Exempt Protocol QIA

IRB Protocol #: Research ID #:

Protocol Title: __________

Investigator Name: __________________________
E-mail: ________________________________

Classification: □ Faculty □ Student □ Other: ________________________________

Assessment Location(s): ________________________________

Other Study Personnel:
(1) ____________________ Active □ Yes □ No (2) ____________________ Active □ Yes □ No
(3) ____________________ Active □ Yes □ No (4) ____________________ Active □ Yes □ No

Study Performance Location: □ On-campus Lab □ Off-campus Lab □ On-line: __________
□ On-campus non-Lab □ Off-campus non-Lab

Initial IRB Approval Date: __________________

Total number of study participants approved at initial IRB review: __________________

Additional participants/study locations approved by Addendum/Modification request(s):
□ No □ Yes, Describe: __________________

Study documents approved to translate. □ No □ Yes, Language(s): __________________

Protocol Category(ies) ______ Investigator confirms category(ies): □ Yes □ No

SECTION I. Protocol Status
Check all that apply:

□ Research is permanently closed to enrollment.

□ Research enrollment is ongoing.

□ Participants have completed all research-related activities.

□ Participants’ research-related activities are on-going.

□ Analysis of information is complete.

□ Analysis of information is on-going.

□ Study did not collect private identifiable data.

□ Study did collect private identifiable data: Format __________; Location ________

1. There is a code list corresponding to the identifiable data. □ No □ Yes
   • Code list is separate from data. □ N/A □ No □ Yes, Location __________
   • Electronic code list is password protected. □ N/A □ No □ Yes
   • Hard copy code list is under lock and key. □ N/A □ No □ Yes, Location: __________
2. Participants were recruited by:
   - Posters, Flyers
   - Personal visit
   - M-Turk/Qualtrics
   - SONA
   - Email listserv
   - Social media postings
   - Snow-ball sampling
   - Other: ________________

3. Study participants audio/video recorded.  □ No  □ Yes, □ Audio  □ Video

4. Recordings stored as stated in protocol.
   - Yes  □ No, Describe: ________________________________

5. Investigator shared the data.  □ No  □ Yes, Describe method: ________________________________
   - To the best of investigator’s knowledge, no other study personnel shared the data.
   - No  □ Yes, List names and describe method: ________________________________

6. Investigator or other co-investigators interacted with participants.  □ Yes  □ No

SECTION II. Explanation of Research

7. The explanation of research document matches the approved version:  □ Yes  □ No

8. There was a consent process.  □ Yes  □ No

9. Consent disclosed the activities that involved research.  □ Yes  □ No

10. Consent disclosed the activities performed.  □ Yes  □ No

11. Consent disclosed that participation was voluntary.  □ Yes  □ No

12. Consent disclosed the name and contact information of the investigator.  □ Yes  □ No

13. Consent disclosed the name and contact information of the IRB office.  □ Yes  □ No

SECTION III. Review of Study Documents

14. Total number of study participants to date: ________________________________

15. Number of study participants on data document(s) match:  □ Yes  □ No

16. No identifiable data contained on data document(s):  □ Yes  □ No

17. Survey questions, focus group questions, and any other study documents viewed by participants match the approved version.  □ Yes  □ No, Describe: ________________________________

SECTION IV. Conflict of Interest

Study Application Section 4.2.

Have you or any co-investigators obtained a financial interest related to the research?
□ No  □ Yes, Describe. ________________________________
SECTION V. Summary and Acknowledgement

**QIA SUMMARY**

This QIA will be submitted to the IRB for review. The IRB will contact the investigator if corrective action or appropriate education and training are needed.

- [ ] Investigator was informed to close out the study in *iRIS* through submission of an IRB Study Closure Request Form.
- [ ] There are/were adequate provisions to maintain the privacy interests of participants.
- [ ] Assessment completed with no corrective actions needed.
- [ ] Advised Investigator(s) of the following corrective actions:
  - [ ] Remove identifiable data from ____________
  - [ ] Electronic survey missing explanation of research as first screen
  - [ ] Electronic survey missing consent verbiage from bottom of screen

**QIA ACKNOWLEDGEMENT**

As a result of the HRPP-QIA completed for the IRB Protocol #__________, I affirm the information contained in this assessment document was completed in conjunction with Research Integrity Compliance staff member, ____________, and to the best of my knowledge, the information contained is accurate and true.

Investigator Signature: ________________

Print Name: _______________________________ Date: ____________

Co-I Signature: ________________

Print Name: _______________________________ Date: ____________