

<b>UC San Diego</b> <b>INSTITUTIONAL REVIEW BOARD ADMINISTRATION</b>	<b>OIA-314 WORKSHEET: Criteria for Approval and Additional Considerations</b>		
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The purpose of this worksheet is to provide support for IRB members reviewing research. This worksheet, or equivalent, must be used. It does not need to be completed or retained.

**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.

**2 Criteria for Approval<sup>1</sup> 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). Additionally, the IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
- 4. Selection of subjects is equitable.** Consider the purposes of the research, the setting in which the research will be conducted, the selection (inclusion/exclusion) criteria, and the subject recruitment and enrollment procedures, 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 subjects, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.
- 5. The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.** (“N/A” if no more than 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.<sup>2</sup>** (“N/A” if no vulnerable subjects)
- 9. The informed consent process is adequate.** The informed consent process meets one of these conditions or checklists  
 **Requirements for informed consent research (OIA-314B) are met**       **Waiver or alteration of consent process (OIA-410)**       **Permanently closed to enrollment**
- 10. The documentation of informed consent is adequate.** The informed consent documentation meets one of these conditions, worksheets, or checklists:  
 **Section 5: Long Form**       **Waiver of documentation (OIA-411)**       **Permanently closed to enrollment**  
 **Short Form (OIA-317)<sup>3</sup>**       **Waiver or alteration of consent process (OIA-410)**
- The protocol is scientifically valid and employs research procedures which are consistent with sound research design. (See OIA-320 WORKSHEET: *Scientific or Scholarly Review*, or equivalent.) (If greater than minimal risk, answer must be “Yes.”)
- Available non-clinical and clinical information is adequate to support the proposed clinical trial. (If clinical trial, answer must be “Yes.”)
- Additional applicable criteria<sup>4</sup> are met. (“N/A” if none)

**3 Additional Considerations:** (Check all that apply.)

- What level of risk does the study present to subjects? (Answer must be yes; determination of risk level must be indicated below.)  
 The study presents no more than minimal risk to subjects.  
 The study presents greater than minimal risk to subjects.
- Should review take place more often than annually?<sup>5</sup> If so, specify period:
- Is verification needed from sources other than the investigator that no material changes have occurred since prior review?<sup>6</sup> (“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)

<sup>1</sup> Numbered criteria for IRB approval of research in this section are from [45 CFR 46.111](#) and [21 CFR 56.111](#)

<sup>2</sup> For Department of Energy (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 (DOE Order [DOE O 443.1C](#)).

<sup>3</sup> Generally, the IRB will only allow the use of a short form consent form in instances in which a subject who does not speak/understand English presents for enrollment in the study and no translated version of the approved long form consent form is available.

<sup>4</sup> Advertisements (OIA-315 WORKSHEET: *Advertisements*); Payments (OIA-316 WORKSHEET: *Payments*); Additional Federal Criteria (OIA-318 WORKSHEET: *Additional Federal Criteria*); Pregnant Subjects (OIA-412 CHECKLIST: *Pregnant Subjects*); Non-Viable Neonates (OIA-413 CHECKLIST: *Non-Viable Neonates*); Neonates of Uncertain Viability (OIA-414 CHECKLIST: *Neonates of Uncertain Viability*); Prisoners (OIA-415: CHECKLIST: *Prisoners*); Children (OIA-416 CHECKLIST: *Children*); Cognitively Impaired Adults (OIA-417 CHECKLIST: *Cognitively Impaired Adults*); Non-Significant Risk Device (OIA-418 CHECKLIST: *Non-Significant Risk Device*).

<sup>5</sup> 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.

<sup>6</sup> Implement when the veracity of the information provided is questioned and/or with consideration of project complexity, previous investigator compliance, continuing review report indicating changes not previously reported, or for any other reason deemed appropriate by the IRB.

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<b>4 Primary Reviewer Criteria for Initial Review:</b> (Check if "Yes" or "N/A." All must be checked; may be determined by a primary reviewer)	
<input type="checkbox"/>	The researcher has the resources necessary to protect subjects. (Adequate facilities and medical/psychosocial resources, qualified investigators and research staff, appropriate qualifications for international research)
<input type="checkbox"/>	The research is acceptable in terms of local context, applicable law, and standards of professional research conduct and practice.
<input type="checkbox"/>	The plan for communication among sites is adequate to protect subjects. ("N/A" if not a multicenter trial where investigator is the lead; not initial review)
<b>5 Long Form Consent Form Documentation:</b> (Check if "Yes" or "N/A." All must be checked)	
<input type="checkbox"/> N/A, consent documentation not required	
<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 <i>OIA-314B Worksheet: Requirements for Informed Consent</i> , or equivalent.
<input type="checkbox"/>	The investigator will give either the subject or legally authorized representative (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. (NA if waiver of documentation of consent has been granted)
<input type="checkbox"/>	The person obtaining consent will sign and date the consent document. (NA if waiver of documentation of consent has been granted)
<input type="checkbox"/>	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)
<input type="checkbox"/>	If there is an LAR or parent signature line, the IRB has approved/will approve inclusion of adults unable to consent, or <u>children</u> , respectively. ("N/A" if no LAR or parent signature line)
<input type="checkbox"/>	When a subject or LAR is unable to read or write: 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)
<input type="checkbox"/>	If there is an impartial witness requirement, a witness signature line is included in the consent document. ("N/A" if no impartial witness is required)
<b>6 Electronic Consent Documentation:</b> (Check if "Yes" or "N/A." All must be checked)	
<input type="checkbox"/> N/A, will not use electronic consent documentation	
<input type="checkbox"/>	The electronic signature is created within a system that generates an encrypted, identifiable signature.
<input type="checkbox"/>	The investigator has described adequate procedures to verify the signature to be legitimate.
<input type="checkbox"/>	The consent document can be produced for review by the potential participant/representative.