Methodist College
UnityPoint Health

METHODIST COLLEGE

INSTITUTIONAL REVIEW BOARD

PROTOCOL APPROVAL REQUEST FOR RESEARCH INVOLVING HUMAN PARTICIPANTS

PART 1: ADMINISTRATIVE INFORMATION

1. **Title of protocol**

2. **Contact Information:**

Principal Investigator
Name:
Email Address
College/Division
Department/unit
Status ☐ **undergraduate student** ☐ **graduate student** ☐ **faculty** ☐ **staff**
☐**Post-Doctoral Fellow** ☐ **other**
Co-PI's and members of research teams:

Name	Email Address	Methodist/Non-Methodist	College/Dept

PART 2: STUDY DESIGN, METHODS, AND PROCEDURES

Protocol Description

A. GENERAL

The IRB is required to assess whether the proposed research design is scientifically sound and will not unnecessarily expose subjects to risk. Please provide a **BRIEF** description of the proposed research. State the goals and/or hypotheses of this study and how these goals relate to previous research in this area. The description must be made in **LAYPERSON'S TERMS**, as the IRB is made up of researchers, non-researchers, and community members with diverse backgrounds and expertise. *Any technical terms or terms of art must be explained.* If the research is being conducted in conjunction with classroom activities, be sure to clearly describe the normal classroom activities separately from the research component.

B. METHODOLOGY

1. **Subject Selection and Recruitment:** The IRB must assure that subjects have been selected equitably in terms of gender, race, and ethnicity; that benefits are distributed fairly among the community's populations; and that additional safeguards are in place to protect vulnerable populations.

   a) Identify all participant groups in the study and indicate criteria for including or excluding individuals from participation, such as gender, race, socioeconomic level, age, etc.

   b) Total number of subjects: ____.

   If targeting males/females specifically, indicate the numbers of: Males ____ and/or Females

   Provide an explanation of why this gender is being targeted:

If targeting a specific age range, indicate the range: From ____ to_____

Provide an explanation of why this age range is being targeted:

c) Federal regulations and guidance contain explicit requirements for conducting research with protected populations such as children, mentally disabled individuals, prisoners, pregnant women (where the condition of being pregnant is related to the research,) and persons unable to provide legal consent, such as the cognitively impaired. Please check all that apply and complete and attach the appropriate appendices to your protocol. This study will involve:

____ Children **(Complete and attach Appendix B)**

____ Prisoners **(Complete and attach Appendix C)**

____ Pregnant Women, Human Fetuses, and Neonates **(Complete and attach Appendix D)**

____ Cognitively Impaired Individuals **(Complete and Attach Appendix E)**

d) Describe how potential participants will be identified and how access to contact information will be obtained. If you plan to obtain information not publicly available, such as non-directory information; any proprietary sources, i.e. listserv, organization roster, or school records; or other information covered under HIPAA or FERPA regulations, IRB approval of the project does not grant automatic access to this information. The individual with authority over the information has the sole responsibility for determining whether to grant access. Please include documentation of permission to use this information or describe how permission will be obtained.

e) Describe how participants will be recruited, including how will they be contacted and by whom. Attach copies of all recruitment documentation, (i.e. e-mail letters, flyers, telephone scripts, etc.).

2. ***Informed Consent/Permission/Assent*****:** Informed consent is the process by which the subjects are provided detailed information as to the purpose of the research, the risks and benefits to them as participants, what will be expected of them, and then given the opportunity to agree to participate or not. Consent documents and scripts must be written in a language and at a level the subjects will understand. The researcher is also responsible for minimizing coercion and undue influence. **Coercion** occurs when there is an overt or implicit threat of harm presented in order to obtain participation, such as when a subject will lose access to certain services if they decline participation, when a student will experience reprisal or disapproval from an instructor, or when an employee will experience reprisal or disapproval from a supervisor. ***Undue influence*** can occur when there is an offer of an excessive or inappropriate reward to secure participation, such as a large cash payment or other gift.

a) *Required Elements of Informed Consent*: The required elements of informed consent are listed in **Appendix A**, which must be completed and can be found at the end of this document. Please also refer to *45 CFR 46.116* for further information on requirements for informed consent and documentation, and the waiver or modification thereof.

