INSTITUTIONAL REVIEW BOARD

INFORMED CONSENT FORM: ADULT INSTRUCTION SHEET

Instructions for Informed Consent Form: Adult

It is expected that all study participants be fully informed of what is expected of them, their rights, and any risks or benefits anticipated. This information must be provided prior to participant enrollment. If the provision of such information runs counter to the study design, or if the requirement for documentation of informed consent can be waived according to 45 CFR part 46, then investigators may request a waiver from the IRB.

The following pages provides instructions of the content that must be included in an informed consent form for adults. The sections of the consent form are structured as questions. After each question are instructions followed by examples. Following these pages is the template for the adult informed consent form. Complete the fillable text boxes and submit this portion with your application to the IRB.

Please note: These forms must be drafted in language appropriate to the culture, context, and typical reading level of the study population. National education statistics suggest that the average reading level for American adults is at the 9th grade level. Adults enjoy recreational reading at two grades lower, but can tolerate reading at two levels higher. Since understanding the information provided in informed consent documents is essential, the IRB recommends materials be written at an 8th grade reading level when studying the public. Lower levels may be necessary if the study population is made of groups with lower reading levels; whereas levels may be higher if the population comprises those with college degrees.

Informed Consent Form: Adult

Study Title:_____

Investigator:_____

Supported By (If applicable):_____

What is the purpose of this study?
Explain the purpose of the study and why the person is being asked to participate.

Example:
The purpose of this study is to limit the amount of times a person is hospitalized for depression. You are being asked to participate in a research study because you have recently been diagnosed with depression.

What will I do if I choose to be in this study?

- **Provide a clear, concise but complete description of what subjects will do or experience.**
- **Include the total time commitment, the number of visits/sessions involved, the length of each visit/session.**
- **Describe all activities in chronological order.**

Examples:

- *You will be asked to come to the DNP Lab at (room number) for two sessions lasting 30 minutes each.*
- *Your participation in this study will last one hour.*
- *You will be asked to sit quietly in a chair and focus on clearing your mind. After about five minutes, the researcher will ask you to come into the interview booth. In the interview booth, a member of our study team will speak to you through a microphone. You will be able to hear the Investigator, but you will not see the Investigator. The Investigator will tell you the things that you are to do. This will include making choices on the computer and answering questions. The Investigator will also ask you to listen to ten different pieces of music. You will be asked to answer questions about each musical composition. During the interview, the lighting in the interview booth will be kept low to reduce stress.*
- *We will conduct this interview in a location of your choice and at a time of your choosing. We will audio record this interview and take detailed notes afterward. We will do so only with your permission. You have the right to review and edit the recording to delete any material you do not want recorded. You may also ask us to turn off the recorder at any point in the conversation.*

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What are the possible risks or discomforts?

Open this section with one of the following statements:

Your participation in this study does not involve any [physical or emotional] risk to you beyond that of everyday life. [For an online survey or an interview there is no physical risk.]

Or

Your participation does not involve any risks other than what you would encounter in daily life.

Or

Your participation in this study may involve the following risks…

Insert appropriate risks here _____

Examples:

- *You may get tired during the tasks. You can rest at any time.*
- *You may feel emotional or upset when answering some of the questions. Tell the interviewer at any time if you wish to take a break or stop the interview.*
- *You may be uncomfortable with some of the questions and topics we will ask about. If you are uncomfortable, you are free to not answer or to skip to the next question.*

What are the possible benefits for me or others?
Describe any benefits that can reasonable be expected.

Exclude:

- Statements indicating that the subjects may benefit from closer monitoring of their condition
- Statements regarding payments or reimbursement to subjects for their participation (this should be listed in the financial information section)

Examples:

You are not likely to have any direct benefit from being in this research study.

Or

Taking part in this study may help researchers to better understand why people with depression are hospitalized and may minimize the likelihood that a person treated for depression will be hospitalized.

What alternatives are available?
Please provide other methods of care or treatment related to the participants' study condition, if applicable.

Examples:
Instead of being in this study you can seek advice from a licensed Psychiatrist regarding your treatment methods with depression.

Or

You may choose to not participate in this research study.

What happens if I don't want to participate anymore?

Please provide details on how a participant can opt out of the study and what happens if they terminate study involvement early.

Example:
At any time in the study, you may decide to withdraw from the study. If you withdraw no more information will be collected from you. When you indicate you wish to withdraw the investigator will ask if the information/materials already collected from you can be used.

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Will it cost me anything to participate?

Example:
Participation in this study will involve no cost to you.

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Example:
Participation in this study will involve no cost to you.

Will I get paid anything if I participate?

Please provide a description of how much a participant is expected to pay for being involved in this study, if applicable.

- **Provide specific information about payment and reimbursement (e.g., dollars per visit, payment for testing, evaluation, transportation).**
- **Specify when payment will be made and in what form (cash, check, gift card).**
- **Indicate whether you will prorate payment for partial participation, and explain exactly how this will be done.**

Examples:
You will be reimbursed for travel and parking expenses up to $200 for a total of 4 visits. You will be paid by check $50 per visit, at the end of each study visit.

What are my rights?
The first 3 paragraphs are required.

If you choose to be in this study, you have the right to be treated with respect, including respect for your decision to stop being in the study. You are free to stop being in the study at any time.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefits to which you are otherwise entitled. Specifically, your choice will not negatively affect your right to any present or future [class standing; employment] **use the appropriate language for your specific subject group**

If you want to speak with someone who is not directly involved in this research, or if you have questions about your rights as a research subject, contact the Chamberlain College of Nursing Institutional Review Board (IRB) Office. You can call the IRB Coordinator – Channan Pondexter at (630-353-7334) or send e-mail to irb@chamberlain.edu.

What about my confidentiality and privacy rights?
Please include information regarding your safeguards for establishing protection of participant confidentiality and privacy.

Audio/Video Recordings ***include only if applicable***
At the end of this consent form, you will be given the option of allowing us to take photographs and/or make audio or video recordings of you. If you agree, these may be used in analyzing the research data only. Permission to use audio or video recordings of you in presentations in the classroom, at professional meetings or in publications will only be requested if it is relevant to understanding the results.

****With the clause above, include check-boxes in the Consent section, stating "I [do] [do not] give permission for photographs or videotapes of me to be used."**
Or
All audio, video, and recorded records will be destroyed at the end of the study.

If recordings will not be destroyed, justify this in the protocol and specify this in the consent form.

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Optional Study Elements

This section should include other explicit consents for optional elements of the research, such as audiotaping, videotaping, storing photographs for future use, or using the subject's actual name in research publications.

Example:

***Initial one of the following to indicate your choice:*

_____ *(initial) I do give permission for photographs or videotapes of me to be used.*

_____ *(initial) I do not give permission for photographs or videotapes of me to be used.*

Consent ensure this section is on one page

I have read this form and the research study has been explained to me. I have been given the opportunity to ask questions and my questions have been answered. If I have additional questions, I have been told whom to contact. I agree to participate in the research study described above and will receive a copy of this consent form after I sign it.

_____ _____

Signature of Subject Date

_____ _____

Signature of Witness *(optional)* Date

This research study was reviewed by the Chamberlain College of Nursing Institutional Review Board (IRB). The goal is to assure that the study protects the rights and safety of the human subjects of this research.