|  |
| --- |
| **Protocol #:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PI Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Reviewer ID#: \_\_\_\_\_\_\_\_****I certify that I do not have any conflict of interest related to this research or my review** [ ]  |
| **SECTION 1 - REVIEW CATEGORY AND JUSTIFICATION** |
| 1a. Appropriate IRB Review Category selected | [ ]  Yes [ ]  No  |
| 1b. Justification for Review Category is acceptable | [ ]  Yes [ ]  No  |
|  ***If no,*** *please identify appropriate category and reasoning* |
| **SECTION 2 - RESEARCH QUESTION AND DESIGN** |
| 2a. Adequate statement of research question/statement/topic and/or hypothesis | [ ]  Yes [ ]  No  |
| 2b. Research design is clear and acceptable. | [ ]  Yes [ ]  No  |
| 2c. PI is using secondary data for the research (data already available as part medical records, surveys  already conducted, etc.) | [ ]  Yes [ ]  No  |
| ***If yes:*** *The description of how the secondary data was collected, the data source, and how the PI plans to use the data is appropriate* | [ ]  Yes [ ]  No [ ]  N/A |
| ***Comments:*** |
| **If the PI is only using secondary data for the research:****Skip to** **SECTION 7 – CONFIDENTIALIY AND DATA SECURITY** |
| **SECTION 3 - RESEARCH PROCEDURES** |
| Adequate description of all activities involving human subjects | [ ]  Yes [ ]  No  |
| Detailed summary of data collection (questionnaires, interviews, observations, tests, other) and methods of data recording (audiotape, videotape, computer entry, etc.) | [ ]  Yes [ ]  No  |
| Will the PI be audio or video recording participants? | [ ]  Yes [ ]  No  |
| ***If yes:*** If using audio or video tapes, does PI identifies whether or not information is identifiable on audio/video tapes and how confidentiality will be protected? | [ ]  Yes [ ]  No [ ]  N/A |
| Approximate number of participants in specified and seems appropriate for study | [ ]  Yes [ ]  No  |
| Time commitment for participation is clearly explained  | [ ]  Yes [ ]  No  |
| Location of data collection / research activities is specified and appropriate | [ ]  Yes [ ]  No  |
| Description of how participants will be allowed to withdraw from the study is sufficient | [ ]  Yes [ ]  No  |
| ***Comments:*** |
| **SECTION 4 - PARTICIPANTS** |  |
| **4a. Target Population** |  |
| Target population for the study purpose is reasonable for the purpose of the research | [ ]  Yes [ ]  No  |
| Inclusion and exclusion criteria for participants is justifiable | [ ]  Yes [ ]  No  |
| Number of anticipated participants is acceptable and justifiable | [ ]  Yes [ ]  No  |
| **4b. Recruitment Procedures** |  |
| Recruitment procedures are acceptable | [ ]  Yes [ ]  No  |
| Recruitment procedures ensure voluntary participation | [ ]  Yes [ ]  No  |
| **4b.1** Email, flyers, brochures, posters, letters, etc. will be used to recruit participants | [ ]  Yes [ ]  No  |
| ***If yes:*** The email language, brochures, posters, letters, etc. that will be used to recruit participants are appropriate. | [ ]  Yes [ ]  No [ ]  N/A |
| **4b.2** Participants are being compensated for their time (being given $, t-shirt, course credit, etc.) | [ ]  Yes [ ]  No  |
| ***If yes:*** Is the compensation appropriate? | [ ]  Yes [ ]  No [ ]  N/A |
| **4c. Research Site** |  |
| Research sites are indicated | [ ]  Yes [ ]  No  |
| Signed permission letters on appropriate letterhead are attached for sites outside of USI (public places) | [ ]  Yes [ ]  No [ ]  N/A |
| ***Comments:*** |
| **SECTION 5- INFORMED CONSENT / ASSENT** |
| **5a. Informed Consent / Assent Procedure** |
| Informed Consent will be sought from each subject. | [ ]  Yes [ ]  No [ ]  N/A |
| Informed Consent procedures appear to be appropriate. | [ ]  Yes [ ]  No [ ]  N/A |
| **5b. Informed Consent Documents** |  |
| Informed Consent document follows USI template ([www.usi.edu/OSPRA](http://www.usi.edu/OSPRA) for examples) | [ ]  Yes [ ]  No [ ]  N/A |
| Informed Consent document is at an appropriate reading level | [ ]  Yes [ ]  No [ ]  N/A |
| Study title on consent document is identical to that listed on the protocol | [ ]  Yes [ ]  No [ ]  N/A  |
|  ***If no****, has justification been provided for the use of a different title?* | [ ]  Yes [ ]  No [ ]  N/A |
