Furman University IRB Form

Institutional Review Board for the Protection of Human Participants

FORM D – Full Review

(45 CFR 46)

USE OF HUMAN PARTICIPANTS

STATEMENT BY PRINCIPAL INVESTIGATOR OR ACTIVITY DIRECTOR

1. Associate or Collaborating Investigator(s), excluding student assistant:

Name Institution Address Tel.# Fax#

1. Describe the Nature of the Research Activity (Please use language that can be understood by reviewers outside of your discipline.) Provide enough detail to adequately and accurately represent the proposed investigation. Include description of each of the following concerns:
	1. Relevant background research with bibliography
	2. Purpose and methodology.

(c) Requirements for the participant population.

Explain the rationale, if the population includes a special group such as prisoners, children, mentally disabled, or those whose ability to give informed consent may be in question.

1. Identify those procedures in which a human participant is used which depart from common and established activities, or which increase the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service.
2. Describe any potential risks –physical, psychological, social, legal, etc., and assess the likelihood and seriousness of such risks.
3. Anticipated statistical analyses to be conducted on the obtained data.
4. If electronic or stressful instrumentation is to be used, provide the name of the manufacturer, the model number, and appropriate specifications of the device, as well as how it is to be used on the participants.
5. a. Is the Activity Director contributing to the design or conduct

 of the study? Yes/No

 b. Do you expect your name (Activity Director)

 to appear on a presentation of publication resulting

 from this study? Yes/No

c. Please describe the specific role of the Activity Director in this research activity:

4. Where are the subjects of this research activity located?

5. If the research activity is taking place elsewhere (not at Furman University), will you have direct contact or intervention with the human subjects?

 Yes/No

 Has the activity been reviewed and approved by an Institutional Review Board (IRB) elsewhere?

 Yes/No

 If “yes,” specify which IRB and when reviewed:

6. What kind of human samples or data are being collected?

 (e.g. questionnaire responses, private information, blood or tissue samples, etc.)

 Will you be:

 collecting samples/data Yes/No

 receiving samples/data Yes/No

 sending samples/data Yes/No

7. Do the samples or data:

a. already exist? Yes/No

 b. or are they being collected for the

 express purpose of this study? Yes/No

 c. or a combination of (a) and (b)? Yes/No

 Please specify

8. Do the samples or data come from any individual(s) who may need special safeguards (e.g., individuals under 18 years of age, pregnant women, handicapped persons, prisoners, etc.)?

 Yes/No

 If “yes” please specify

9. Are the samples or data you expect to collect, receive or send anonymous?

 Yes/No

 If “yes” your proposal may be eligible for IRB Exemption.

 If “no: explain how the anonymity of your participants will be assured.

10. Does your research design involve, in any way, the conveying of Instructions or other information that is deceptive or misleading?

 Yes/No

 If “yes” explain (a) why the deception is necessary to successful completion of the Investigation and (b) how the participants will be protected from any potential harm occurring as a result of this deception.

 Include a copy of your debriefing statement/procedure (see section XX of FUIRB Guidebook).

11. Is participation in the activity completely voluntary? Yes/No

 If “No”, explain.

12. May any participant withdraw from the activity at any time without penalty?

 Yes/No

 If “No”, explain.

13. Is any kind of incentive offered to the participant? Yes/No

 If “Yes”, explain the type and amount.

14. Describe subject recruitment procedures.

15. Describe procedures for maintaining participant confidentiality.

16. Describe debriefing procedure. Include copy of debriefing statement.

Submit the original copy of Form A and D, your consent from, debriefing statement and any other supporting materials via email or interoffice mail to Brianne Pochard, Administrator, Furman University Institutional Review Board, brianne.pochard@furman.edu or Admn. Building Room 205.

\*See section XX of the FUIRB Guidebook for a description of appropriate consent form preparations.