b) *Informed Consent Procedures*:

i. **Consent** may be obtained only from persons legally competent to give it. For research involving minors, **parental permission** as well as **minor assent** may be required. For research involving cognitively impaired individuals, consent must be given by a Legally Authorized Representative. Refer to the IRB website for guidance on this issue. From whom will consent/assent/permission be obtained for this study?

ii. Describe what procedures will be used (and in what order) to secure informed consent/assent. Include whether there will be written or verbal presentation, and whether signatures will be required. If written consent, permission, or assent forms are being used, attach exact copies. If presented verbally, attach a copy of the presentation script. Requests to waive informed consent and/or the documentation of consent must be justified based on language contained in the Code of Federal Regulations, CFR 46.116 and 46.117.

iii. Describe who will obtain informed consent and how coercion and undue influence will be minimized.

3. ***Compensation:*** Compensation (e.g. payment, gifts, extra credit) for participation is allowable if it is not excessive or inappropriate. Compensation is not a benefit of participation.

Will compensation be offered? _____Yes _____No. If yes, complete the following:

a) Indicate the type and amount.

b) Describe how compensation will be disbursed, including how it will be handled for participants who withdraw from the study.

c) Identify the funding source for the compensation (e.g. personal, grant, departmental).

4. ***Research Location:*** Where will the research take place? Please be as specific as possible. If research is confidential in nature, please explain how location will help preserve confidentiality.

C. PROCEDURE

1. Individuals collecting the data must be appropriately trained to handle foreseeable adverse events, such as a subject being injured or becoming emotionally distressed. They must also fully understand the research project, including confidentiality issues. Please describe who will be collecting the data and their relevant training.

2. Describe what participants will be expected to do, and in what order.

3. The use of psychological interventions, deception, or biomedical procedures, requires special review procedures, as each has particular risks. Please check all that apply:

____ *Psychological Interventions*: e.g. contrived social situations, manipulation of the subjects' attitudes, opinions, or self-esteem. **(Complete and attach Appendix F)**

____ *Deception:* e.g. false information is given to subjects, false impressions created, or information relating to the subjects' participation is withheld from them. **(Complete and attach Appendix G)**

____ *Biomedical procedures:* e.g. the taking or withholding of medication, ingestion of any food or other substances, injections, blood drawing, or any other procedure which would normally be done under medical supervision. **(Complete and attach Appendix H)**

4. ***Audio recording, video recording, and recording still images, including digital recordings,*** of participants can present special concerns, particularly regarding confidentiality. Projects involving these must make specific mention of them in the consent documents, including information about the storage of recorded material and how and when they will be destroyed. Please check all that apply below, and **complete and attach Appendix I if required**. This project will involve:

____ Audio recording ____ Video recording ____ Still images

D. INSTRUMENTS/APPARATUS

Describe any forms, surveys, or instruments you plan to use. (Copies of each must be attached to the protocol.) If online surveys will be used, please identify the system to be used and describe the system's confidentiality protections.

E. DATA

Data security is critical to the protection of subjects' identities and private information. The IRB must evaluate whether the systems in place to protect the data are appropriate for the level of risk to the subjects.

1. Data can either be anonymous, confidential, or, if the subjects agree, neither anonymous nor confidential. Please note that even if names are not collected, it may be possible to identify subjects through IP addresses for web-based surveys, the collection of certain demographic information, etc. Please consider this when checking one of the following:

____ Anonymous (subjects cannot be identified, either directly or through identifiers)

____ Confidential (subjects will be identified, but their identities will be protected from disclosure)

____ Neither (subjects will be informed that their identities will be disclosed)

2. Describe how and where will the data and signed informed consent forms be stored and kept secure. Please specify the building and room number, if applicable.

3. Indicate who will have access to the data and signed consent form.

4. Describe how the data will be used, both during and after the research. Indicate whether it will be disseminated through publication, presentation or other means, and in what form (e.g. identifiable raw data, aggregate results with no identifiers, etc.).

5. Describe how and when the data will be disposed of.

PART 3: RISKS AND BENEFITS

F. RISKS

Risks to the subjects must be reasonable in relation to anticipated benefits, if any, to subjects, and the importance of knowledge that may reasonably be expected to result. *Physical risks* include anything potentially harmful to the body, including injury, illness, or death, while *psychological risks* can include reactions such as emotional distress or anxiety. *Social risks* include exposure to criminal or civil liability, or damage to the subjects' financial standing, employability, or reputation. Please note that all risks must be articulated in the consent form.