| Does the protocol call for a waiver or alteration of any elements of informed consent?  | [ ]  Yes [ ]  No [ ]  N/A |
| ***If yes,*** *are all the criteria for a waiver or alteration appropriate, that is:* | [ ]  Yes [ ]  No [ ]  N/A |
|  1. The research involves no more than minimal risk to the subjects? 2. The waiver or alteration will not adversely affect the rights and welfare of the subjects?  3. Whenever appropriate, the subjects will be provided with additional pertinent information after participation?  |  |
| **Informed Consent Documents includes:** |  |
| * Title of the study
 | [ ]  Yes [ ]  No [ ]  N/A |
| * The purpose of the research
 | [ ]  Yes [ ]  No [ ]  N/A |
| * A description of the research procedure
 | [ ]  Yes [ ]  No [ ]  N/A |
| * Location where the research will take place
 | [ ]  Yes [ ]  No [ ]  N/A |
| * Length of time the participant is expected to participate
 | [ ]  Yes [ ]  No [ ]  N/A |
| * A description of any potential risks to the subject, including physical, psychological, social harm, discomfort, or inconvenience
 | [ ]  Yes [ ]  No [ ]  N/A |
| * Whether identifying information will be collected, and if so, how it will be kept confidential
 | [ ]  Yes [ ]  No [ ]  N/A |
| * Benefits of the research to society and/or the individual
 | [ ]  Yes [ ]  No [ ]  N/A |
| * If confidentiality cannot be maintained/guaranteed, has the subject been made aware?
 | [ ]  Yes [ ]  No [ ]  N/A |
| * How confidentiality of records identifying the participant will be maintained (including where the data is stored, who has access to the data and how long the data will be kept)
 | [ ]  Yes [ ]  No [ ]  N/A |
| * A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled
 | [ ]  Yes [ ]  No [ ]  N/A |
| * A statement that the subject may withdraw from the study at any time without penalty
 | [ ]  Yes [ ]  No [ ]  N/A |
| * Who to contact for answers to questions or in the event of a research-related injury or emergency
 | [ ]  Yes [ ]  No [ ]  N/A |
| ***Comments regarding consent:*** |  |
| **5c. Are participants between the ages of 7 and 17? (If no 🡪 skip to SECTION 6)** | [ ]  Yes [ ]  No [ ]  N/A |
| Informed Assent will be sought from each subject. | [ ]  Yes [ ]  No [ ]  N/A |
| Informed Assent procedures appear to be appropriate. | [ ]  Yes [ ]  No [ ]  N/A |
| **5d. Informed Assent Documents** |  |
| Informed Assent document follows USI template ([www.usi.edu/OSPRA](http://www.usi.edu/OSPRA) for examples) | [ ]  Yes [ ]  No [ ]  N/A |
| Informed Assent document is at an appropriate reading level | [ ]  Yes [ ]  No [ ]  N/A |
| Study title on Assent document is identical to that listed on the protocol | [ ]  Yes [ ]  No [ ]  N/A  |
|  ***If no****, has justification been provided for the use of a different title?* | [ ]  Yes [ ]  No [ ]  N/A |
| Does the protocol call for a waiver or alteration of any elements of informed assent?  | [ ]  Yes [ ]  No [ ]  N/A |
| ***If yes,*** *are all the criteria for a waiver or alteration appropriate, that is:* | [ ]  Yes [ ]  No [ ]  N/A |
|  1. The research involves no more than minimal risk to the subjects? 2. The waiver or alteration will not adversely affect the rights and welfare of the subjects?  3. Whenever appropriate, the subjects will be provided with additional pertinent information after participation?  |  |
| **Informed Assent Documents includes:** |  |
| * Title of the study
 | [ ]  Yes [ ]  No [ ]  N/A |
| * The purpose of the research
 | [ ]  Yes [ ]  No [ ]  N/A |
| * A description of the research procedure
 | [ ]  Yes [ ]  No [ ]  N/A |
| * Location where the research will take place
 | [ ]  Yes [ ]  No [ ]  N/A |
| * Length of time the participant is expected to participate
 | [ ]  Yes [ ]  No [ ]  N/A |
| * A description of any potential risks to the subject, including physical, psychological, social harm, discomfort, or inconvenience
 | [ ]  Yes [ ]  No [ ]  N/A |
| * Whether identifying information will be collected, and if so, how it will be kept confidential
 | [ ]  Yes [ ]  No [ ]  N/A |
| * Benefits of the research to society and/or the individual
 | [ ]  Yes [ ]  No [ ]  N/A |
| * If confidentiality cannot be maintained/guaranteed, has the subject been made aware?
