IRB Appendix U - Final Study Report

Rev. March 2015

Principal Investigator:

Protocol Short Title:

Protocol Number:

If any contact information has changed since the last IRB review - provide details:

1. Research Status

Check all that apply to URI research:

- ☐ Research was never initiated.
- ☐ No research participants were ever enrolled (or participant records, specimens, etc. obtained).
- ☐ Research has been discontinued, and there will be no further data collection (including long term follow-up or re-contact) or analysis of identifiable/coded data. ***If analysis of identifiable/coded data is ongoing, complete a continuing review application.***
- ☐ Sponsor is discontinuing the research.
- ☐ Principal Investigator and/or co-investigator are leaving the university.
- ☐ Other --> specify:

2. Research Progress

a. Summarize the results of the study, including any plans for scholarly/scientific presentation or publications.

b. Summarize any IRB-approved amendments or changes made to the research since last IRB review (initial or continuing). If IRB approval was not obtained for changes, provide an explanation.

c. Discuss whether any significant new findings or other information should be provided to past participants.

d. Discuss what will happen to the identifiable/coded data, if any, at the end of the study. ***Primary research data should be retained for a minimum of five years after final project closeout. Other research-related records should be retained for a period of at least three years after the research has been discontinued (i.e., no further data collection, long term follow-up, re-contact, or analysis of identifiable/coded data.)***

- ☐ Identifiable data were not collected
- ☐ Identifiers will be permanently removed from the data and destroyed (resulting in de-identified data)
- ☐ Identifiable or coded/linked data will be retained and stored securely (as appropriate)
- ☐ Identifiable data will be retained and may be made public with participant consent (e.g., ethnographic research)

Section 3. Number of Participants

The number of participants is defined as the number of individuals who agreed to participate (i.e., those who provided consent or whose records were accessed, etc.) even if all did not prove eligible or complete the study.

a. Is this a multi-center study? ◯ Yes --> Indicate the total number of participants to be enrolled across all sites:

◯ No

b. For research approved by the URI IRB, provide:

- IRB approved number of participants (or records, specimens, etc.):
- Total number of participants enrolled in the research to date:
- Number of participants enrolled since last IRB review (initial or continuing):

c. If actual total enrollment to date (section 3b.) is significantly different (over or under) from IRB approved number (section 3a.), provide an explanation:

Section 4. Risk Assessment

a. Since the last IRB review (initial or continuing), did any unanticipated problems involving risks to subjects or others or adverse events occur in research at URI or at a site(s) approved by the IRB?

◯ Yes
◯ No

b. Was the research subject to Data and Safety Monitoring Board (DSMB) or other similar committee/group review?

◯ Yes --> ***Provide a copy of the final or most current report***

◯ No --> Indicate one of the following:

☐ Events occurred in research approved by a non-URI IRB
☐ No external events to report

Section 5. Participant Complaints & Voluntary Withdrawals

a. Have any participants made complaints about the research since last IRB review?

◯ Yes
◯ No

If Yes --> List and describe each **complaint** and any **actions taken** to resolve the complaint(s).

b. Have any participants voluntarily withdrawn from the research since last IRB review? ***Do not include individuals whose participation was discontinued by the investigator or sponsor because of unanticipated problems, study completion, etc.***

◯ Yes
◯ No

If Yes --> List and describe each **withdrawal** and any **actions taken** (e.g., changes to the research or consent process) in response to the withdrawal(s).