HRP-314 | 12/4/2024

WORKSHEET: Criteria for Approval

The purpose of this worksheet is to provide support for IRB members reviewing research. It does not need to be completed or retained. (LAR = "subject's Legally Authorized Representative").[i]

1. General Considerations (Check if **"Yes"** or **"NA"**. 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. **("NA" if not initial review) NA: ☐**

☐ Materials are complete.

2. Criteria for Approval (Check if "**Yes**" or "**NA**". All must be checked) (Applies to initial, continuing, and modifications)

☐ Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk.

☐ Risks to subjects are minimized by using procedures already being performed on the subjects for diagnostic or treatment purposes. **("NA" if none) NA: ☐**

☐ 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.[ii]

☐ Selection of subjects is equitable.[iii] (Consider the purpose and setting of the research, involvement of vulnerable subjects, selection criteria, and recruitment, enrollment, and payment procedures.)

☐ The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. **("NA" if ≤ Minimal Risk) NA: ☐** [iv]

☐ There are adequate provisions to protect the privacy of subjects.[v]

☐ There are adequate provisions to maintain the confidentiality of data. [vi]

☐ Additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence. **("NA" if no vulnerable subjects) NA: ☐**

☐ The informed consent process meets one of these worksheets or checklists:

- ☐ **HRP-314a - WORKSHEET - Criteria for Consent**
- ☐ **HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process**
- ☐ **Permanently closed to enrollment**

☐ The informed consent documentation meets one of these worksheets or checklists:

☐ **HRP-314a - WORKSHEET - Criteria for Consent**
☐ **HRP-317 - WORKSHEET - Short Form**
☐ **HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent**
☐ **HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process**
☐ **Permanently closed to enrollment**

☐ Additional applicable criteria[vii] are met **("NA" if none) NA: ☐**

3. Additional Considerations (Check all that apply.)

☐ Does the research involve no more than Minimal Risk to subjects?

☐ Does the research require Continuing review? (**Note that for FDA or DOJ overseen research or research subject to Pre-2018 Requirements, there is no option not to require Continuing review.**)

The research does not require Continuing review if one of the following apply:

☐ The research is eligible for expedited review. **(See HRP-313 – WORKSHEET - Expedited Review)**
☐ The research has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study: (A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or (B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

☐ Should review take place more often than annually?[viii] If so, specify period.

☐ Is verification needed from sources other than the investigator that no material changes have occurred since prior review?[ix] **("NA" if initial) NA: ☐**

☐ Does information need to be provided to subjects because it may affect their willingness to continue participation? **("NA" if initial) NA: ☐**

4. Primary Reviewer Criteria for Initial Review (Check if "**Yes**" or "**NA**". 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 plan for communication among sites is adequate to protect subjects. **("NA" if not a Multi-Site Study where PI is the lead or not initial) NA: ☐**

☐ There are no inconsistencies between the DHHS grant and protocol. **("NA" if research subject to 2018 Requirements or if there is no DHHS grant.) NA: ☐**

[i] This document satisfies AAHRPP elements I.1.E, I.1.F, I.7.C, I-9, II.1.E, II.2.E-II.2.E.2, II.2.F-II.2.F.3, II.2.I, II.3.A, II.3.B, II.3.C-II.3.C.1, II.3.D, II.3.E, II.3.F, II.3.G, II.4.A, II.4.B, III.1.F

[ii] In evaluating risks and benefits, the IRB should 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). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

[iii] In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

[iv] When the IRB determines that data and safety monitoring is appropriate, the IRB will evaluate the adequacy of those plans by considering such issues as reporting mechanisms, the frequency of the monitoring, the entity that will conduct the monitoring, the specific data to be monitored, procedures for analysis and interpretation of the data, actions to be taken upon specific events or end points, and procedures for communication from the data monitor to the IRB and sites. (AAHRPP Tip Sheet #6, section 5)

[v] The IRB will consider it appropriate to include adequate provisions to protect the privacy of subjects when there is a reasonable expectation that prospective research subjects will want to control how, and with whom, they interact and communicate, particularly on issues that may be “sensitive” or “private.” The IRB will determine whether there are adequate provisions to protect the privacy of subjects by considering subjects’ potential comfort with the procedures being performed, comfort with the research setting, and comfort with the information being sought. (AAHRPP Tip Sheet #5 section 2b-c)

[vi] The Secretary of HHS will, after consultation with the Office of Management and Budget’s privacy office and other Federal departments and agencies that have adopted this policy, issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data. In the interim, the IRB will consider it appropriate to make adequate provisions to maintain confidentiality of data any time confidentiality is promised by the investigator, or when there are legal/ethical requirements to maintain data confidentiality. The IRB will determine whether there are adequate provisions to maintain the confidentiality of that data based on a review of the procedures that are in place to meet those promises or legal/ethical requirements (e.g. What information is included in the data, how it is stored, how long it will be stored, who will have access to it, and who will be responsible for receiving/transmitting it.) (AAHRPP Tip Sheet #4 section 2b-c)

[vii] HRP-315 - WORKSHEET - Advertisements; HRP-316 - WORKSHEET - Payments; HRP-318 - WORKSHEET - Additional Federal Agency Criteria; HRP-412 - CHECKLIST - Pregnant Women; HRP-413 - CHECKLIST - Non-Viable Neonates; HRP-414 - CHECKLIST - Neonates of Uncertain Viability; HRP-415 - CHECKLIST - Prisoners; HRP-416 - CHECKLIST - Children; HRP-417 - CHECKLIST - Adults with Impaired Decision-Making Capacity; HRP-418 - CHECKLIST - Non-Significant Risk Device.

[viii] 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.

[ix] Implement when the veracity of the information provided is questioned.