**CHECKLIST: Requirements for IRB Review and Approval (Biomedical)**

Lincoln University’s researchers and IRB members share responsibility for ensuring that human research conducted under LU’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

1. 10.1/2.0 Statement of purpose is adequate   
2. 10.1/3.0 Preliminary data are adequate   
3. 1.1-1.1a Study personnel appear appropriate/qualified   
4. 2.2 Lay language summary is appropriate/understandable   

**2. SECTION 1.1 /7.1/10.1 - STUDY RESOURCES** YES NO N/A

1. Study personnel are sufficient in numbers and qualifications   
2. Facilities are adequate   
3. Medical or psychological resources that subjects may need as a consequence of the research   

are available

1. Letters of support from involved units are provided or appropriate co-investigators   

from those units are named

**3. STUDY DESIGN** YES NO N/A

1. 10.1/4.0 Design is adequate to address research question   
2. 10.1/6.0 Rationale for the number of subjects is justified   

*[Formal sample size is required except for pilot studies]*

1. 11.1/4.0-5.0 Inclusion/exclusion criteria are appropriate   

**4. SECTION 9.2-9.5 - PRIVACY AND CONFIDENTIALITY** YES NO N/A

1. 9.2a Privacy protection measures are adequate   
2. 9.3-9.5 Confidentiality of identifiable data measures are adequate   
3. Certificate of Confidentiality is warranted   

**5. SECTION 10.1 - PROCEDURES** YES NO N/A

1. Study utilizes procedures already performed for diagnosis/treatment   
2. Frequency and duration are stated   
3. Research procedures are clearly differentiated from standard of care   
4. Procedures are performed at acceptable facilities by trained staff   
5. Data collection/recording methods are explained   

**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.

1. 11.1-11.2 Selection of subjects is equitable   
2. 19.1-19.3 Screening procedures are acceptable   
3. 18.1-18.10 Recruitment methods and materials are appropriate   
4. 16.1-16.2 Payments/reimbursements are not coercive/unduly influential   
5. 16.2 Any coercion/undue influence to participate is avoided or minimized   
6. 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]

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

1. 12.1 Minors enrollment justified   
2. 12.3 Adults with diminished capacity or unable to provide informed consent justified   
3. 12.4-12.5 Pregnant Women, Human Fetuses, and Neonates enrollment justified   
4. 12.8 Prisoners enrollment justified   
5. 12.7.1 Wards enrollment justified (45 CFR 46.209) - Applicable if research falls under 45 CFR 46.406   

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

1. Risks are well described, including physical, psychological, social, legal, or economic risks   
2. Risks are minimized   
3. Risks and benefits are well described   
4. 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

1. Injury/illness due to research is addressed.   

**9. SECTION 15 .1-15.2 - DATA SAFETY AND MONITORING** YES NO N/A

1. Plans for data/statistical analysis are defined and justified   
2. Provisions for monitoring safety data are adequate to ensure   

the safety of participants (Required for research over minimal risk)

1. Stopping rules are explained and sufficiently detailed   
2. 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.

1. Consent will be sought from each prospective participant or their legal representative   
2. If consent is waived, or consent process or documentation is altered from standard,   

appropriate justification is provided.

1. The consent process minimizes the possibility of coercion or undue influence   
2. Consent form language is appropriate/understandable to subjects   
3. Consent form is accurate and complete and includes all required elements   

[See sections 11 and 12]

1. Consent procedure is described; sufficient time is allowed   
2. Any exception to signed consent by adult subjects (e.g., surrogates, children) is justified   

in protocol and reflected in consent documentation

1. If those who do not use English as a primary language will be enrolled,   

application indicates whether translated consent forms will be used.

1. Communications with the participant, both written and verbal,   

will be in language understandable to the participant or representative

1. All translated consent documents are included with application   
2. 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.

1. 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

**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.

1. A statement that the study involves research;   
2. an explanation of the purpose of the research;   
3. an explanation of the expected duration of the research;   
4. a description of the procedures to be followed;   

and identification of any procedures that are experimental.

1. A description of any reasonable foreseeable risks or discomforts to the subject   

(including ineffective treatment).

1. A description of the benefits to the subject or to others that may be expected from the research.   
2. A disclosure of appropriate alternative procedures or courses of treatment,   

if any, that might be advantageous to the subject.

1. A statement describing the extent, if any, to which confidentiality of the records identifying   

the subject will be maintained. ***See OHRP checklist if DOJ supported.***

1. A statement that the records may be inspected by the Agency(CRO or other designee),   

the FDA (for FDA-regulated research), the OHRP or other authorized parties.

1. 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.

1. An explanation of whom to contact for questions:
	1. about the research;   
	2. about rights as a research subject; and.   
	3. in the event of a research-related injury.   
2. 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.

1. Deception language in consent document(s) (if applicable)   
2. Research conducted within Bureau of Prisons   

***See OHRPP DOJ checklist for required elements of disclosure.***

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

1. 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.

1. Anticipated circumstances under which the subject’s participation   

may be terminated by the investigator.

1. Any additional costs to the subject that may result from participation in the research.   
2. The consequences of and procedures for withdrawing from the research study.   
3. 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.

1. The approximate number of subjects in the study.   
2. ***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.

**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.

1. 17.2/19.2: Waiver of informed consent (and HIPAA authorization, if applicable) to identify potential   

subjects

1. 19.3: Waiver of documented (signed) informed consent to screen potential subjects   
2. 20.2: Waiver of documented (signed) informed consent for the study (or a component of the study)   
3. 20.4: Waiver of informed consent for the study (or a component of the study)   
4. 17.1: Waiver of HIPAA authorization for the study (or a component of the study)   
5. 21.6: Waiver of parental permission   
6. 21.1: Waiver of documented (signed) parental permission   
7. 21.1: Waiver of minor assent   
8. 8.4: Alteration of informed consent (deception or partial disclosure)   
9. 9.2: Suicide Plan   

**13. REGULATORY ISSUES – DRUGS AND DEVICES**

YES NO N/A

1. Approval status of drug or device clearly explained   
2. 8.6: Drugs - IND Required (IND# on file: )   
3. 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:\_

**14. OTHER** YES NO N/A

1. References are appropriate   
2. Frequency of review is stated if less/greater than standard 12 months   
3. Federal grant and IRB application are consistent   

**15. ENROLLMENT STATUS (CONTINUING REVIEW AND AMENDMENTS)** YES NO N/A

1. Study Permanently Closed to Enrollment   
2. Long-term Follow-up in progress   
3. Only Analysis of Subject Identifiable Data in progress   

**16. SECTION CRC - CONTINUING REVIEW AND MODIFICATIONS** YES NO N/A

1. The current or proposed consent document is accurate and complete   
2. Do significant new findings that may relate to a participant’s willingness   

to continue taking part in the research study need to be provided?

* 1. If so, is the plan to provide new findings to participants acceptable?   
1. Is it necessary to obtain verification from sources other than the investigator   

to ensure that no material changes have occurred since previous IRB review?

**RECOMMENDATION FOR REVIEW OUTCOME**

* Approve
* Accept Pending Modification(s)

Defer

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* 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)

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