



CHECKLIST: Requirements for IRB Review and Approval (Biomedical)

UCLA researchers and IRB members share responsibility for ensuring that human research conducted under UCLA’s jurisdiction meets the ethical principles of the Belmont Report and federal criteria for IRB approval of research and informed consent.

This checklist outlines the criteria for IRB approval of BIOMEDICAL AND CLINICAL RESEARCH.

Important Note: Some items may not be applicable to individual studies.

1. PURPOSE AND BACKGROUND	YES	NO	N/A
a) 10.1/2.0 Statement of purpose is adequate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) 10.1/3.0 Preliminary data are adequate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) 1.1-1.1a Study personnel appear appropriate/qualified	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) 2.2 Lay language summary is appropriate/understandable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. SECTION 1.1 /7.1/10.1 - STUDY RESOURCES	YES	NO	N/A
a) Study personnel are sufficient in numbers and qualifications	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Facilities are adequate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Medical or psychological resources that subjects may need as a consequence of the research are available	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Letters of support from involved units are provided or appropriate co-investigators from those units are named	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. STUDY DESIGN	YES	NO	N/A
a) 10.1/4.0 Design is adequate to address research question	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) 10.1/6.0 Rationale for the number of subjects is justified <i>[Formal sample size is required except for pilot studies]</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) 11.1/4.0-5.0 Inclusion/exclusion criteria are appropriate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. SECTION 9.2-9.5 - PRIVACY AND CONFIDENTIALITY	YES	NO	N/A
a) 9.2a Privacy protection measures are adequate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) 9.3-9.5 Confidentiality of identifiable data measures are adequate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Certificate of Confidentiality is warranted	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. SECTION 10.1 - PROCEDURES	YES	NO	N/A
a) Study utilizes procedures already performed for diagnosis/treatment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Frequency and duration are stated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Research procedures are clearly differentiated from standard of care	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Procedures are performed at acceptable facilities by trained staff	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) Data collection/recording methods are explained	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. STUDY POPULATION AND RECRUITMENT PROCEDURES	YES	NO	N/A

IMPORTANT NOTE: Protocol specific information supporting the required IRB determinations regarding **vulnerable populations** is provided by investigators in the webIRB application.

If you disagree with the determinations, provide your comments in the **webIRB Submit Expedited Review Activity screen** for review using Expedited review procedures, or **discuss during the meeting** for protocols reviewed by the convened Board.

a) 11.1-11.2 Selection of subjects is equitable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) 19.1-19.3 Screening procedures are acceptable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) 18.1-18.10 Recruitment methods and materials are appropriate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) 16.1-16.2 Payments/reimbursements are not coercive/unduly influential	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) 16.2 Any coercion/undue influence to participate is avoided or minimized	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) 12.1-12.6 Vulnerable subject populations* are identified and adequately protected, and additional safeguards are provided where needed to protect subjects' rights and welfare and minimize coercion or undue influence [*e.g., children, prisoners, pregnant women, mentally disabled persons, economically or educationally disadvantaged persons]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7. SECTION 11.2 - REGULATORY ISSUES – POPULATIONS YES NO N/A

a) 12.1 Minors enrollment justified	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) 12.3 Adults with diminished capacity or unable to provide informed consent justified	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) 12.4-12.5 Pregnant Women, Human Fetuses, and Neonates enrollment justified	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) 12.8 Prisoners enrollment justified	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) 12.7.1 Wards enrollment justified (45 CFR 46.209) - Applicable if research falls under 45 CFR 46.406	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8. SECTION 14.1 - RISKS AND BENEFITS YES NO N/A

a) Risks are well described, including physical, psychological, social, legal, or economic risks	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Risks are minimized	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Risks and benefits are well described	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Risks are reasonable in relation to potential benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) Injury/illness due to research is addressed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9. SECTION 15.1-15.2 - DATA SAFETY AND MONITORING YES NO N/A

a) Plans for data/statistical analysis are defined and justified	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Provisions for monitoring safety data are adequate to ensure the safety of participants (Required for research over minimal risk)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Stopping rules are explained and sufficiently detailed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) When UCLA is the coordinating center or the prime grant holder provisions for communicating risks and material protocol changes between sites are adequate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10. SECTIONS 20-23 - INFORMED CONSENT YES NO N/A

IMPORTANT NOTE: Protocol specific information supporting the required IRB determinations regarding consent waivers is provided by investigators in the webIRB application.

If you disagree with the determinations, provide your comments in the **webIRB Submit Expedited Review Activity screen** for review using Expedited review procedures, or **discuss during the meeting** for protocols reviewed by the convened Board.

a) Consent will be sought from each prospective participant or their legal representative	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) If consent is waived, or consent process or documentation is altered from standard, appropriate justification is provided.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) The consent process minimizes the possibility of coercion or undue influence	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Consent form language is appropriate/understandable to subjects	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) Consent form is accurate and complete and includes all required elements [See sections 11 and 12]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) Consent procedure is described; sufficient time is allowed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g) Any exception to signed consent by adult subjects (e.g., surrogates, children) is justified	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

in protocol and reflected in consent documentation

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| h) If those who do not use English as a primary language will be enrolled, application indicates whether translated consent forms will be used. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| i) Communications with the participant, both written and verbal, will be in language understandable to the participant or representative | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| j) All translated consent documents are included with application | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| k) Information communicated during the consent process will not include exculpatory language through which the participant or representative is made to waive or appear to waive legal rights or release or appear to release the investigator, sponsor, institution, or their agents from liability for negligence. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| l) Where surrogates/legally authorized representatives will consent, the required additional safeguards are in place | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

11. SECTION 20.3 - BASIC ELEMENTS OF INFORMED CONSENT [45 CFR 46.116(a) AND 21 CFR 50.25(a)] YES NO N/A

IMPORTANT NOTE: Protocol specific information supporting the required IRB determinations regarding an alteration of consent is provided by investigators in the webIRB application.

