



WORKSHEET: Criteria for Approval

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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")

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.
- For research that involves community members in the research process, including the design and implementation of research and the dissemination of results, the IRB agrees that there was appropriate opportunity for such input.

2 Criteria for Approval of Research: (Check if "Yes" or "N/A". All must be checked) (Applies to initial, continuing, modifications)

- Risks to subjects are minimized by using procedures, which are consistent with sound research design and which 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.
 "N/A" if none
- 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.ⁱ
- Selection of subjects is equitable.ⁱⁱ (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. ("N/A" if ≤ Minimal Risk).
Consider all of the following:
 - The frequency and methods for collection of safety information, including serious adverse events, are appropriate.
 - Cumulative safety data will be reviewed regularly.
 - Stopping points, if necessary, are clearly defined and appropriate.
 - If "greater than minimal risk," the study will be monitored by a DSMB, data monitoring committee or other entity not otherwise associated with the research and such oversight is appropriate
 - "N/A" if ≤ Minimal Risk
- There are adequate provisions to protect the privacy of subjects.
- There are adequate provisions to maintain the confidentiality of data.ⁱⁱⁱ
- Additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence.^{iv} ("N/A" if no vulnerable subjects)
- The informed consent process meets one of these sections or checklists
 Section 5: Consent Process **Waiver or alteration of consent process (HRP-410)** **Permanently closed to enrollment**
- The informed consent documentation meets one of these sections, worksheets, or checklists
 Section 6: Long Form **Waiver of documentation (HRP-411)** **Permanently closed to enrollment**
 Short Form (HRP-317) **Waiver or alteration of consent process (HRP-415)**
- Additional applicable criteria^v are met ("N/A" if none)

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, 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 "WORKSHEET: Expedited Review (HRP-313)."**)
 - 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?^{vi} If so, specify period.
- Is verification needed from sources other than the investigator that no material changes have occurred since prior review?^{vii}
 "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

4 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 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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Complete remaining items when applicable

5 Consent Process (Check if “Yes”. All must be checked)

<input type="checkbox"/>	The investigator will obtain the legally effective informed consent of the subject or LAR.
<input type="checkbox"/>	The circumstances of consent provide the prospective subject or LAR sufficient opportunity to consider whether or not to participate.
<input type="checkbox"/>	The circumstances of consent minimize the possibility of coercion or undue influence.
<input type="checkbox"/>	Information to be given to the subject or LAR will be in language understandable to the subject or LAR.
<input type="checkbox"/>	The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
<input type="checkbox"/>	Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subejst or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
<input type="checkbox"/>	Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject’s or legally authorized representative’s understanding of the reasons why one might or might not want to participate.
<input type="checkbox"/>	There is no exculpatory language through which the subject or LAR is made to waive or appear to waive the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability from negligence.
<input type="checkbox"/>	Consent will disclose the elements in Section 7: Elements of Consent Disclosure

6 Long Form of Consent Documentation (Check if “Yes” or “N/A”. All must be checked)

<input type="checkbox"/>	The written consent document is accurate, complete, and consistent with the protocol.
<input type="checkbox"/>	The written consent document embodies the elements in Worksheet 314-B
<input type="checkbox"/>	The investigator will give either the subject or LAR adequate opportunity to read the consent document before it is signed.
<input type="checkbox"/>	The subject or LAR will sign and date the consent document.
<input type="checkbox"/>	The person obtaining consent will sign and date the consent document.
<input type="checkbox"/>	A copy of the signed and dated consent document will be given to the person signing the document.
<input type="checkbox"/>	If there is an LAR or parent signature line, the IRB has approved inclusion of adults unable to consent or children. <input type="checkbox"/> “N/A” if no signature line
<input type="checkbox"/>	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. <input type="checkbox"/> “N/A” if all subjects are able to read

- ⁱ 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.
- ⁱⁱ 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.
- ⁱⁱⁱ 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.
- ^{iv} When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.
- ^v Advertisements (HRP-315); Payments (HRP-316); Additional Federal Agency Criteria (HRP-318); Pregnant Women (HRP-412 -); Non-Viable Neonates (HRP-413); Neonates of Uncertain Viability (HRP-414); Prisoners (HRP-415); Children (HRP-416); Cognitively Impaired Adults (HRP-417); Non-Significant Risk Device (HRP-418)
- ^{vi} 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.
- ^{vii} Implement when the veracity of the information provided is questioned.