MIRB STAFF SCREENING CHECKLIST

CRITERIA FOR COMPLETE SUBMISSION:
Determine whether the researcher has provided the materials outlined below, as applicable. Missing materials and/or inconsistent content should be communicated to the investigator in order to request the materials/corrections necessary to provide the IRB reviewers with complete and accurate information.

1. Application Form:	**YES**	**NO**	**N/A**
2.1 Indicates appropriate application type	❑	❑	❑
5.1 Level of Review and Committee Assignment: ❑Full Committee Review ❑Expedited Review ❑MIRB1 ❑ MIRB2 ❑ MIRB3			

2. Progress Report for Continuing Review (WebIRB Conversions ONLY)**:**	**YES**	**NO**	**N/A**
CRC sections should provide a description of the study progress. ✓ *CRC1.6 – CRC1.8: Current enrollment information, description of the ongoing study procedures* ✓ *CRC1.9: Reason for late submission/request to continue procedure during IRB approval lapse* ✓ *CRC2.1: Description of PARs which occurred in the prior approval period* ✓ *CRC3.2: A description of all proposed modifications submitted w/ conversion*	❑	❑	❑

3. Funding:	**YES**	**NO**	**N/A**
6.1 Indicates whether the proposed research is/will be funded. ✓ ***If funded by ED, DOJ, DOD, EPA, or DOE, see OHRPP checklists for additional requirements.***	❑	❑	❑
6.2 Relevant funding documents attached in Item 1.7 ✓ ***If project is federally funded & UCLA is the primary awardee – A copy of the funding proposal*** ✓ *If project is federally funded & UCLA is NOT the primary awardee (i.e., subaward to UCLA) -- A copy of the UCLA scope of work.* ✓ *Evaluate on a case by case basis if documents are needed prior to review. (e.g., the scope of work or contract details may be required to determine UCLA's involvement/responsibility for collaborative projects.*	❑	❑	❑

4. Methods & Procedures:	**YES**	**NO**	**N/A**
8.1 All appropriate options in section 8.1 should be selected ✓ *Evaluate on a case-by-case basis whether missing sections constitute an incomplete application for which there is not enough information for the Board to adequately review the study (For example, a clinical trial of an investigational drug or device, will require the option for "Drugs/Biologics/Dietary Supplements" or "Devices" be selected. However, for most studies, the application is not considered incomplete if the options for "Certificate of Confidentiality" or "Radiation" are not selected).*	❑	❑	❑
Regulatory Issues			
8.6 Drugs / Biologics / Dietary Supplements: consistent with procedures and guidance	❑	❑	❑
8.5 Device / Diagnostics (including Humanitarian Use Devices – HUD): consistent with procedures and guidance	❑	❑	❑
10.1 Item 4.0 must include a description of study procedures and/or accurate reference to an attached protocol/study summary.	❑	❑	❑
10.1 Relevant study documents should be attached in item 1.0 ✓ *Including but not limited to protocols, questionnaires, case report forms, study diaries and logs - Evaluate on a case by case basis if missing documents make the application incomplete (For example, an application is incomplete without a copy of the sponsor's protocol but not incomplete if a subject medication log is missing)*	❑	❑	❑

5. Information about Study Data and Data Security:	**YES**	**NO**	**N/A**
9.2 – 9.10 These sections should provide a clear and comprehensive description of how data/specimens will be handled during the course of the research and at study completion. *These sections will not generally make an application incomplete; however any major inconsistencies may require clarification prior to review.*	❑	❑	❑

6. Eligibility Criteria and Study Populations:	**YES**	**NO**	**N/A**
11.1 Items 4.0 and 5.0 must include a description of the inclusion/exclusion criteria and/or accurate reference to an attached protocol/study summary	❑	❑	❑
11.2 If the study will enroll populations which require additional protections (i.e., children, prisoners, pregnant women, adults unable to provide informed consent) have the appropriate options been selected? *This is necessary in order to generate required sections of the application regarding regulatory requirements for inclusion of protected populations.*	❑	❑	❑
Regulatory Issues			
12.1: Minors (*See ED checklist for required considerations if minors are studied in schools)*	❑	❑	❑
12.3: Adults with diminished capacity or unable to provide informed consent	❑	❑	❑
12.4-12.5: Pregnant Women, Human Fetuses, and Neonates	❑	❑	❑
12.8 Prisoners (*See DOJ checklist for additional requirements)*	❑	❑	❑
12.7.1 Wards (45 CFR 46.209) – Applicable if research falls under 45 CFR 46.406	❑	❑	❑

