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| The purpose of this worksheet is to provide support for IRB members reviewing research. This worksheet must be used. It does not need to be completed or retained. (LAR = “subject’s legally authorized representative”) | | | | |
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| 1. **General Considerations** (Check if **“Yes”** or **“N/A”**. All must be checked) | | | | |
| **☐** | | The convened IRB (or Designated Reviewer) has, or has obtained through consultation, adequate expertise. | | |
| **☐** | | For initial review, the principal investigator is not Restricted. **(“N/A” if not initial review)** | | |
| **☐** | | Materials are complete. | | |
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| 1. **Criteria for Approval of Research:** (Check if **“Yes”** or **“N/A”**. All must be checked) (Applies to initial, continuing, modifications) | | | | |
| **☐** | | **1. Risks to subjects are minimized by using procedures, which are consistent with sound research design and which do not unnecessarily expose subjects to risk.** | | |
| **☐** | | **2. Risks to subjects are minimized by using procedures already being performed on the subjects for other purposes. (“N/A” if none)** | | |
| **☐** | | **3. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.** Consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). | | |
| **☐** | | **4. Selection of subjects is equitable.** Consider the purposes of the research and the setting in which the research will be conducted. Being cognizant of the special problems of research involving a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, individuals with impaired decision-making capacity, or economically or educationally disadvantaged person. | | |
| **☐** | | **5. The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.** **(“N/A” if < Minimal Risk)** | | |
| **☐** | | **6. There are adequate provisions to protect the privacy of subjects.** | | |
| **☐** | | **7. There are adequate provisions to maintain the confidentiality of data.** | | |
| **☐** | | **8. Additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence.[[1]](#footnote-0) (“N/A” if no vulnerable subjects)** | | |
| **☐** | | **9. The informed consent process is adequate.** The informed consent process meets one of these sections or checklists | | |
| **☐ Requirements for Informed Consent Review (SU1) are met** | **☐ Waiver or alteration of consent process (AC1.2)** | **☐ Permanently closed to enrollment** |
| **☐** | | **10. The documentation of informed consent is adequate.** The informed consent documentation meets one of these sections, worksheets, or checklists | | |
| **☐ Section 5: Long Form** | **☐ Waiver or alteration of consent process (AC1.2)** |  |
| **☐ Short Form (AC1.1)** | **☐ Permanently closed to enrollment** |  |
| ☐ | | (If greater than minimal risk, answer must be “Yes.”)The protocol is scientifically valid and employs research procedures which are consistent with sound research design (See GR4: Scientific Validity) | | |
| **☐** | | (If clinical trial, answer must be “Yes.”) Available nonclinical and clinical information is adequate to support the proposed clinical trial. | | |
| **☐** | | Additional applicable criteria[[2]](#footnote-1) are met **(“N/A” if none)** | | |
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| 1. **Additional Considerations (**Check all that apply.) | | | | |
| **☐** | | Does the research involve no more than Minimal Risk to subjects? | | |
| **☐** | | Should review take place more often than annually?[[3]](#footnote-2) If so, specify period. | | |
| **☐** | | Is verification needed from sources other than the investigator that no material changes have occurred since prior review?[[4]](#footnote-3) **(“N/A” if initial)** | | |
| **☐** | | Does information need to be provided to subjects because it may affect their willingness to continue participation? **(“N/A” if initial)** | | |
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| 1. **Primary Reviewer Criteria for Initial review** (Check if **“Yes”** or **“N/A”**. All must be checked; May be determined by a primary reviewer) | | | | |
| **☐** | | The research has the resources necessary to protect subjects. (Time to conduct and complete the research; adequate facilities, subject pool, and medical/psychosocial resources; qualified investigators and research staff; appropriate qualifications for international research.) | | |
| **☐** | | The research is acceptable in terms of institutional commitments and regulations, local context, applicable law, and standards of professional conduct and practice. | | |
| **☐** | | There are no inconsistencies between the DHHS grant and protocol. **(“N/A” if there is no DHHS grant, or reviewed under the 2018 Common Rule or burden reducing provisions.)** | | |
| **☐** | | The plan for communication among sites is adequate to protect subjects. **(“N/A” if not a multicenter trial where PI is the lead or not initial)** | | |
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| 1. **Long Form of Consent Documentation** (Check if **“Yes”** or **“N/A”**. All must be checked) | | | | |
| ☐ | The written consent document is accurate, complete, and consistent with the protocol. | | | |
| ☐ | The written consent document embodies the elements in **HRP-314B “Requirements for Informed Consent Research”** | | | |
| ☐ | The investigator will give either the subject or LAR adequate opportunity to read the consent document before it is signed. | | | |
| ☐ | The subject or LAR will sign and date the consent document. (NA if Waiver of Documentation of Consent has been granted) | | | |
| ☐ | The person obtaining consent will sign and date the consent document. (NA if Waiver of Documentation of Consent has been granted) | | | |
| ☐ | A copy of the signed and dated consent document will be given to the person signing the document. (NA if Waiver of Documentation of Consent has been granted) | | | |
| ☐ | If there is an LAR or parent signature line, the IRB has approved inclusion of adults unable to consent or children. **(“N/A” if no signature line)** | | | |
| ☐ | When a subject or LAR is unable to read: An impartial witness will be present during the entire consent discussion and the consent document notes that the witness attests that the information in the consent document and any other information provided was accurately explained to, and apparently understood by, the subject or LAR, and that consent was freely given. **(“N/A” if all subjects are able to read)** | | | |

1. For DOE studies, employees and contractors are considered vulnerable subjects and Policies must indicate that employees and the IRB must consider if additional protections are required for research involving these subjects. [↑](#footnote-ref-0)
2. Advertisements (SU2); Payments (FN2); Additional Federal Agency Criteria (SU3); Pregnant Women (AC1.3); Prisoners (AC1.6); Children (AC1.4); Cognitively Impaired Adults (AC1.4) [↑](#footnote-ref-1)
3. Consider nature and level of risks; degree of uncertainty regarding the risks; subject vulnerability; investigator experience; IRB’s experience with investigator or sponsor; projected rate of enrollment; and whether study involves novel procedures. [↑](#footnote-ref-2)
4. Implement when the veracity of the information provided is questioned. [↑](#footnote-ref-3)