*
  - *If the subjects are susceptible to pressures, are there mechanisms that might be used to reduce the pressures or minimize their impact?*
- *If you are unsure about this population or have questions, please contact the IRB office prior to the meeting. An ad hoc consultant can be identified to help answer any concerns.*

Clear

### Investigator Resources and Responsibilities

- Yes Have all financial conflicts of interest for applicable investigators and study staff been managed, reduced, or eliminated in an acceptable manner?
- No
- N/A
- Clear
- *N/A if there are no investigators or study staff with financial conflicts of interest.*
  - *For University of Utah Investigators, financial conflict of interest management plans can be viewed on the study workspace on the Ancillary Approvals tab. The Conflict of Interest Committee determines management plans based upon financial disclosures.*
  - *For VA Investigators, financial conflict of interest management plans are attached to the Documents and Attachments page of the application. The R&D Committee determines management plans based upon financial disclosures.*

- Yes Do the investigators and study staff have the appropriate background, experience, and resources to conduct the research?
- No

Clear

#### Specific Concerns:

*If any, explain any concerns you may have and WHY they are of concern. You must be very specific. If you have none, please state "None."*

#### Resolutions to Concerns:

*Provide specific resolutions to concerns listed above. Your requested clarifications, suggestions, and revisions must be specific.*

**REMINDER:** If you need more information than is in the current application to resolve issues related to the approval criteria, the IRB encourages you to contact the PI before the Board meeting. Your IRB coordinator can contact the PI on your behalf (if you wish to remain anonymous).

**DETERMINATION:** Are the approval criteria met?

- Yes.
- Yes, if the above stipulation is met.
- No.

Clear

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## Vulnerable Populations

### HELP?

- The research involves pregnant women or fetuses as participants.  
*The pregnant women or fetuses checklist will be required.*
- The research involves neonates as participants.  
*The neonate checklist will be required.*
- The research involves prisoners as participants.  
*The prisoner checklist will be required.*
- The research involves children as participants.  
*The children checklist will be required.*
- The research involves children who are wards of state (or another agency, institution or entity).  
*The ward of state checklist will be required.*
- The research involves mentally disabled individuals as participants.
- The research involves individuals with cognitive or decisional impairment.
- The research involves economically or educationally disadvantaged persons.
- The research involves students, staff or faculty of the research institution.
- Other participants likely to be vulnerable to coercion or undue influence.  
*Please list:*

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## Additional Considerations

### Instructions:

The following questions may or may not apply to this study. Please mark "N/A" if the study does not need to address these issues. You may request modifications if necessary in the "Specific Concerns" section.

### HIPAA

- This section is N/A
- Authorization for use of PHI will be waived for all or part of the study.  
*Select if a waiver of authorization will be used to review PHI for recruitment purposes.*
- Authorization for use of PHI will be documented in writing for all or part of the study.
- A HIPAA Limited Data Set will be used for all or part of the study.
- A Safe Harbor or Statistical Analysis De-Identified Data Set will be used for all or part of the study.

### Compensation

- This section is N/A

Is compensation offered to the participants appropriate?

- Yes
- No  
Clear
- The Application and Consent Document should indicate any compensation provided for participation, including the schedule for payment(s).*
  - Appropriate compensation is about \$20/hour of the participant's time, in most cases. If more, the PI should provide justification. Some especially unpleasant or uncomfortable procedures may be compensated at a higher level.*
  - If applicable, participants should be offered a pro-rated amount if they choose to withdraw from the study early. This should be addressed in the Application and the Consent Document.*

### Recruitment

- This section is N/A

- Yes Do the recruitment methods, including advertisements, support an equitable selection of participants?
- No  
Clear
- Refer to the Study Information page of the application, which should describe the recruitment of participants.*
  - There are many ways recruitment may be inappropriate: it may produce a biased sample; it may intrude unnecessarily on a participant or his/her caregivers at a stressful time; it may done prior to a regularly scheduled office visit, where the participant feels coerced into agreeing, etc.*
- Yes
- No Advertisements, flyers, radio scripts, etc. have been submitted and meet current IRB guidelines (see Investigator Guidance Series: Recruitment Methods and Advertisements)
- N/A  
Clear

