**IRB**

IRB File No.:

Date Received:

# Mod Instances:

 **Expedited or Full Review Checklist for Modification of Research Protocol**

**Protocol Information**

**Title of Project:**

**Principal Investigator:**   **Co-PI / Faculty Sponsor:**

**Department: Original Approval Date:**

If the research involves minors as subjects, complete and attach the review checklist for [*Expedited*](https://www.eiu.edu/grants/files_irb/IRB%20Expedited%20Review%20Checklist-Children.doc) or *Full* Review-Minors

If the research involves prisoners as subjects, complete and attach [*IRB Review Checklist-Prisoners*](https://www.eiu.edu/grants/files_irb/IRB%20Review%20Checklist-Prisoners.doc)

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| --- |
| **Verification of Expedited Review Status** |
| 1. The research activities present [ ]  No more than minimal risk to subjects [ ]  More than minimal risk to subjects – Document justification in the comments section*A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed 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 [*[*45 CFR 46.102(i)*](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.102)*]* |
| 2. The research activities involve only procedures in one or more of [expedited review categories](https://www.eiu.edu/grants/Expedited%20Criteria.docx) [ ]  Yes – Category Number(s): [ ]  No – Full Review is required. Document justification in the comments section |
| **Regulatory Criteria for Review and Approval****Please provide justification in the comments section for any item with a response of “No”** |
| 1. Risks to subjects are minimized [[45 CFR 46.111a(1)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.111)]*Risk: The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study.*Considerations:* Risks are minimized using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk
* Adequate provisions are in place to minimize research risk, especially for those with any special physiological, psychological, or social characteristics that could pose special risk
* Research personnel are qualified

[ ]  Yes [ ]  No – document justification in the comments section |
| 2. Risks are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result [[45 CFR 46.111a(2)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.111)]*Benefit: Something of health-related, psychological, or other value to an individual research subject, or something that will contribute to the acquisition of generalizable knowledge.*Considerations:* Consider only those risks and benefits that may result from the research, not risks and benefits of therapies subjects would receive even if not participating in the research
* The research involves the prospect of direct benefit to individual subjects, and/or, is likely to contribute to the acquisition of generalizable knowledge
* Foreseeable risks and anticipated benefits to subjects and the knowledge researchers expect to gain are accurately and clearly identified and considered
* The proposed research population’s perception of risks and benefits are taken into account

 [ ]  Yes [ ]  No – document justification in the comments section |
| 3. Selection of subjects is equitable [[45 CFR 46.111a(3)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.111)]Considerations:* The purpose of the research, its setting, and whether it requires or justifies using the proposed subject population
* Will solicitation of subjects avoid placing a disproportionate share of the burdens of research on any single group?
* To the extent that risks and benefits to the subjects are anticipated, are they distributed fairly?
* Are inclusion / exclusion criteria appropriate?
* Participant recruitment / enrollment procedures are appropriate and not based solely on researcher convenience
* Influence of incentives on participants

 [ ]  Yes [ ]  No – document justification in the comments section |
| 4. Informed consent will be adequately sought from each prospective subject or the subject’s legally authorized representative [[45 CFR 46.116](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116)] Considerations:* Informed consent process is adequately described in application
* All [basic elements of informed consent](https://www.eiu.edu/grants/files_irb/Informed%20Consent%20Checklist.doc) are included, as well as any applicable additional elements
* Circumstances of consent process (e.g. timing, place, person obtaining consent) minimize coercion/undue influence
* Circumstances of the consent process provide sufficient opportunity for the subject or subject’s legally authorized representative (LAR) to consider whether or not to participate
* Informed consent does not include exculpatory language (i.e. waives or appears to waive any of the subject’s legal rights or releases or appears to release the investigator, sponsor, institution or its agents from liability for negligence)
* Information is in language understandable to the subject or LAR and does not include undefined technical terms

[ ]  Yes [ ]  No – document justification in the comments section [ ]  N/A, Informed consent will be waived – Complete 4a |
| 4a. All of the following criteria have been satisfied for waiver of informed consent (or waiver of parental permission, or waiver of child assent) [[45 CFR 46.116e](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116(e))]:* The research involves no more than minimal risks to subjects; **AND**
* The research could not be practicably carried out without the waiver/alteration; **AND**
* If the research involves using identifiable private information or biospecimens, the research could not be practicably carried out without using such information or biospecimens in an identifiable format; **AND**
* Waiver/alteration will not adversely affect the rights and welfare of subjects; **AND**
* Whenever appropriate, subjects will be provided with additional pertinent information after participation

