**Appendix F:**

**Study Amendment Request**

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| **Project ID#:** |  | | | | | | | | | |
| **Project Title:** | |  | | | | | | | | |
| **Principal Investigator:** | | | | |  | | | | | |
| **Mailing Address:** | | |  | | | | | | | |
| **Telephone**: |  | | | | | **E-mail**: |  | | | |
| **Primary Contact:** | | | |  | | **Telephone**: | |  | **E-mail**: |  |

**SECTION 1:** Description of Study Modifications

Please indicate the specific modification(s) for which Illinois Department of Public Health (IDPH) Institutional Review Board (IRB) review is requested, and submit all supporting documents.

**Changes in Funding:** Describe any new sources of funding for this research and what activities this new funding will support.

**Changes in Conflict of Interest:** Describe any changes that may raise a concern about a potential financial or non-financial conflict of interest on the part of a member of the research team or a member of his/her immediate family, and explain how this potential conflict of interest will be managed.

**Changes in Study Purpose:** Describe the change(s) in the purpose of the study, and provide reason(s) for this change.

**Revisions in the Study Population and/or Sample Frame**: Describe the proposed change(s), including changes in the inclusion/exclusion criteria, anticipated number of subjects, and how new subjects will be identified. Provide a justification for each change in the study population.

**Revisions in Recruitment Procedures:** Describe the revised procedures, explain why the revisions are being proposed, and identify the subjects with whom they would be used. (Submit all new scripts, letters, flyers, brochures, web site text, and other recruitment materials. If currently approved documents are being revised, submit them with r**evisions clearly indicated**.)

**Changes in Study Sites:** Explain the reason(s) for changes in study sites. Specify any sites to be terminated. For each new study site, list the name, address, and all the activities that will take place and how security will be maintained. Include relevant information requested in IDPH *Application* sections 15 and 19.1. (Submit a letter of cooperation from each new site.)

**Revisions in Study Procedures, Interventions and/or Instruments:** Describe the proposed revisions, and provide justification for each revision. Indicate whether the proposed revisions affect all subjects or only a subset of the study subjects. (Submit copies of new or revised instruments, data collection forms, assessments, etc.)

**Request for Additional Data:** For identifiable data, explain why the personal records are needed. Specify the source of the records and define the parameters of the request. Explain whether written consent will be obtained for the disclosure, or if IRB approval for disclosure of the records is requested.

**New Principal Investigator (PI):** Submit a curriculum vita and certification of completion of training in the protection of human subjects for the new PI or Co-PI.

Is the current PI still affiliated with the research?

Yes  No

Will the new PI have access to IDPH identifiable records that were disclosed under a waiver of authorization?

Yes  No

Is the new PI affiliated with IDPH?

Yes  No

**Additional Research Staff:** Submit certification of completion of training in the protection of human subjects for each new research staff member who would 1) have contact with human subjects, and/or 2) access to identifiable records disclosed for the research under a waiver of authorization.

**Changes in Consent/Assent:** Please explain why revisions are needed.

**Attach all revised consent/assent documents in markup format** to show where changes have been made, as well as in the form it would be used in the research.

**Other (e.g., Authorization/Waiver of Authorization):** Describe the proposed modification, and explain how it relates to overall study objectives.

**SECTION 2**: Changes in Risks and Benefits

Do any of the proposed modifications change risks and/or benefits to subjects in any way?

No  Yes

If yes, describe the change(s) in risks and/or benefits associated with each proposed modification, and submit revised consent/assent documents, which include new information on risks and/or benefits.

**INVESTIGATOR’S STATEMENT:**

By submitting this form, I affirm that this research is being conducted in compliance with all IDPH IRB approved procedures and requirements and that this report is accurate complete. I acknowledge that I am required to submit any proposed study modifications to the IDPH IRB and that changes to study procedures may not be implemented until they are approved by the IDPH IRB and after the execution of an amendment to the IDPH data use agreement. I also acknowledge that I am responsible for reporting to the IDPH IRB any future unanticipated problems or reportable adverse events.

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| --- | --- | --- |
|  |  |  |
|  |  |
| Signature |  | Date |

Send an electronic copy of this form and all attachments to: DPH.IRB@Illinois.gov: (Include the Project ID# in the Subject line.)