UCLA Research Administration
Human Research Protection Program

CHECKLIST: Requirements for IRB Review and Approval

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 ALL 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	❑	❑	❑
b) 10.1/3.0 Preliminary data are adequate	❑	❑	❑
c) 1.1-1.1a Study personnel appear appropriate/qualified	❑	❑	❑

2. SECTION 1.1 /7.1/10.1 - STUDY RESOURCES	YES	NO	N/A
a) Study personnel are sufficient in numbers and qualifications	❑	❑	❑
b) Medical or psychological resources that subjects may need as a consequence of the research are available	❑	❑	❑
c) Letters of support from involved units are provided or appropriate co-investigators from those units are named	❑	❑	❑

3. STUDY DESIGN	YES	NO	N/A
a) 10.1/4.0 Design is adequate to address research question	❑	❑	❑
b) 10.1/6.0 Rationale for the number of subjects is justified *[Formal sample size is required except for pilot studies]*	❑	❑	❑
c) 11.1/4.0-5.0 Inclusion/exclusion criteria are appropriate	❑	❑	❑

4. SECTION 9.2-9.5 - PRIVACY AND CONFIDENTIALITY	YES	NO	N/A
a) 9.2a Privacy protection measures are adequate	❑	❑	❑
b) 9.3-9.5 Confidentiality of identifiable data measures are adequate	❑	❑	❑
c) Certificate of Confidentiality is warranted	❑	❑	❑
d) Data to be retained in subject's medical record is explained	❑	❑	❑

5. SECTION 10.1 - PROCEDURES	YES	NO	N/A
a) Study utilizes procedures already performed for diagnosis/treatment	❑	❑	❑
b) Frequency and duration are stated	❑	❑	❑
c) Research procedures are clearly differentiated from standard of care	❑	❑	❑
d) Procedures are performed at acceptable facilities by trained staff	❑	❑	❑
e) Data collection/recording methods are explained	❑	❑	❑
f) Adverse Event reporting is addressed	❑	❑	❑

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	❑	❑	❑
b) 19.1-19.3 Screening procedures are acceptable	❑	❑	❑
c) 18.1-18.10 Recruitment methods and materials are appropriate	❑	❑	❑
d) 16.1-16.2 Payments/reimbursements are not coercive/unduly influential	❑	❑	❑
e) 16.2 Any coercion/undue influence to participate is avoided or minimized	❑	❑	❑
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, decisionally-impaired, incapacitated, economically or educationally disadvantaged persons]	❑	❑	❑

7. SECTION 11.2 - REGULATORY ISSUES – POPULATIONS	YES	NO	N/A
a) 12.1 Minors enrollment justified	❑	❑	❑
b) 12.3 Adults with diminished capacity or unable to provide informed consent justified	❑	❑	❑
c) 12.4-12.5 Pregnant Women, Human Fetuses, and Neonates enrollment justified	❑	❑	❑
d) 12.8 Prisoners enrollment justified	❑	❑	❑
e) 12.7.1 Wards enrollment justified (45 CFR 46.209) - Applicable if research falls under 45 CFR 46.406	❑	❑	❑
f) Non-emergency proxy consent justified	❑	❑	❑

8. SECTION 14.1 - RISKS AND BENEFITS	YES	NO	N/A
a) Risks are well described, including physical, psychological, social, legal, or economic risks	❑	❑	❑
b) Risks are minimized	❑	❑	❑
c) Risks and benefits are well described	❑	❑	❑
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	❑	❑	❑
e) Injury/illness due to research is addressed	❑	❑	❑

9. SECTION 15 .1-15.2 - DATA SAFETY AND MONITORING	YES	NO	N/A
a) Plans for data/statistical analysis are defined and justified	❑	❑	❑
b) Provisions for monitoring safety data are adequate to ensure the safety of participants (Required for research over minimal risk)	❑	❑	❑
c) Stopping rules are explained and sufficiently detailed	❑	❑	❑
d) When UCLA is the coordinating center or the prime grant holder, provisions for communicating risks and material protocol changes between sites are adequate	❑	❑	❑

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	❑	❑	❑
b) If consent is waived, or consent process or documentation is altered from standard, appropriate justification is provided. The consent process minimizes the possibility of	❑	❑	❑

coercion or undue influence. Waivers and alterations may be granted if the following criteria has been met:

- The research involves no more than minimal risk to the participants; and
- The waiver or alteration will not adversely affect the rights and welfare of the participants; and
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever appropriate, the participants or legally authorized representatives will be provided with additional pertinent information after participation.
- If the research involved using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format

c) Consent form language is appropriate/understandable to subjects	❑	❑	❑
d) Consent form is accurate and complete and includes all required elements [See sections 11 and 12]	❑	❑	❑
e) Consent procedure is described; sufficient time is allowed	❑	❑	❑
f) Any exception to signed consent by adult subjects (e.g., surrogates, children) is justified in protocol and reflected in consent documentation	❑	❑	❑
g) If those who do not use English as a primary language will be enrolled, application indicates whether translated consent forms will be used.	❑	❑	❑
h) Communications with the participant, both written and verbal, will be in language understandable to the participant or representative	❑	❑	❑
i) 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.	❑	❑	❑
j) Where surrogates/legally authorized representatives will consent, the required additional safeguards are in place	❑	❑	❑