[ ]  Yes [ ]  No – document justification in the comments section [ ]  N/A  |
| 5. Informed consent will be appropriately documented [[45 CFR 46.117](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.117)] *Informed consent shall be documented using a written consent form signed by the subject or the subject’s LAR.* [ ]  Yes [ ]  No – document justification in the comments section [ ]  N/A, documentation of informed consent will be waived – Complete 5a |
| 5a. At least one of the following criteria have been satisfied to waive the requirement of the investigator to obtain a signed consent form (or parent permission form) [[45 CFR 46.117c](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.117)]:* The only record linking the subject and the research would be the consent document and the principle risk would be potential harm resulting from a breach of confidentiality; **OR**
* The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; **OR**
* The subjects or LAR are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is a mechanism for documenting that informed consent was obtained.

[ ]  Yes [ ]  No – document justification in the comments section [ ]  N/A  |
| 6. Provisions to protect the privacy of subjects and to maintain confidentiality of data are adequate, when appropriate [[45 CFR 46.111a(7)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.111)].*Consider the nature, probability, and magnitude of harms that would be likely to result from a disclosure of collected information outside the research.*Considerations:* There are adequate provisions for protecting the confidentiality of the data through anonymizing techniques, coding systems, destruction of identifying information, limiting access to the data, or other methods appropriate to the study
* Investigator’s disclosures to subjects about confidentiality are adequate
* Procedures for sharing data are described and satisfactory
* Plans for storage and retention of records are described and satisfactory
* Plans for future use of data are adequate and satisfactory

[ ]  Yes [ ]  No – document justification in the comments section  |
| 7. If applicable, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects [[45 CFR 46.111a(6)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.111)].*Monitoring: The collection and analysis of data as the project progresses to assure the appropriateness of the research, its design, and subject protections. NOTE: The presence of a data and safety monitoring plan is* ***not*** *required for research that is deemed no more than minimal risk.*Considerations:* Does the researcher need to monitor the data frequently to determine if there needs to be a change in the research design, a change in the information presented to subjects, or even termination of the study before the end date?
* Would the use of a research oversight process enhance subject safety?

[ ]  Yes [ ]  No – document justification in the comments section [ ]  N/A  |
| 8. When applicable, safeguards are in place for vulnerable populations [[45 CFR 46.111b](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.111)].*When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.*Considerations:* Procedures to address subjects’ vulnerabilities are included and are appropriate and adequate
* Procedures to assess subjects’ decisional capacity and understanding of the research are adequate
* If applicable, procedures for obtaining consent from legally authorized representative are adequate

[ ]  Yes [ ]  No – document justification in the comments section [ ]  N/A  |
| **Review Recommendation Summary** |
| Are there any potential concerns in this study regarding inclusivity or potential points of tension with exclusivity? | [ ]  Yes [ ]  No |
| Are there any potential concerns regarding the scientific merit of this study and the competency of the investigator(s) to conduct the study? | [ ]  Yes [ ]  No |
| Are there any potential concerns regarding the investigators’ knowledge about the regulations and policies governing research with human subjects? | [ ]  Yes [ ]  No |
| **IRB Action**:[ ]  Modification approved, no continuing review required [ ]  Modification approved, continuing review required in the following timeframe: [ ]  12 months [ ]  Other: Explain why continuing review would enhance the protection of research subjects in the comments section.[ ]  Modifications required to secure approval of this modification (*see comments*)[ ]  Refer to the convened IRB for Full Review - Document justification in the comments section[ ]  IRB review of this modification is not required *For minor modifications that do not change the substance of the project, the level of risk to the subjects, or the level of review required, the IRB chairperson, vice chairperson, or a designated IRB member may conduct the review, and a second review is not required.* [ ]  The requested modification does not require a second review based on the listed above |
| Comments: |
| **Signature of Reviewer**\***:** | **Date:** |

\*For Full Board Review, only IRB Chair or Vice Chair Signature is required.