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| --- | --- | --- | --- |
| **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 | |