1. Describe foreseeable risks to the subject.

2. Describe how these risks will be minimized.

3. If these risks are greater than those encountered in everyday activities (more than "minimal risk,") additional explanation is required

Are these risks greater than minimal risk? ____ Yes ____ No. If yes, complete the following:

a) Explain how they are outweighed by the sum of the benefits to the individual subject and to the importance of the knowledge to be gained.

b) Discuss the alternative ways of conducting this research and why the one chosen is superior.

c) Explain fully how the **rights and welfare** of such subjects at risk will be protected (e.g., equipment closely monitored, psychological screening of prospective subjects, medical exam given prior to procedure).

G. BENEFITS

Benefits to the subjects must be weighed against foreseeable risks, and are to be distributed fairly among the community's population. Benefits may include anything health-related, psychosocial, or other direct value for individual subjects, or may yield generalizable knowledge that may further society's understanding of a disorder or condition. Compensation for participation is not a benefit.

1. Describe what you hope to learn from the study.

2. Who might find these results useful?

3. Describe direct benefits to the participants, if any?

4. Explain how the benefits justify the associated risks.

IV. Checklist

Please complete this checklist to assure that all required components of your protocol have been included prior to submitting your protocol to the IRB. Incomplete protocols will be returned to the PI.

____ Informed consent procedures/documentation, or the request for modification or waiver thereof, have been clearly explained. Appendix A is attached.

____ This project involves the following vulnerable populations:

- ____ Minors. Appendix B is attached.
- ____ Prisoners. Appendix C is attached.
- ____ Pregnant women, (where the condition of pregnancy is related to the study), human fetuses or neonates. Appendix D is attached.

____ Cognitively impaired individuals. Appendix E is attached.

____ Psychological interventions will be employed, such as contrived social situations, manipulation of the subject's attitudes, opinions or self-esteem, psychotherapeutic procedures, or other psychological influences. Appendix F is attached.

____ Elements of deception will be used. Appendix G is attached.

____ Biomedical procedures will be used. Appendix H is attached.

____ Audio recording, video recording, or still images will be used. Appendix I is attached.

____ International research will be conducted. Appendix J is attached.

Appendix A: Elements of Informed Consent

Federal regulations specify the required elements of informed consent. The regulations also allow for waiver or alteration of these elements under specific circumstances. If no waiver or alteration of the elements of informed consent has been requested, the informed consent procedures described in the protocol and consent documents must contain all of the elements listed below. Please mark "Yes" to indicate they are included in both the protocol and the consent documents, unless you have requested to waive or alter a particular element.

____ Yes 1. A statement that the study involves research

____ Yes 2. An explanation of the purposes of the research

____ Yes 3. The duration of the participant's participation

____ Yes 4. A description of procedures to be followed

____ Yes 5. A description of foreseeable risks or discomforts to the participant

____ Yes 6. A description of any benefits to the participants or any others that may be expected from the research

____ Yes 7. A statement describing the extent, if any, that confidentiality will be maintained

____ Yes 8. An explanation as to whom to contact concerning questions about the research; this should include the Principal Investigator's name and contact information. In addition, for questions about research participants' rights and/or a research related injury or adverse effects, list the IRB name and contact information

____ Yes 9. A statement that participation is voluntary

____ Yes 10. A statement that refusal to participate involves no penalty or loss of benefits

____ Yes 11. A statement that the subject may discontinue participation at any time without penalty or loss of benefits

If the IRB deems it appropriate, *additional elements* of informed consent may be required as follows:

□ A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable

□ Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent

□ Any additional costs to the subject that may result from participation in the research;

- □ The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject

- □ A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject

- □ The approximate number of subjects involved in the study

Appendix B: Research Involving Children as Subjects

45 CFR 46.401 covers specific requirements for research involving children. The regulations define children as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." Children are considered a protected population because of their inability to provide legal consent. Instead, the typical process involves permission from the parent or guardian and assent from the child. Requirements regarding this depend on the risk level of the research. A thorough risk/benefit analysis is required.

Projects involving no more than minimal risk require the assent of the children and the permission of the parents or guardians. **Please note** that the portion of Exempt Category 2 regarding educational survey or interview procedures does not apply to children, nor does the observation of public behavior unless the investigator is not participating in the activities being observed.

