Proposal # \_\_\_\_\_\_\_\_\_\_ Expires: \_\_\_\_\_\_\_\_\_ IRB office

**IRB- Project Modification Form**

Institutional Review Board

347 S. Gladstone Ave

Aurora, IL 60506

Researcher: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

This form is to be used when substantial changes are being made to the study. Federal regulations require "prompt reporting to the IRB of proposed changes in a Research activity" and "such changes in approved Research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject." (45 CFR 46 103(b)(4)(iii)).

Formal approval of modifications by IRB must be received before any substantial modifications can be implemented.

Please answer each of the following questions, attach documents as requested, and return this form to the IRB Office ***as soon as possible***. The project being reviewed is listed below. Please review and correct this title as needed.

Project Title

**MODIFICATIONS:**

1. **Type of Modifications**

☐ Procedures/Study activities

☐ Study population (ages, selection criteria, inclusion of vulnerable participants, change in number of participants)

☐ Consent form/consent process

☐ Instruments used or data collected

☐ Recruitment methods or advertising

☐ Administrative information only

☐ Change in researchers/principal investigator

☐ Change in contact information

☐ Change in title

☐ Change in funding sources

1. Describe in detail the proposed modification(s), including a rationale. List all modifications, if there is more than one. If a document (such as the consent form) is being modified, please describe where in the document the change occurs\*.

|  |  |
| --- | --- |
| 1. Currently Approved   Proposed Revision |  |
|  |
| 1. Currently Approved   Proposed Revision |  |
|  |

\*New boxes should be added for each revision or modification.

1. Risk: Does the proposed modification affect the risk to subjects (either increased or decreased)? If yes, explain.
2. Affiliates: Does the proposed modification impact off-campus sites, organizations, or other affiliates involved in the study? If yes, then how will these sites be informed of any relevant modifications?
3. Communication: Are modifications of the study/protocol going to be communicated to past and/or current participants?

|  |  |
| --- | --- |
| Yes: How and by whom? |  |
| No: Provide Justification (e.g., minor changes do not impact participants) |  |

1. Add to this document any materials affected by the modification, such as the consent form, recruitment tools, or instruments. Attach copies of the most recent IRB approved consent forms that you are currently using with this project, sending the most recent versions that have been date stamped by the IRB. (If modifications are also being requested, submit appropriately revised informed consent documents).

1. **RESEARCHER ASSURANCES:** The signature (faxed or scanned version acceptable) of the Researcher is required before this application can be processed. Other researchers who are responsible for these assurances are encouraged to sign.

I certify that the information provided in this application, and in all attachments, is complete and correct.

I understand that I have ultimate responsibility for the protection of the rights and welfare of human subjects, the

conduct of this study, and the ethical performance of this project.

I agree to comply with all AU policies and procedures, the terms of its Federal Wide Assurance, and all applicable federal, state, and local laws regarding the protection of human subjects in research.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Researcher Date