# Conflict of Interest (CoI) Disclosure

Yes
No
Clear

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?

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:**

# 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

# Amendment Checklist Page

**Risk/Benefit Determination of Amendment:**

Yes
No
Clear

The amendment does not alter the study's current approval, because the following are still true:

- Risks are minimized.
- The risk/benefit ratio remains appropriate.
- Participants are selected equitably.
- The informed consent process and/or waivers of consent are appropriate.
- The data and/or safety monitoring plans are appropriate.
- The privacy and confidentiality of participants are protected.
- The inclusion of vulnerable populations is appropriate.

*If new study components are being added or if components change significantly, you may be required to complete separate checklists as part of this amendment (e.g. for informed consent, waivers, vulnerable populations, etc.).*

Yes
No
Clear

Does the risk level for this study remain the same?

- *This means that risk determination for this study does not change (e.g. if the study is minimal risk, it remains minimal risk, etc.).*

Yes
No
N/A
Clear

If information relating to changes in the study appears that they may affect the willingness of the participant to continue his/her participation, a plan has been provided to relay this information to them.

- *N/A if no information relating to changes in the study needs to be relayed to participants.*

Yes
No
N/A
Clear

Based on the information provided, may the study proceed without an audit or observation of the consent process?

- *N/A if there is no consent process in this study.*
- *If the IRB is concerned about the conduct of a study, the IRB may consider whether, as part of providing adequate oversight of the study, an active audit is warranted. The IRB also has the authority to observe the consent process. Please see the Board Member Guidance Series: IRB Authority-Observation of Consent and Conduct of Research.*

**Requested Revisions/Clarifications of Amendment:**

**Document Review:**

Please compare the currently approved study protocol (if applicable) and consent/parental permission/assent documents that have been provided by the IRB office.

Yes
No
N/A
Clear

**Revised consent document(s), parental permission document(s), and/or assent document(s) are submitted and appropriate.**

- *N/A if changes to these documents are not necessary for this amendment.*

Yes **Revised study application or full protocol are submitted and appropriate.**

No

N/A

- *Changes to the study application are made through the Update/Modified Study Application.*
- *N/A if changes to the application are not necessary for this amendment or if there is not a full protocol for this study.*

Clear

**Requested Revisions/Clarifications**: Provide more information if you answered "No" to any questions above.

# 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.*

## 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

# Amendment Application - Minor Changes for Expedited Review

***Instructions:***
*Please determine whether this amendment involves only minor changes and qualifies for an expedited review by the following questions and guidelines.*

**All of the following must be true:**

True
False
Clear

The proposed changes do not involve greater than minimal risk to the participants.

True
False
Clear

The proposed changes do not have a significant impact on the

- Risk level of the study
- Risk: benefit ratio of the study
- Participants' willingness to participate in the study

**Determination:**

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

Clear

# Amendment Application - Research Previously Eligible for Expedited Review

***Instructions:***
*Amendments for studies that were expedited at last review (new study or continuing review) can be expedited if the expedited status does not change.*

*You must re-confirm the expedited review category(ies) for the study, to ensure that the proposed amendment does not make the whole study ineligible for expedited review in the future.*

*If the amendment changes the category(ies) under which this study may be expedited in the future, select all appropriate categories.*

*Click on the Category to See Examples*

**All of the following must be true:**

**The IRB Administrator/Coordinator selected the following category:**

| Category | Description |
|---|---|
| There are no items to display | |

**1. The research presents no more than minimal risk to the participants.**
◯ Yes ◯ No Clear

**2. The identification of the subjects or their responses will not reasonable 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.**
◯ Yes ◯ No Clear

**3. The research is not classified.**
◯ Yes ◯ No 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. |
| View | Category 9 | Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two through eight 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. |

**Determination:**

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

Clear