

**Human Subjects Research Review Committee
Continuation Report for Research Involving Human Subjects
Portland State University**

The Institutional Review Board (HSRRC) is required by Title 21, Code of Federal Regulations (Part 56.109) and Title 45, Code of Federal Regulations (Part 46.109) to conduct continuing review of ongoing projects not less than once per year. Your assistance in meeting these federal requirements is appreciated. Please complete all required sections and submit required attachments—thank you.

Principal Investigator _____ **E-Mail** _____

Co-Principal Investigator _____ **E-Mail** _____

Other (GA, Project Mgr., etc.) _____ **E-Mail** _____

Department _____ **Dept. Head** _____

Mailing Address _____ **Campus Ext.** _____

_____ **Home/Work #** _____

Project Title _____

I certify that this report is accurate and that the research activities involving human subjects were conducted as stated in the approved protocol. I will abide by the Federal and University policies related to research involving human subjects.

SIGNATURE OF PRINCIPAL INVESTIGATOR

DATE

STEP 1:

Project Funded?

- Yes
 No
 Pending

Federal/Federal Pass-Through?

- Yes
 No

Funding Agency Name:

STEP 2: Are all activities involving human subjects, data collection and analysis complete?

Yes Data analysis was completed as of _____ . *Do not proceed to Step 3. Submit only this page to the HSRRC.*

No Proceed to Step 3.

STEP 3: In the space provided, please type a one-page summary of the project, or attach the summary as a separate document. The summary should both describe the project as it was originally conceived and provide a detailed account of its current status.

STEP 4:

1. Please attach a copy of the current Consent Form/Script/Letter to this report even if it is identical to a previously submitted one or already on file with the HSRRC. Reports submitted without this attachment will be considered incomplete and returned to the investigator.

2. Are you still using Consent Forms/Scripts/Letters with subjects?

- Yes
- No

3. Do you wish to submit any changes to the Consent Form/Script/Letter for approval during this Continuing Review?

- Yes:** Please attach the new version to this report with changes highlighted in bold.
- No

STEP 5: If more space is required for explanations, please attach a separate document.

1. Please check one:

- Data collection will continue
- Data collection is complete and the data is being analyzed
- Other:** *Please write in the space provided below:*

2. How many subjects were originally planned for inclusion in this study? _____

3. How many subjects have been enrolled so far? _____

4. How many subjects do you still plan to recruit? _____

5. Have any subjects withdrawn from participating in the research project after giving informed consent? (If yes, indicate the number of subjects who have withdrawn and the reasons.)

- Yes** #: **Reasons:** *Please write in the space provided below:*

- No

6. Have you withdrawn any subjects from the research project after they gave informed consent? (If yes, indicate the number of subjects whom you have withdrawn and the reasons.)

Yes #: **Reasons:** *Please write in the space provided below:*

No

7. Have there been any complaints about the research? (If yes, please explain.)

Yes **Explain:** *Please write in the space provided below:*

No

STEP 6:

Questions A-D relate to minor changes to the application, E-K relate to major changes. If more space is required for explanations, please attach a separate document.

A. Are there any changes in researcher/project director/advisor names, addresses, telephone numbers, or ending date?

Yes **Explain:** *Please write in the space provided below:*

No

B. Are there any changes that leave the research population at the same or lower risk than risk(s) already approved?

Yes **Explain:** *Please write in the space provided below:*

No

C. Have additional subjects of the same type of population indicated in the original application been recruited/added?

Yes **Explain:** *Please write in the space provided below:*

No

D. Are there any other minor changes you wish to include in this report?

Yes **Explain:** *Please write in the space provided below:*

No

E. Are there any changes that leave the research population at a higher risk than risk(s) already approved?

Yes **Explain:** *Please write in the space provided below:*

No

F. Are you adding a subject population different from those already approved?

Yes **Explain:** *Please write in the space provided below:*

No

G. Are you adding questions to a questionnaire or instrument? If yes, please attach a list of added questions or highlight the additions on the instrument.

Yes **Explain:** *Please write in the space provided below:*

No

H. Are you adding any elements that may breach the subjects' confidentiality?

Yes **Explain:** *Please write in the space provided below:*

No

I. Are you adding any deceptive elements to the research or changing the debriefing procedures for previously approved deception?

Yes **Explain:** *Please write in the space provided below:*

No

J. Are you changing the way subjects are compensated for participation in research (such as increasing the amount, changing from a lottery to cash, etc.)?

Yes **Explain:** *Please write in the space provided below:*

No

K. Are there any other major changes you wish to include in this report?

Yes **Explain:** *Please write in the space provided below:*

No

Please return this Continuing Review Report and any attachments to:

Mailing Address:

HSRRC
Office of Research and Sponsored Projects (ORSP)
Portland State University
PO Box 751
Portland, OR 97207-0751

Delivery address:

600 Unitus Bldg
2121 SW 4th Av
Portland, OR 97201
Campus Mail Code: ORSP

For questions or concerns, call (503) 725-4288, or send e-mail to hsrrc@lists.pdx.edu.

*** *Did you remember to attach your consent form(s)?* ***