### VA Studies

- Yes
- No Will this study be conducted at or in collaboration with the Salt Lake City VA?  
*If Yes, the VA Checklist will be required.*
- Clear

### Leading a Multi-Center Study

- This section is N/A if the PI on the application is not the lead investigator

If the PI on this application is the lead investigator (i.e., the location for which the IRB is reviewing is the lead site) for a multi-center study, is there an adequate plan for management and communication among sites for information obtained in its research that may be relevant to the protection of research participants?

- Because the University of Utah IRB conducts reviews for many different institutions, the PI of this application may act as the lead investigator at one of the following locations:*

- Yes
    - University of Utah
    - VASLCHCS
    - Primary Children's Medical Center
    - Shriners' Hospital for Children
    - Another location that has signed a reliance agreement with the University of Utah IRB
  - No
    - Refer to the Study Location and Sponsors page of the application, which should describe this plan.
- Clear

### External Sites

- This section is N/A
  - Yes If there are external sites participating within the city or state, is there an adequate plan for management and communication among sites for information obtained in its research that may be relevant to the protection of research participants?
  - No
    - Refer to the Study Location and Sponsors page of the application, which should describe this plan.
- Clear

### Investigational Drugs

- This section is N/A
  - Yes Has an IND (Investigational New Drug) number been provided and verified for this study?
  - No
    - The IRB accepts the FDA letter, sponsor letter or other sponsor-generated document with the IND number listed (e.g. company protocol) as verification of an IND.
    - Refer to the column #1 of the Investigational Use of a Drug page of the application, which should provide the IND number if one has been assigned by the FDA.
- Clear
- Does the IRB need to determine whether an IND is required?  
If yes, the IND Determination checklist will be required.
- Yes
    - If there is no IND provided for the study and you are unsure whether an IND is required, check "yes".
    - If there is no IND provided for off-label use of an approved drug, check "yes".
  - No
    - If the FDA has issued an IND Exemption, check "no".
    - Refer to column #2 of the Investigational Use of a Drug page of the application for any relevant details provided by the investigator.
- Clear
- Yes Has the investigator provided an adequate plan to control for the use of the investigational drug in this study?
  - No
    - Refer to the Investigational Drug Data Form page of the application, which should describe a plan for control of the investigational drug.
- Clear

### Investigational Devices

- This section is N/A
  - Yes Does the study involve the use of an investigational device?
  - No
    - If yes, the Risk Determination for Devices checklist will be required.
- Clear
- Yes Has the investigator provided an adequate plan to control for the use of the investigational device in this study?
  - No
    - Refer to the Investigational Use of a Device page of the application, which should describe a plan for control of the investigational device.
- Clear

### Placebo Guidelines

- This section is N/A

The IRB may accept placebo comparator under any of the following situations. If the study is designed to include placebo, select the appropriate category:

- 1. There are no established effective therapies for the population and for the indication under study as determined by the board.
- 2. Existing evidence raises substantial doubt regarding the net therapeutic benefit of available therapies
- 3. Participant(s) is/are refractory to the available therapies by virtue of their past treatment history of known medical history.
- 4. The study involves adding a new investigational therapy to an established effective therapy (established effective therapy + new therapy vs. established effective therapy + placebo).
- 5. Participants have determined that the response to the established effective therapies for their condition is unsatisfactory to them.
- 6. Participants have previously refused established effective therapies for their conditions.
- 7. Minor health problems. This includes conditions for which both informed participants and their physicians might reasonably elect to withhold treatment (e.g., baldness, tension headache, allergic rhinitis).

- 8. Placebo cross-over designs will be evaluated on a study by study process.
- 9. The proposed placebo exposure is of a specified duration such that evidence supports the exposure as no more than minimal risk. Such cases will be reviewed by the IRB on a case by case basis.