7. Risks and Benefits:	**YES**	**NO**	**N/A**
14.1 This section must provide the investigators risk/benefit analysis for the study, a specific discussion of potential risk/discomforts posed by the research procedures and a description of any anticipated benefits to subjects or society. *Note: It is <u>not</u> appropriate to reference a subsequent document (protocol, ICF) in this section*	❑	❑	❑

8. Data Safety Monitoring (if applicable):	**YES**	**NO**	**N/A**
15.1 – 15.3 These sections should provide a clear and comprehensive description of the study's data safety monitoring plan and/or accurate reference an attached protocol/study summary *These sections will not generally make an application incomplete; however any major inconsistencies may require clarification prior to review.*	❑	❑	❑

9. Recruitment Materials:	**YES**	**NO**	**N/A**
18.1 – 18.10 These sections should provide a clear and comprehensive description of the plan for identification and recruitment of subjects. *These sections will not generally make an application incomplete, however any major inconsistencies may require clarification prior to review.*	❑	❑	❑

10. Screening (if applicable):	**YES**	**NO**	**N/A**
19.1 – 19.4 These sections should provide a clear and comprehensive description of how subject screening will be conducted. *If screening procedures will occur prior to consent being obtained for the study make sure the appropriate options are selected in section 19.2 item 2.0 and relevant screening scripts are attached.*	❑	❑	❑
19.1: Screening procedures to select/identify subjects described	❑	❑	❑
19.2: Screening documents for all identified populations	❑	❑	❑
Regulatory Issues			
17.2/19.2: Waiver of informed consent (and HIPAA authorization, if applicable) to identify potential subjects	❑	❑	❑
19.3: Waiver of documented (signed) informed consent to screen potential subjects	❑	❑	❑

11. Informed Consent Documents:	**YES**	**NO**	**N/A**
20.1 – 21.11 Must describe the plans for obtaining consent/assent and a description of how the consent/assent process will be conducted. (1) All consent/assent forms to be used during in the study are required for review – missing documents constitute an incomplete submission. (2) For conversion to webIRB where the study is closed to enrollment, copies of the previously approved consent/assent documents must be attached in the application.	❑	❑	❑
20.3: Consent/assent process described for all identified populations	❑	❑	❑
20.3: Consent/parental permission/assent forms for all identified populations (unless waivers justified)	❑	❑	❑
Language level appropriate to study populations(s)	❑	❑	❑
UCLA template format or reasonably acceptable variation; includes all basic (required) and additional (optional) elements of informed as applicable	❑	❑	❑

Regulatory Issues

20.2: Waiver of documented (signed) informed consent for the study (or a component of the study)	❑	❑	❑
17.2/20.4: Waiver of informed consent (and HIPAA authorization, if applicable) for the study (or a component of the study)	❑	❑	❑
21.6: Waiver of parental permission	❑	❑	❑
21.1: Waiver of documented (signed) parental permission	❑	❑	❑
21.1: Waiver of minor assent	❑	❑	❑
8.4: Alteration of informed consent (deception or partial disclosure)	❑	❑	❑

12. General / Overview:	**YES**	**NO**	**N/A**
a. Consistency among all application documents	❑	❑	❑
b. Study procedures described for all identified populations	❑	❑	❑
c. Instruments submitted for all study procedures described	❑	❑	❑
d. Multi-site: Information related to non-UCLA sites has been provided for research that will be conducted by/at more than one location	❑	❑	❑
e. Research is covered by HIPAA	❑	❑	❑
f. CITI and HIPAA certifications (as applicable) completed for PI and faculty sponsor	❑	❑	❑
g. External scientific or scholarly review has been completed	❑	❑	❑
h. PI is affiliated with UCLA (i.e., UC Policy 900 faculty, volunteer, student, staff) ***Note:*** If not affiliated cannot serve as PI; PIs without a UC Policy 900 faculty appointment need a Faculty Sponsor	❑	❑	❑
i. PI needs a Faculty Sponsor	❑	❑	❑
j. PI assurances and FS assurances (as applicable) completed.	❑	❑	❑