Adena Health Systems
Institutional Review Board (IRB)
Project Outline Form

Proposal Title:

Investigator Information

Primary Investigator

Name (First, Middle, Last):

Department:

Address:

Email:

Phone:

Training Completed? ☐

Co-investigators

Name:

Address:

Email:

Training Completed? ☐

Name:

Address:

Email:

Training Completed? ☐

Advisor

Name:

Address:

Email:

Training Completed? ☐

Research Assistants

Name:

Address:

Department:

Training Completed? ☐

Name:

Address:

Department:

Training Completed? ☐

Study Timeline

Start Date (Study cannot begin prior to IRB approval.):

Duration of Study: Years☐ Months☐ Other:

Funding

Yes☐ No☐

Source:

Relationship:

Use:

Review Level

Your research qualifies for*?

☐Exempt Review Category

☐Expedited Review Category

☐Full Board Review

*It is the discretion of the IRB to determine the category from the description enclosed.

Recruitment

Maximum number of participants including screenings:

Characteristics of subjects

☐Minors ☐Disabled ☐Students:

☐Adults ☐Legally Incompetent

☐Prisoners ☐Cognitively Impaired

☐Pregnant ☐Non-English Speaking

Describe the criteria for the selection of subjects.

Describe how you will identify and recruit participants.

Records

Accessing private, medical, educational, or employment records? Yes ☐ No ☐

If yes,

Describe process for obtaining approval for the use of the records. A letter of support from the holder of the records must be attached.

Describe your relationship with the potential participants.

Attach Copies of all recruitment tools. Please label as APPENDIX C

Performance Sites and Location of Research

☐Adena Health Systems

☐Public Location

☐Other-

Please Describe and provide letters of support.

Project Description

Please provide a brief summary of this project. Please note that this needs to be done in non-technical terms. This descriptions needs to be no more than one page.

Please describe the specific scientific objectives of this research. Please include any previous relevant research.

Please describe in sequential order the procedures that will be performed with human participants.

Please describe any potential risks or discomforts of the participations along with the steps to prevent or minimize them.

Please describe the anticipated benefits to the participants. Please note that compensation is not an acceptable benefit. If there are no benefits, please state that.

Please describe the anticipated benefits to society and/or the scientific community. (There needs to be some benefit to justify the use of human subjects.)

Instruments

Please list all questionnaires, instrument, and standardized tests. Please include a brief description and provide a copy of each. Label the copies as APPENDIX D.

Data Analysis

How will the data be analyzed? What procedures will be used to test the hypotheses?

Confidentiality

Please check all that apply:

☐Data is collected anonymously

☐Data will be recorded without possibility of identification

☐Data will be recorded with a code replacing identifiers and a master list connecting the code and the

☐identifier exists for some period of time

☐Data will be recorded with identifying information

☐Nature of data makes it potentially identifiable (e.g. material with DNA or photographs)

If master code list is used, please provide detail about where the list will be stored and how it will be destroyed.

If data is stored with identifiers, please provide details of how the data will be securely stored and the timeframe for when the data will be de-identified.

Will identifiable data be share with anyone outside of the research team? Yes ☐ No ☐

If Yes, please describe

Will the participants be:

Audio recorded? Yes ☐ No ☐

Video recorded? Yes ☐ No ☐

If yes, please describe how the recordings will be secured. Please include who will have access to the recording and the estimated date they will be destroyed.

Comments

Compensation

Will the participants receive a gift? Yes ☐ No ☐

If yes, list the items and its value

Will the participants receive services, treatment, or supplies that have a monetary value? Yes ☐ No☐

If yes, please describe and provide the value.

Will the participants receive course credit? Yes ☐ No ☐

If yes, please describe non-research alternatives to earn the credit. Please include the number of points awarded.

Will the participants receive monetary compensation? Yes ☐ No ☐

If yes, please detail the amount per session and total compensation. Please include what compensation amount is paid to participants who discontinue participation prior to completion.*

* If Adena funds are used to compensate participants, minimally, the name and address of participants will need to be provided to the Finance Office at Adena Health Systems. If participants will be paid $250 or more in a calendar year, participant social security numbers must be provided to Finance. The consent form must reflect this.