If the research involves greater than minimal risk, but presents the prospect of direct benefit to the individual subjects, the risk must be justified by the anticipated benefit to the subject, and adequate provisions must be made for obtaining the assent of the children.

If the research involves greater than minimal risk and no prospect of direct benefit to the individual subjects, but is likely to yield generalizable knowledge about the subject's disorder or condition, the permission of both parents is required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

1. Provide a justification for the inclusion of minors that documents the benefits that are likely to accrue to a child participating in the project.

2. Specify how **parental permission** will be obtained and documented. Attach copies of all letters and permission forms.

3. Specify how you will obtain **assent** of minor subjects. Attach copies of assent forms for children who can read (8 to 17 years) or script (for children under 8 years) for verbal assent. If you will not be obtaining assent, please justify why assent shouldn't be required.

4. If subjects are school children and class time is used to collect data, describe in detail the activity planned for non-participants. Who will supervise those children? This information must also be included in the consent form.

5. For projects involving children under 8 years of age, what non-verbal cues will you watch for to indicate the child is ready to end or pause participation?

6. Specify provisions for minimizing **coercion** of minors to participate.

Appendix C: PRISONERS

Under 45 CFR 46.303, "Prisoner" means any individual involuntarily confined or detained in a penal institution. Individuals are prisoners if they are in any kind of penal institution, such as a prison, jail, juvenile offender facility, or court-ordered substance abuse facilities, and their ability to leave the institution is restricted. Prisoners may be convicted felons, or may be untried persons who are detained pending judicial action, for example, arraignment, or trial.

1. Research involving prisoners is permissible only if the research involves one or more of four permissible categories, or if the research meets the criteria described in an HHS Secretarial waiver that applies to certain epidemiological research. Please indicate under which category your research falls:

   ____ The study of the possible causes, effects, and processes of incarceration, and of criminal behavior

   ____ The study of prisons as institutional structures or of prisoners as incarcerated persons

   ____ Research on conditions particularly affecting prisoners as a class; vaccine trials and other research on hepatitis and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults. Research in this category funded by HHS may proceed only after the HHS Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and has published notice in the Federal Register of his or her intent to approve the research

   ____ Research on practices, either innovative or accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In this category, if the IRB-approved proposal is a study in which some prisoners will be assigned to a control group and these prisoners may not benefit from their participation in research.

2. List any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, and quality of food, amenities and opportunity for earnings in the prison. They must not be of such a magnitude that his or her ability to weigh the risks of the research against the value of receiving such advantages in the limited-choice prison environment is impaired.

3. Describe how the risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers.

4. Demonstrate that procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides the IRB with written justification for following some other procedures, control subjects must be selected randomly from the group of available prisoners that meet the characteristics needed for that particular research proposal.

5. Confirm information is presented in language that is understandable to the subject population.

6. Provide adequate assurance that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole.

7. Should there be a need for follow-up examination or care of participants after the end of their participation, adequate provision must be made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

Appendix D: PREGNANT WOMEN, HUMAN FETUSES, AND NEONATES

45 CFR 46 Subpart B regulates research activities involving this protected population. There are very specific criteria that must be met in order to allow the IRB to approve research involving pregnant women, human fetuses, or neonates. Please indicate whether your proposed research involves:

____ Pregnant women

____ Human fetuses

____ Neonates

1. **45 CFR 46.204 provides information on the criteria that must be met to approve research involving pregnant women or human fetuses.**

    a. Have appropriate studies on animals and nonpregnant humans been conducted and provide data for assessing potential risks to pregnant women and fetuses?

    b. If there is no prospect of direct benefit to the woman or the fetus, the risk to the fetus must not be greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means. Describe whether any risk to the fetus caused solely by the intervention or procedure holds out the prospect of direct benefit to the woman or the fetus.

    c. Is the risk to the fetus the least possible consistent with the research objectives?

    d. Special consent requirements; If the research holds out the prospect of direct benefit solely to the fetus, then the consent of the pregnant woman and the father must be obtained, unless the father is unavailable, incompetent, or temporarily incapacitated, or if the pregnancy resulted from rape or incest. In all other cases, only the consent of the woman is required.

        i. Will the individual(s) providing consent be adequately informed of the potential risk to the fetus and of alternative treatments and their risks and benefits?

        ii. Will any inducements, monetary or otherwise, be offered to terminate a pregnancy?

iii. Will anyone engaged in the research have any part in any decisions as to the timing, method, or procedures used to terminate a pregnancy?

iv. Will anyone engaged in the research have any part in determining the viability of a neonate?