 | [ ]  Yes [ ]  No [ ]  N/A |
| * How confidentiality of records identifying the participant will be maintained (including where the data is stored, who has access to the data and how long the data will be kept)
 | [ ]  Yes [ ]  No [ ]  N/A |
| * A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled
 | [ ]  Yes [ ]  No [ ]  N/A |
| * A statement that the subject may withdraw from the study at any time without penalty
 | [ ]  Yes [ ]  No [ ]  N/A |
| * Who to contact for answers to questions or in the event of a research-related injury or emergency
 | [ ]  Yes [ ]  No [ ]  N/A |
| ***Comments regarding assent:*** |  |
| **SECTION 6 - POTENTIAL RISKS AND BENEFITS** |
| **6a. Potential Risks to Participants** |
| Description of potential risks to participants is adequate (including likelihood, level of seriousness, and efforts / safeguards to minimize risk) | [ ]  Yes [ ]  No  |
| Research procedures subject participants to significant psychological, physical, social or legal risks | [ ]  Yes [ ]  No  |
| ***If yes:*** *Is the justification for why the risks are necessary adequate* | [ ]  Yes [ ]  No [ ]  N/A |
| ***If yes:***  *Does the PI identify m*edical or psychological resources will be made available to the participants may need  |  [ ]  Yes [ ]  No [ ]  N/A |
| **6b. Deception of Participants** |  |
| The research design involves the deception of participants | [ ]  Yes [ ]  No  |
|  ***If yes,*** *Explanation of why deception is necessary is adequate* | [ ]  Yes [ ]  No [ ]  N/A |
|  ***If yes****, PI includes a plan for debriefing participants about the deception after participation in the research is complete* | [ ]  Yes [ ]  No [ ]  N/A |
| **6c. Benefits of the Research** |
| Adequate description of how the results of the study will benefit society and/or participant | [ ]  Yes [ ]  No  |
| Potential benefits to society outweigh the risks being incurred by the participants | [ ]  Yes [ ]  No  |
| ***Comments:*** |
| **SECTION 7 – CONFIDENTIALITY AND DATA SECURITY** |
| **7a**. The specific steps that will be taken (i.e. during study participation, after study participation and with the publication of study results) to ensure the subject’s participation will be confidential are provided and are adequate/appropriate. | [ ]  Yes [ ]  No  |
| **7b.** PI lists where the data will be stored, the security of the location and the duration data will be kept | [ ]  Yes [ ]  No  |
|  ***If no,*** *what information is missing?* |
| **7c**. The individuals who will have access to the data is appropriate. | [ ]  Yes [ ]  No  |
| ***Comments:*** |
| **In this reviewer’s opinion, this project is ready to be approved:** | [ ]  Agree [ ]  Disagree [ ]  Revisions Requested (as noted in comments) |
| ***Additional Reviewer Comments:*** |
| **IRB OFFICE ONLY****Basic Protocol Information** |
| Project Title is listed | [ ]  Yes [ ]  No |
| PI signature | [ ] Yes [ ] No  |
| Faculty Sponsor verified | [ ]  Yes [ ]  No [ ]  N/A |
| CITI IRB Training Completion Date and Reference Number | Date & Reference #:  |
| Research funding proposal is attached, if applicable | [ ]  Yes [ ]  No [ ]  N/A |
| Informed Consent documents are attached, if applicable | [ ]  Yes [ ]  No [ ]  N/A |
| Data Collection instruments are attached (surveys, focus group guides, tests, observation guides, etc.) are attached, if applicable | [ ]  Yes [ ]  No [ ]  N/A |
| Recruitment flyers ads, letters, emails, etc. are attached, if applicable  | [ ]  Yes [ ]  No [ ]  N/A |
| If the location of the actual research activities take place somewhere besides USI? (ex. a clinic, school, etc.) are the appropriate approval / verification letters attached? | [ ]  Yes [ ]  No [ ]  N/A |