Informed Consent Process

Select One of the Following Options:

☐ I am obtaining signed consent for this study (Attach copies of all consent documents as APPENDIX B, using the templet provided.

☐ I am requesting a waiver or alterations of Informed Consent (provide details below and attach information that will be provided to the participants as APPENDIX B

Waiver of signature

- ☐ Exempt study
- ☐ Waiver needed to protect the privacy of participants
- ☐ Waiver needed due to cultural norms
- ☐ Impracticable
- ☐ Other

Incomplete Disclosure

- ☐ Necessary to avoid participants altering behavior (e.g. not informing of 2 way mirror)

Additional information

How and where will the consent process occur? Will the participants' questions be answered? What steps will be taken to avoid coercion or undue influence?

Will the investigator(s) be obtaining all of the informed consents? ☐Yes ☐No

If no, identify by name who will be describing the research to the subjects and inviting their participation.

Will all adult participants have the capacity to give informed consent? ☐Yes ☐No

If no, explain the procedures to be followed.

Will any participants be minors? ☐Yes ☐No

If yes, please include parental consent form in APPENDIX B

Will participants be deceived or incompletely informed regarding the study? ☐Yes ☐No

If yes, please provide the rationale for the use of deception**.

**Please attach copies of post-study debriefing information and label as APPENDIX E. Questions regarding consent form waiver or alteration must be completed.

Investigator Assurance

I certify that the information provided in this outline form is complete and correct.

I understand that as Principal Investigator, I have ultimate responsibility for the protection of the rights and welfare of human subjects, conduct of the study and the ethical performance of the project.

I agree to comply with the Adena Health Systems policies on research and investigation involving human subjects (under the Med Ed. Office of Research IRB and Office of Compliance), as well as with all applicable federal, state and local laws regarding the protection of human subjects in research, including, but not limited to the following:

- The project will be performed by qualified personnel, according to the IRB approved protocol.
- No changes will be made in the protocol or consent form until approved by the IRB.
- Legally effective informed consent will be obtained from human subjects if applicable, and documentation of informed consent will be retained, in a secure environment, for three years after termination of the project.
- Adverse/Unexpected events will be reported to the Adena Health Systems IRB promptly.
- All protocols are approved for a maximum period of one year. Research must stop at the end of that approval period unless the protocol is re-approved for another term.

I further certify that the proposed research is not currently underway and will not begin until approval has been obtained. A signed approval form, on Office of Research Compliance letterhead, communicates IRB approval.

Primary Investigator Signature_____**Date** _____

(Please print name) _____

Co-Investigator Signature_____**Date** _____

(Please print name) _____

Faculty Advisor/Sponsor Assurance (if applicable)

By my signature as sponsor on this research application, I certify that the student(s) or guest investigator is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accord with the approved protocol. In addition:

- I agree to meet with the investigator(s) on a regular basis to monitor study progress.
- Should problems arise during the course of the study, I agree to be available, personally, to supervise the investigator in solving them.
- I assure that the investigator will report adverse/unexpected events to the IRB in writing promptly.
- If I will be unavailable, as when on sabbatical or vacation, I will arrange for an alternate faculty sponsor to assume responsibility during my absence.

I further certify that the proposed research is not currently underway and will not begin until approval has been obtained. A signed approval form, on Office of Research Compliance letterhead, communicates IRB approval.

( ) Not applicable or signed as below

Advisor/Faculty Sponsor Signature_____**Date** _____

(Please print name) _____

*The faculty advisor/sponsor must be a member of the faculty of a university supported by Adena Health Systems. Such a list is kept at the Med Ed Office of Research - Adena Health Systems. The faculty member is considered the responsible party for legal and ethical performance of the project (not the student)

Checklist:

☐ Completed and Signed Project Outline Form (this form)

☐ Appendix A- Copy of proposal

☐ Appendix B - copies of all consent documents (in 12 pt. Font) including

___ Informed Consent to Participate in Research (adult subjects)

___ Parental Permission/Informed Consent (parents of subjects who are minors or children)

___ Assent to Participate in Research (used when subjects are minors or children)

☐ Appendix C - copies of any recruitment tools (advertisements, posters, etc.)

☐ Appendix D – copies of all instruments (surveys, standardized tests, questionnaires, interview topics, etc.).