2. <u>45 CFR 46.205 provides very detailed information on the criteria that must be met to approve research involving neonates, depending on their viability.</u>

a. <u>If the project involves nonviable neonates or neonates of uncertain viability</u>:

i. Have scientifically appropriate, preclinical and clinical studies been conducted that provide data for assessing potential risk to neonates?

ii. Have all persons required to provide consent been informed of the reasonable foreseeable impact of the research on the neonate?

iii. Will anyone engaged in the research have any part in determining the viability of the neonate?

b. <u>For projects involving neonates of uncertain viability</u>, consent may be typically be obtained from either parent or their legally authorized representative. For these projects, the following questions must also be addressed:

i. Describe how the research may enhance the probability of survival of the neonate to the point of viability.

ii. Is the risk to the neonate the least possible for achieving that objective?

iii. Is the purpose of the research to develop important biomedical knowledge that cannot be obtained by other means?

iv. Will there be any added risk to the neonate resulting from the research?

c. <u>For projects involving nonviable neonates</u>, consent must typically be obtained from both parents or their legally authorized representatives. For these projects, the following questions must also be addressed:

i. Will the vital functions of the neonate be artificially maintained?

ii. Will the research terminate the heartbeat or respiration of the neonate?

iii. Will there be any added risk to the neonate resulting from the research?

iv. Is the purpose of the research to develop important biomedical knowledge that cannot be obtained by other means?

3. For studies of lactating women, is the supply and content of breast milk adequately protected?

4. For studies of conception or contraception, are the risks, benefits, reversibility, and alternatives adequately explained? In contraceptive studies, is there adequate explanation of possible failure and of the options available for dealing with unintended pregnancies?

Appendix E: COGNITIVELY IMPAIRED INDIVIDUALS

Federal regulations require additional safeguards to protect the rights and welfare of all subjects who are "likely to be vulnerable to coercion or undue influence." 45 CFR 46.111(b) includes "mentally disabled persons" in this category. This can include persons with impaired decision-making capacity as a result of trauma, mental retardation, some forms of mental illness, or dementia, whether temporary, progressive, or permanent. While the regulations do not specify what additional consent requirements must be observed, the IRB must be assured that the rights of the subject and in a manner consistent with the laws of the jurisdiction in which the research is conducted. Generally, if an adult subject lacks capacity to consent, consent may only be given by that individual's legally authorized representative. If you will be seeking a waiver or alteration of the consent process, please so indicate in the appropriate section below, including a justification for the waiver or alteration.

1. Describe the level of the subjects' incapacity.

2. If the subject is not legally capable of providing consent, describe how consent will be obtained from the subject's legally authorized representative.

3. Should the subject regain or develop the capacity to consent, then his or her consent must be obtained for any further research, as the consent of the legally authorized representative is no longer valid. Describe how the consent will then be obtained, if applicable.

4. Should the subject experience effects of progressive or intermittent disorders that lead to decisional impairment during the course of the study, investigators should consider the need to discuss with the prospective subjects whether they should designate someone to serve as a legally authorized representative at the outset of the study, consistent with all applicable laws. Even if a subject has consented on his or her own accord, a designated representative would be ready to step in as the legally authorized representative if the subject's ability to assess his or her own needs and interests becomes compromised during the study. If this pertains to your study, please describe how it will be addressed.

5. It is also usually desirable to obtain the assent of the subject. Describe how you will explain the study in a way that will be understandable to the subjects.

Appendix F: RESEARCH INVOLVING PSYCHOLOGICAL INTERVENTION

Will the subjects of this study be exposed to any psychological interventions such as contrived social situations, manipulation of the subject's attitudes, opinions or self-esteem, psychotherapeutic procedures, or other psychological influences?

1. Identify and describe the **psychological intervention and behavior** expected of subject(s) and the context of the behavior during the psychological intervention.

2. Describe how **data** resulting from this procedure will be gathered and recorded.

3. Identify anticipated and possible psychological, physiological, or social **consequences** of this procedure for the subjects.

4. Indicate the investigator's competence and identify his/her **qualifications** by training and experience, to conduct this procedure.

