

**Committee for the Protection of Human Subjects**

***Reviewer’s Worksheet***

|  |  |  |  |
| --- | --- | --- | --- |
| **1st Reviewer:** |  | **P.I.:** |  |
| **2nd Reviewer:** |  | **CPHS Log #:** |  |

Please check the number of any corresponding item(s) that you believe may present a concern for the well-being of the research subjects of the present study. Further, reviewers should note the specific concern/issue in the comments section below.

KEY:

* “Application” Items: Pertain specifically to items on the CPHS application. The items on this document follow the sequence of items on the application.
* “IC” Items: Pertain to the requirements of the Informed Consent document
* “Procedure” Items: Pertain to questions, comments, or changes to the procedure described in the application or to other procedures that may be required by the CPHS.
* “General” Items: Pertain to issues, questions, comments, or changes not covered elsewhere.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **√** | **#** | **Issue** |  | **√** | **#** | **Issue** |
|  | 1 | Application: Principal Investigator ID/UHD affiliation |  |  | 19 | IC: Risks/discomforts adequately described |
|  | 2 | Application: Faculty Sponsor name & phone # |  |  | 20 | IC: Description of benefits |
|  | 3 | Application: Qualify for exemption? |  |  | 21 | IC: Description of compensation/extra credit or treatment |
|  | 4 | Application: General Purpose of the Research |  |  | 22 | IC: How confidentiality/anonymity maintained |
|  | 5 | Application: Description of sample (number of subjects, ages, gender, where project is to be performed) |  |  | 23 | IC: Nonparticipation statement |
|  | 6 | Application: Recruitment procedures/source of subjects |  |  | 24 | IC: CPHS review statement |
|  | 7 | Application: Subject inclusion/exclusion criteria |  |  | 25 | IC: Risk mitigation: Referrals or additional assistance present |
|  | 8 | Application: Description of procedure (incl. frequency, duration, and location of procedure) |  |  | 26 | IC: Disposition of audio/video tapes |
|  | 9 | Application: Description of risks or discomforts |  |  | 27 | IC: Termination of subject participation by PI |
|  | 10 | Application: Risk mitigation, including debriefing |  |  | 28 | IC: Child answers not confidential |
|  | 11 | Application: Description of benefits |  |  | 29 | IC: Formulation of parental consent |
|  | 12 | Application: Adequate description of consent process |  |  | 30 | IC: Formulation of child assent |
|  | 13 | Application: Adequate description of efforts toward confidentiality/anonymity |  |  | 31 | Procedure: Phone procedure/script |
|  | 14 | Application: Necessary signatures present |  |  | 32 | Procedure: Interview, materials, instruments |
|  | 15 | IC: In lay language |  |  | 33 | Procedure: Consent from site |
|  | 16 | IC: Language invites participation |  |  | 34 | General: Typos, grammar, and/or syntax |
|  | 17 | IC: PI contact information |  |  | 35 | General: Need more information/description |
|  | 18 | IC: Time commitment |  |  | 36 | General: Miscellaneous or unique issues |

|  |  |
| --- | --- |
| **#** | **Specific Comments/Issues** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **In my judgment, the project should be (√) :** | | | | | | | | |
|  | Exempt | |  | Contingently Exempt | | |
|  | Approved | |  | Contingently Approved | | |
|  | Disapproved | |  | Tabled | | |
| **Signature of Reviewer:** | | |  | | | **Date:** |  | |