☐ Appendix E - Copies of debriefing text

☐ Appendix F - Approval from other IRB, School District, Corporation, etc.

☐ Appendix G - Any additional materials that will assist the Board in completing its review

☐ Appendix H – Copies of any IRB approvals

☐ Appendix I – Copies of Human Subjects Research Training Certificates

All fields on the form must be completed, regardless of review level. If a field is not applicable, indicate by inserting N/A. Incomplete forms will result in delayed processing.

Forward this completed form and all attachments to:

Human Subjects Research

Med Ed Office of Research

446 Hospital Rd Chillicothe, OH 45601

POC is Ms. Katie Oberley 740-779-8454

If you have the capability to scan the signed form and all relevant attachments, you may submit by email to The Administrator of the IRB (Ms. Oberley) at koberley@adena.org

The consent form template that follows is for you, the researcher, to follow, when creating the consent form to be signed by participants of your study. Please insert the details that are specific to your study. Additionally, here are some tips for creating the consent form:

- Keep the language simple. Consent forms should be written at an 8th grade reading level or below. Avoid use of technical terms. When using acronyms or abbreviations, spell out the full meaning the first time used.

- Compose the consent form to speak TO the participants, not ABOUT them, i.e. "You will be asked to…" instead of "The participant will be asked to…"

- The title of the study on the consent form need not mention the title of the study in the project outline form. Sometimes it is warranted to use a simpler title for the consent form.

- Most sections are required. However, you may remove the Compensation section if no compensation is offered to participants.

- To see templates for other consent form models (parental consent, assent, etc.), please ask Ms. Oberley at koberley@adena.org

- If the researcher is a student, please include researcher and advisor's contact information in the Contact Information section.

- Include a version date in the footer of the consent form. If revisions are requested by the board, update the version date when requested revisions are made.

Adena Health System - Consent Format (must be on Adena letterhead)

Title of Research:
Researchers:

You are being asked to participate in research. For you to be able to decide whether you want to participate in this project, you should understand what the project is about, as well as the possible risks and benefits in order to make an informed decision. This process is known as informed consent. This form describes the purpose, procedures, possible benefits, and risks. It also explains how your personal information will be used and protected. Once you have read this form and your questions about the study are answered, you will be asked to sign it. This will allow your participation in this study. You should receive a copy of this document to take with you.

Explanation of Study

This study is being done because…

If you agree to participate, you will be asked to…

You should not participate in this study if… ***[List exclusionary criteria, if applicable]***

Your participation in the study will last…

Risks and Discomforts

Risks or discomforts that you might experience are… **OR**

No risks or discomforts are anticipated

Benefits

This study is important to science/society because…

Individually, you may benefit… **OR**
You may not benefit, personally by participating in this study.

Confidentiality and Records

Your study information will be kept confidential by…

Additionally, while every effort will be made to keep your study-related information confidential, there may be circumstances where this information must be shared with:

* Federal agencies, for example the Office of Human Research Protections, whose responsibility is to protect human subjects in research;
* Representatives of Med Ed. Office of Research - Adena Health System - the Institutional Review Board, a committee that oversees research;
* *[**Insert sponsors of the research, if any, who will have access to identifiable data]***

Compensation

As compensation for your time/effort, you will receive… **OR**

No compensation will be provided. ***[Or remove the Compensation section completely]***

Contact Information

If you have any questions regarding this study, please contact ***[insert Researcher/Advisor & email and phone number.]***

If you have any questions regarding your rights as a research participant, please contact Dr. Todd Dombroski, Director of Research Compliance and the Chairman of the IRB at, Adena Health Systems (740)779-8891 or rdombroski@adena.org

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By signing below, you are agreeing that:

- you have read this consent form (or it has been read to you) and have been given the opportunity to ask questions and have them answered
- you have been informed of potential risks and they have been explained to your satisfaction.
- you understand Ohio University has no funds set aside for any injuries you might receive as a result of participating in this study
- you are 18 years of age or older
- your participation in this research is completely voluntary
- you may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you and you will not lose any benefits to which you are otherwise entitled.

Signature_____ Date_____

Printed Name_____

Version Date: ***[insert mm/dd/yy]***