Appendix G: DECEPTION

A study is deceptive if false information is given to subjects, false impressions created, or information relating to the subjects' participation is withheld from the subjects. When deception is involved, traditional informed consent cannot be obtained prospectively. In order to waive or alter any of the elements of informed consent, the IRB must determine that all four of the following conditions be met:

a) The research involves no more than minimal risk to the subjects;
b) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
c) The research could not practicably be carried out without the waiver or alteration; **AND**
d) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

1. Describe in detail the **deception** involved, including any instructions to subjects or false impressions created.

2. Explain in detail why deception is necessary to accomplish the goals of the research (care should be taken to distinguish cases in which disclosure would invalidate the research from cases in which disclosure would simply inconvenience the investigator).

3. An initial informed consent process is required, although the elements may be waived or altered as indicated above. As soon as possible after the deception, a **debriefing** is required whereby the participant is fully informed about the exact nature of and reason for the deception. The debriefing should also include a second consent form that provides the participant the opportunity to either give permission to have the data used, or to withdraw from participation and not have their data used. Describe, in detail, the plan for debriefing subjects (attach copies of the initial informed consent, the debriefing statement, and the second consent form to be used at the debriefing).

Appendix H: BIOMEDICAL PROCEDURES

If the proposed research involves biomedical procedures (e.g., the taking or withholding of medication, ingestion of any food or other substances, injections, blood drawing, or any other procedure which would normally be done under medical supervision) please provide the following information:

1. Describe, in detail, the biomedical **procedures** involved in this project. Please note that universal blood and body fluid precautions (also known as "universal precautions") recommended by the Centers for Disease Control and Prevention (CDC) must be used in all research protocols in which blood or other bodily fluid specimens are collected. Compliance with CDC guidelines should be addressed in the description of the study that is submitted to the IRB. Such activities may also require review and approval by the Institutional Biosafety Committee.

2. Identify anticipated and possible physiological **consequences** of this procedure for the subject(s) and steps to be taken to screen out subjects who may be at exceptional risk.

3. Identify the **site** where the procedure will occur.

4. Indicate the investigator's competence and identify his/her **qualification**, by training and experience, to conduct this procedure.

5. Describe what procedures will be in place should there be an adverse event, such as the provision of emergency medical services, who will incur the cost thereof, etc.

Appendix I: RECORDING – VIDEO, AUDIO, STILL IMAGE, DIGITAL

Recording an individual's voice and/or image creates unique handling and storage issues, particularly if the content may be considered sensitive. Subjects must be informed ahead of time that such recording will occur. Subjects must also be provided with information about the storage, confidentiality, and future use of the resulting tape. Only what is necessary for the purpose of the study should be recorded.

If a research protocol involves the recording of research subjects, complete the questions listed below:

1. **What type of recording will be utilized?**

2. **What identifiers will be recorded, e.g., partial facial features, full facial features, subject's name?**

3. **Is the recording necessary for participation in the research? If so, why?**

4. **What additional risks to the subject may arise from the recording?**

5. **Who will have access to the recording(s)?**

6. **Will the recordings be transcribed? If so, provide details as to how the transcriptionists will gain access to the recordings. If the transcriptionists have access to identifiable data, they will need to be CITI trained and be listed on the protocol. Will the transcriptionists keep a copy of the data?**

7. **How will the recording(s) be used, e.g. educational or commercial purposes, analysis by the research team, future unspecified use?** Please note that any public use of the recordings requires separate, explicit consent for such use.

8. **What mechanisms in place to protect the confidentiality of the person(s) being recorded?**

9. **Will the recording(s) be kept indefinitely?** If not, provide a clear indication of when and how they will be destroyed.

10. **Will the subjects receive any compensation for allowing themselves to be taped? If so, describe the amount and the method of compensation.**

Additional Informed Consent Requirements: In addition to the standard elements of informed consent, consent forms for projects involving recordings must make specific mention of the elements included above.

□ If the recording is an optional procedure, the subject must have the choice of participating in the recording. The consent for this is separate and distinct from consent to participate in the project, therefore separate signature and date lines are required.

□ If the recording is an integral part of the research and not an optional procedure, a separate informed consent document is not required. However, documentation of the considerations listed above must be still be included within the body of the informed consent document, as well as any additional risks that may arise due to the recording.

References:

Illinois State University, Normal Il.

Cornell University

Vanderbilt University