



Wichita State University Institutional Review Board (IRB) Research Project Continuation Form

IRB #: Approval Expiration Date: Date of this Report:

Title of Research Study:

Principal Investigator(s):

Department:

E-Mail (for IRB contact person):

***Please answer all questions. Use provided space on page four for additional explanation.**

A. Project Status

1. Please indicate the current status of the project (select one):

Recruitment, enrollment, and/or subject intervention are active.

Enrollment is permanently closed; subject intervention is active. *(No new consent forms will be issued.)*

Enrollment is open but no subjects have been enrolled and no additional risks have been identified.

Enrollment is permanently closed; all subjects have completed all research-related interventions; the research remains active only for long-term follow-up of subjects or data analysis. *(No new consent forms will be issued.)*

Other:

2. Why is the study being continued?:

Multi-year study that is continuing as originally planned.

Unexpected results required us to revise our protocol procedures or perform additional data analysis which increased the length of the study. *(An amendment must be submitted to the IRB for all protocol changes.)*

Recruitment of participants took longer than anticipated.

Funding delays pushed back our start date.

Other:

B. Notification of Changes

1. Have there been any changes to the protocol including but not limited to procedures, consent form, study population, or personnel that have not been approved by WSU IRB?

Yes - *submit an amendment form and all relevant documents.*

No

2. Has the study sponsor or the funding source changed?

Yes – *Please explain*

No

N/A

C. Accrued Participants

1. How many total participants have been enrolled since the beginning of the research project?

2. Has the total number of participants enrolled exceeded the number of participants specified in the protocol?

Yes - *provide details*

No

3. Have any participants withdrawn from participation?

Yes - *please indicate the number and provide detailed information on the reason(s) for withdrawal.*

No

Unknown – *explain*

D. Informed Consent

****Please submit the Word version of the current consent form(s)***

1. Was informed consent obtained from all enrolled participants?

N/A (No participants have been enrolled)

N/A (WSU IRB has approved a waiver of written consent)

N/A (Online survey)

Yes

No *Explanation*

2. Consent Form Copies Enclosed?

N/A (No participants have been enrolled)

N/A (WSU IRB has approved a waiver of written consent)

N/A (Online survey)

Copies for last 3 participants enrolled

Fewer than 3 consented. *If fewer than 3 consented, submit for those you have.*

E. Investigator's Summary

1. Have there been any complaints about the research since the application was approved by the IRB? *If Yes, please provide information on the complaints made.* Yes No

2. Have there been any adverse events or unanticipated problems involving risks to the participants or others since the application was approved by the IRB? Yes No
If Yes, contact the IRB Administrator immediately if they have not already been reported.
3. Have any new risks been identified since the last WSU IRB review? Yes No
If Yes, explain
4. Have any new benefits to participants been identified since the last IRB review? Yes No
If Yes, explain
5. Have there been any changes to measures to ensure confidentiality? Yes No
If Yes, explain
6. Have the data from this study been published? Yes No
If Yes, list publications

F. Data and Safety Monitoring

1. What type of data and safety monitoring was approved for this project?
 Data and Safety Monitoring Committee, Data Monitoring Committee, or Medical Monitor
 Study Team Only
 Not Applicable
2. Do the outcomes of the data and safety monitoring confirm that the study is still safe to continue?
 Not Applicable
 Yes
 No - *If No, explain*

G. Personnel

| Investigator Name | myWSU ID# | Department | Human Subjects Training completed (Yes or No and which one e.g. Yes, CITI) |
|-------------------|-----------|------------|--|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

H. Please provide a brief summary of the study activities that took place in the past year.

I. Space is provided below for any additional information to be included.

PI Signature: _____ Date of Request: _____