**Specific Concerns:**

*If any, explain any concerns you may have and WHY they are of concern. You must be very specific. If you have none, please state "None."*

**Resolutions to Concerns:**

*Provide specific resolutions to concerns listed above. Your requested clarifications, suggestions, and revisions must be specific.*

**REMINDER:**

*If you need more information than is in the current application to resolve issues related to the approval criteria, the IRB encourages you to contact the PI before the Board meeting. Your IRB coordinator can contact the PI on your behalf (if you wish to remain anonymous).*

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## Final Decision

- Refer to guidance "Categories of Action" section in the IRB Member Handbook.

Approved as submitted  
 Approved with changes/clarifications reviewed by IRB chairman or designee  
 Tabled  
 Disapproved  
[Clear](#)

### Continuing Review:

If you are reviewing an amendment, proceed to "Final Comments" below.

Continuing Review of research should be conducted by the IRB at intervals appropriate to the degree of risk and not less than once per year. Please select how often this study should be reviewed:

**IRB Administrator Recommendation:** 1 Year

### Other (if applicable):

A study can be approved for up to 2 years when it is **minimal risk** AND it **is not** initiated, funded, or supported by the U.S. Government. U.S. Government includes groups like the VA, DHHS, NIH, FDA. Click Help for the full list of government agencies. Also, studies involving UPDB may not be approved for 2 years.

[HELP?](#)

6 Months  
 1 Year  
 2 Years  
 Other  
[Clear](#)

If Other: Please explain (example: after first 5 participants enrolled, for a period of 4 months):

The IRB may consider the following factors when deciding to increase the frequency of continuing review:

1. Whether the study involves new or novel therapeutic modalities, drugs, biologics, or significant risk medical devices
2. The degree of uncertainty regarding the risks involved
3. The vulnerability of the subject population
4. The experience of the investigators in conducting the research
5. The IRB's previous history with the investigators
6. The projected rate of enrollment
7. Other situations where the IRB determines it is appropriate to conduct review more frequently than annually

### Final Comments:

### Attachments:

Add

Name	Version	Date Created	Date Modified
There are no items to display			

**Please Note:** All studies also undergo administrative review by at least two IRB staff members. The revision letter sent to the investigator will contain reviewer comments, comments from the board discussion, as well as the staff members' comments.

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Finish

## Final Decision

If "Disapproved", mark disapproval criteria below.

The risks to participate are not minimized.

*Examples:*

- *The study is poorly or improperly designed such that meaningful conclusion cannot be derived.*
  - *Unnecessary risks are created.*
- Risks outweigh the benefits to participants or society.
- Selection of subjects is inequitable through biased recruitment, enrollment, or coercive compensation.
- Procedures for obtaining and documenting informed consent are inadequate.
- The monitoring plan to ensure the safety of participants is inadequate.
- Participant privacy and/or confidentiality are not adequately protected.
- Vulnerable populations are likely to experience coercion or undue influence.
- The study violates any laws or regulations of the United States, the state of Utah, or the University of Utah

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Finish

## New Study Application - Expedited Review

The IRB Administrator selected the following category:

Category	Description
There are no items to display	

There are no items to display

**1. The research presents no more than minimal risk to the participants.**

True  False [Clear](#)

**2. The identification of the subjects 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.**

True  False [Clear](#)

**3. The research is not classified.**

True  False [Clear](#)

**4. Please indicate all of the categories for which this research qualifies.**

[View](#) **Category 1** Clinical studies of drugs and medical devices only when one of the following conditions is met.

- a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required.
- b. Research on medical devices for which one of the following is true:
  - i. An investigational device exemption application (21 CFR Part 812) is not required
  - ii. The medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

[View](#) **Category 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;
- 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.

[View](#) **Category 3** Prospective collection of biological specimens for research purposes by noninvasive means.  
[Click on the Category to See Examples](#)

[View](#) **Category 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.  
[Click on the Category to See Examples](#)

[View](#) **Category 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).

[View](#) **Category 6** Collection of data from voice, video, digital, or image recordings made for research purposes.

[View](#) **Category 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.

**Determination:**

- The application IS eligible for expedited review.
- The application is NOT eligible for expedited review.

[Clear](#)