APPENDIX A

SAMPLE CONSENT FORM

(Leave space for IRB Stamp in upper right-hand corner. Use the format specified below. Items in italics may be deleted if not applicable. All other items should be included. Also, include any applicable items listed on the preceding instructions. Delete instructions and inapplicable italicized items before submission.)

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

_____
(Full Institution Name)

TITLE OF STUDY:

_____
(If the study involves an external agency, list official sponsor protocol title)

INVESTIGATOR INFORMATION:

_____
(Principal Investigator Name) (Telephone Number)

I, _____, have been asked to participate in a research study under the direction of _____ _____ *and the medical supervision of Dr.*_____. Other professional persons who work with him/her/them as study staff may assist or act for him/her/them.

PURPOSE:

I understand that I have _____,
(Medical Diagnosis)
which makes me eligible to participate in this research study.

The purpose of this research study is _____.

DURATION AND LOCATION:

(Describe the expected duration of the subject's participation in the study and the location of the project [e.g., Georgia Southwestern State University, Sumter Regional Hospital].)

_____
Subject Initials

My participation in this study will last for approximately _____.

The study will be conducted at _____.

PROCEDURES:

I have been told that during the course of this study, the following will occur:

_____
_____
_____
_____

The following procedures/devices are considered to be investigational:

_____

EXCLUSIONS

I should not participate in this study if any of the following apply to me:

_____
_____
_____

RISKS/DISCOMFORTS:

I have been told that the study may involve the following risks and/or discomforts:

_____
_____
_____

There also may be risks and discomforts that are not yet known.

BENEFITS:

OPTION #1

I have been told that the direct benefits to me of participating in this study may be:

_____
_____
_____

_____
Subject Initials

However, I may receive no benefit from participating in this study.

(OR)

OPTION #2

I have been told that I will receive no direct benefit from my participation in this study, but my participation may help health care practitioners/psychologists/business researchers/etc. better understand:

_____
_____

ALTERNATIVE PROCEDURES OR TREATMENTS:

The following alternative procedures or treatments are available if I choose not to participate in this study:

_____

_____

NEW FINDINGS:

I have been told that I will receive any new information during the course of the study concerning significant findings that may affect my willingness to continue my participation.

CONFIDENTIALITY:

Every effort will be made to maintain the confidentiality of my study records. The data from the study may be published; however, I will not be identified by name. My identity will remain confidential unless disclosure is required by law.

Agents of Georgia Southwestern State University and/or any external agency (including any sponsoring agency) will be allowed to inspect sections of my medical and research records related to this study.

I have been informed that because this study involves articles regulated by the FDA (Food and Drug Administration), the FDA may choose to inspect records identifying me as a subject in this study. I authorize review of the pertinent sections of my records for this purpose only.

_____
Subject Initials

COSTS TO THE SUBJECT:

I understand that if I am a patient at the VAMC, I may be subject to charges (co-payment) for which the VA will not pay.

COMPENSATION IN CASE OF INJURY:

I understand that in the event of injury resulting from the research procedures, no form of compensation (i.e., payment) is available from Georgia Southwestern State University. Medical treatment may be provided at my own expense; or at the expense of my health care insurer (e.g., Medicare, Medicaid, BC/BS), which may or may not provide coverage. If I have questions, I should contact my insurer.

In the event of emergency resulting from the research procedures, _____
(sponsoring agency)
will provide reimbursement for the reasonable costs of medical treatment to the extent that the costs are not covered by my insurance or by third party or government program providing coverage.

PAYMENTS TO PARTICIPANTS:

I have been told that I will receive _____ for my participation in this study.

RIGHT TO REFUSE OR WITHDRAW:

I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of any benefits to which I am entitled.

I also understand that the investigator has the right to withdraw me from the study at any time. I understand that my

withdrawal from the study may be for reasons related to me (e.g., not following the study-related directions, a serious study-related injury) or because the entire study has been terminated.

I understand that _____ *has the right to terminate the study or the*
(sponsoring agency)
investigator's participation in the study at any time.

_____
Subject Initials

OFFER TO ANSWER QUESTIONS:

If I have questions about this study, I may call _____ at _____.

If I have questions about my rights as a research subject, I may call _____ at _____

If a research-related injury occurs, I will call _____ at _____.

SIGNATURES:

I understand my rights as a research subject and I voluntarily consent to participate in this study. I understand what the study is about and why it is being done. I will receive a signed copy of this consent form.

_____ _____
Signature of Research Subject Date
(or legally authorized representative)

_____ _____
Signature of Witness Date

_____ _____
Signature of Investigator Date