**Descriptions of Items for Review on the CPHS’ Reviewer’s Worksheet**

|  |  |
| --- | --- |
| 1 | What, if any, is the principal investigator's affiliation with UHD? This should be clearly stated in the application and any informed consent material. |
| 2 | Does the application include contact information, by mail and by phone, for the principal investigator (or faculty sponsor, if applicable)? (Informed consent(s) documents for student projects should disclose that the research is being supervised by a faculty sponsor and contain contact information for the sponsor) |
| 3 | Does the application include information that qualifies the research for an exemption under categories 1 through 6 ( http://www.uhd.edu/research/phs/exempt\_catagories.html)? |
| 4 | Is the general purpose of the research stated clearly and in layman’s terms? |
| 5 | Is the sample described, including number of subjects, ages, gender, and where research is to be performed? |
| 6 | Does the application clearly describe how research subjects will be recruited, and will that procedure help distribute the burdens of research fairly among the populations likely to benefit from the study? Does the application include a copy of any recruitment ads? |
| 7 | Does the application clearly describe the study's inclusion or exclusion criteria for human subjects, and will those criteria help distribute the burdens of research fairly among the populations likely to benefit from the study? |
| 8 | Is the procedure to be used clearly described, including frequency, duration, and location of all procedures to be used with human subjects? |
| 9 | Are the reasonably likely risks or discomforts that could be a result of participation in the study described clearly in the application? |
| 10 | If there are any physical or emotional risks associated with participation in the study and the risk can be mitigated through a debriefing process, does the application include specific plans and/or a script for such a debriefing? |
| 11 | Are the benefits for subject participation clearly described in the application? |
| 12 | Is the process by which informed consent will be obtained from subjects clearly defined in the application? |
| 13 | Are efforts made toward ensuring confidentiality/anonymity of subjects clearly described? If confidentiality/anonymity is not ensured, is the reason explained adequately? |
| 14 | Is the application signed by all necessary parties, including the PI and faculty sponsor? |
| 15 | Is the informed consent (IC) form or script in language that is easily understood by lay people (nonscientists)? Does it clearly describe the research, its purpose, and what subjects will be asked to do? |
| 16 | Does the IC invite participation in the research, rather than assume it? |
| 17 | Does the IC provide subjects with contact information on how to reach the principal investigator (PI) with questions or concerns? |
| 18 | Is the total time commitment for subjects clearly described in the IC? |
| 19 | Are the reasonably likely risks or discomforts that could as a result of participation in the study adequately described in the IC? If the research involves answering potentially sensitive questions or viewing potentially upsetting materials, are examples included in the IC? |
| 20 | Are the benefits for subject participation in the study included in the I.C.? |
| 21 | Is any compensation that is offered for the subjects' time, such as extra class credit for students, both appropriate and clearly described in the IC? |
| 22 | Does the IC clearly indicate how the identity of the subjects (anonymity) or the information obtained from them (confidentiality) will be protected? Are those protections adequate? |
| 23 | Does the IC clearly tell subjects that their participation is voluntary, and that they may refuse to answer any question or drop out of the research study at any time without penalty? |
| 24 | Does the IC include the CPHS review statement telling subjects that the UHD committee reviewed the human subjects protections of this study, and how to contact that body with complaints or questions? |
| 25 | If the study could lead to physical or emotional risks for some subjects, does the IC offer contact information on how to secure the appropriate post-study assistance or referrals? |
| 26 | Does the IC clearly indicate how long any audio/video tapes of subjects will be kept by the researcher, how they will be kept confidential, and what will be done with them at the end of that time period? Is this procedure adequate to protect the subjects’ privacy? |
| 27 | If applicable, does the IC tell subjects that the researcher may choose to drop them from the study at any time? |

|  |  |
| --- | --- |
| 28 | Does any Parental Informed Consent form or script acknowledge that certain types of information obtained from children during the research process (such as reported abuse) cannot legally be kept confidential? |
| 29 | If the proposed subjects include children under the age of 18, is a parental consent form included? |
| 30 | If the proposed subjects include children old enough to assent to the study, is an age-appropriate child assent form or script included? |
| 31 | If the researcher proposes to recruit or contact subjects by telephone, is a phone script included in the application? |
| 32 | Does the application include a copy of any interview/survey questions or other research instruments? |
| 33 | Does the application include any required consents from site? |
| 34 | Are there typographical, grammatical, or syntax errors requiring correction on any of the research materials to be disseminated to subjects or funding sources? |
| 35 | Does the application provide the committee with all pertinent information it needs to understand and assess how the research might impact human subjects? |
| 36 | Other miscellaneous or unique issues. |