**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:

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1 Indicates appropriate application type</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.1 Level of Review and Committee Assignment:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full Committee Review</td>
<td>Expedited Review</td>
<td>MIRB1</td>
</tr>
</tbody>
</table>

### 2. Progress Report for Continuing Review (WebIRB Conversions ONLY):

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:

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.1 Indicates whether the proposed research is/will be funded.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.2 Relevant funding documents attached in Item 1.7</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 4. Methods & Procedures:

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.1 All appropriate options in section 8.1 should be selected</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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).</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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

### 5. Information about Study Data and Data Security:

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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S:\R-Website\About_IRB\Med_Staff_Screening.dot Author DW
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 not 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.
☐ ☐ ☐