If you disagree with the determinations, provide your comments in the **webIRB Submit Expedited Review Activity screen** for review using Expedited review procedures, or **discuss during the meeting** for protocols reviewed by the convened Board.

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| a) A statement that the study involves research; | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b) an explanation of the purpose of the research; | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| c) an explanation of the expected duration of the research; | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| d) a description of the procedures to be followed; and identification of any procedures that are experimental. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| e) A description of any reasonable foreseeable risks or discomforts to the subject (including ineffective treatment). | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| f) A description of the benefits to the subject or to others that may be expected from the research. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| g) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| h) A statement describing the extent, if any, to which confidentiality of the records identifying the subject will be maintained. See OHRPP checklist if DOJ supported. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| i) A statement that the records may be inspected by the Sponsor (CRO or other designee), the FDA (for FDA-regulated research), the OHRPP or other authorized parties. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| j) For research involving more than minimal risk, an explanation as to whether any compensation will be paid, whether any medical treatments are available if injury occurs, and, if so, what those treatments consist of or where further information may be obtained. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| k) An explanation of whom to contact for questions: | | | |
| i. about the research; | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| ii. about rights as a research subject; and. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| iii. in the event of a research-related injury. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| l) A statement that participation is voluntary, and that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue at any time without penalty. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| m) Deception language in consent document(s) (if applicable) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| n) Research conducted within Bureau of Prisons
See OHRPP DOJ checklist for required elements of disclosure. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

12. SECTION 20.3 - ADDITIONAL ELEMENTS (IF APPLICABLE) [45 CFR 46.116 (b) AND 21 CFR 50.25(b)] YES NO N/A

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| a) A statement that the particular treatment/procedure may involve risks to the subject (or to the fetus or embryo, if the subject is or may become pregnant) which are currently unforeseeable. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
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| b) Anticipated circumstances under which the subject's participation may be terminated by the investigator. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| c) Any additional costs to the subject that may result from participation in the research. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| d) The consequences of and procedures for withdrawing from the research study. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| e) A statement that significant new findings that may affect subject's willingness to continue participation [such as safety risks] learned during the course of the research will be provided to the subject. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| f) The approximate number of subjects in the study. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| g) FDA regulated clinical trials: a statement that data collected cannot be withdrawn from study
If appropriate, statements concerning continued follow-up of associated clinical outcome information. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

13. REGULATORY ISSUES – CONSENT/HIPAA AUTHORIZATION	YES	NO	N/A
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IMPORTANT NOTE: Protocol specific information supporting the required IRB determinations regarding **HIPAA waivers** is provided by investigators in the webIRB application.

If you disagree with the determinations, provide your comments in the **webIRB Submit Expedited Review Activity screen** for review using Expedited review procedures, or **discuss during the meeting** for protocols reviewed by the convened Board.

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| a) 17.2/19.2: Waiver of informed consent (and HIPAA authorization, if applicable) to identify potential subjects | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b) 19.3: Waiver of documented (signed) informed consent to screen potential subjects | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| c) 20.2: Waiver of documented (signed) informed consent for the study (or a component of the study) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| d) 20.4: Waiver of informed consent for the study (or a component of the study) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| e) 17.1: Waiver of HIPAA authorization for the study (or a component of the study) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| f) 21.6: Waiver of parental permission | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| g) 21.1: Waiver of documented (signed) parental permission | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| h) 21.1: Waiver of minor assent | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| i) 8.4: Alteration of informed consent (deception or partial disclosure) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| j) 9.2: Suicide Plan | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

13. REGULATORY ISSUES – DRUGS AND DEVICES	YES	NO	N/A
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| a) Approval status of drug or device clearly explained | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b) 8.6: Drugs - IND Required (IND# on file: _____) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| c) 8.5: Devices: | | | |
| <input type="checkbox"/> Non-Significant Risk (NSR) | | | |
| <input type="checkbox"/> Significant Risk (SR) – IDE# on file: _____ | | | |
| <input type="checkbox"/> Exempt from requirements of 21 CFR Part 812 | | | |
| <input type="checkbox"/> Humanitarian Use Device (HUD) – HDE# on file: _____ | | | |

14. OTHER	YES	NO	N/A
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|--|--------------------------|--------------------------|--------------------------|
| a) References are appropriate | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b) Frequency of review is stated if less/greater than standard 12 months | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| c) Federal grant and IRB application are consistent | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

15. ENROLLMENT STATUS (CONTINUING REVIEW AND AMENDMENTS)	YES	NO	N/A
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| a) Study Permanently Closed to Enrollment | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b) Long-term Follow-up in progress | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| c) Only Analysis of Subject Identifiable Data in progress | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

16. SECTION CRC - CONTINUING REVIEW AND MODIFICATIONS

YES NO N/A

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|--|--------------------------|--------------------------|--------------------------|
| a) The current or proposed consent document is accurate and complete | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b) Do significant new findings that may relate to a participant's willingness to continue taking part in the research study need to be provided? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| i. If so, is the plan to provide new findings to participants acceptable? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| c) Is it necessary to obtain verification from sources other than the investigator to ensure that no material changes have occurred since previous IRB review? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

RECOMMENDATION FOR REVIEW OUTCOME

- Approve Accept Pending Modification(s) Defer

 Disapprove (use only after multiple attempts have been made to resolve issues and IRB and PI have reached an impasse or if IRB determines that science is clearly inadequate, sufficient resources are unavailable, or research is inappropriate).
 Table (use only if unable to review because of loss of quorum, nonscientific member not present, or appropriate expertise is not available at meeting)