11. SECTION 20.3 - BASIC ELEMENTS OF INFORMED CONSENT [45 CFR 46.116(a) AND 21 CFR 50.25(a)]	YES	NO	N/A
a) Key information summary (required only for studies reviewed under the 2018 common rule and over 4 pages);	❑	❑	❑
b) A statement that the study involves research;	❑	❑	❑
c) an explanation of the purpose of the research;	❑	❑	❑
d) an explanation of the expected duration of the research;	❑	❑	❑
e) a description of the procedures to be followed; and identification of any procedures that are experimental.	❑	❑	❑
f) A description of any reasonable foreseeable risks or discomforts to the subject (including ineffective treatment).	❑	❑	❑
g) A description of the benefits to the subject or to others that may be expected from the research.	❑	❑	❑
h) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.	❑	❑	❑
i) 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.***	❑	❑	❑
j) 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.	❑	❑	❑
k) 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.	❑	❑	❑
l) An explanation of whom to contact for questions:			
i. about the research;	❑	❑	❑
ii. about rights as a research subject; and.	❑	❑	❑
iii. in the event of a research-related injury.	❑	❑	❑

m) 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.	❑	❑	❑
n) Deception language in consent document(s) (if applicable)	❑	❑	❑
o) Research conducted within Bureau of Prisons ***See OHRPP DOJ checklist for required elements of disclosure.***	❑	❑	❑
p) Statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent; OR Statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies	❑	❑	❑

12. SECTION 20.3 - ADDITIONAL ELEMENTS (IF APPLICABLE) [45 CFR 46.116 (b) AND 21 CFR 50.25(b)]	YES	NO	N/A
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.	❑	❑	❑
b) Anticipated circumstances under which the subject's participation may be terminated by the investigator.	❑	❑	❑
c) Any additional costs to the subject that may result from participation in the research.	❑	❑	❑
d) The consequences of and procedures for withdrawing from the research study.	❑	❑	❑
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.	❑	❑	❑
f) The approximate number of subjects in the study.	❑	❑	❑
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.	❑	❑	❑
h) Statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit	❑	❑	❑
i) Statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions	❑	❑	❑
j) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing	❑	❑	❑

13. REGULATORY ISSUES – CONSENT/HIPAA AUTHORIZATION	YES	NO	N/A

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.

a) 17.2/19.2: Waiver of informed consent to identify potential subjects	❑	❑	❑
b) 17.1: Waiver of HIPAA authorization to identify potential subjects	❑	❑	❑
c) 19.3: Waiver of documented (signed) informed consent to screen potential subjects (required only for studies reviewed under the pre-2018 common rule)	❑	❑	❑
d) 20.2: Waiver of documented (signed) informed consent for the study (or a component of the study)	❑	❑	❑
e) 20.4: Waiver of informed consent for the study (or a component of the study)	❑	❑	❑
f) 17.1: Waiver of HIPAA authorization for the study (or a component of the study)	❑	❑	❑
g) 21.6: Waiver of parental permission	❑	❑	❑

h) 21.1: Waiver of documented (signed) parental permission	❑	❑	❑
i) 21.1: Waiver of minor assent	❑	❑	❑
j) 8.4: Alteration of informed consent (deception or partial disclosure)	❑	❑	❑
k) 9.2: Suicide Plan	❑	❑	❑

14. REGULATORY ISSUES – DRUGS AND DEVICES	YES	NO	N/A
a) Approval/cleared status of drug or device clearly explained	❑	❑	❑
b) 8.6: Drugs - IND Required (IND# on file: _____)	❑	❑	❑

c) 8.5: Devices:

- ❑ Non-Significant Risk (NSR)
- ❑ Significant Risk (SR) – IDE# on file: _____
- ❑ Exempt from requirements of 21 CFR Part 812
- ❑ Humanitarian Use Device (HUD) – HDE# on file:_____
- ❑ Enforcement discretion

14. OTHER	YES	NO	N/A
a) References are appropriate	❑	❑	❑
b) Frequency of review is stated if less/greater than standard 12 months	❑	❑	❑
c) Federal grant and IRB application are consistent	❑	❑	❑

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

16. SECTION CRC - CONTINUING REVIEW AND MODIFICATIONS	YES	NO	N/A
a) The current or proposed consent document is accurate and complete	❑	❑	❑
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?	❑	❑	❑
i. If so, is the plan to provide new findings to participants acceptable?	❑	❑	❑

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)