UCLA Office of the Human Research Protection Program

GIRB 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**
a. 2.1 Indicates appropriate application type	❑	❑	❑
b. 5.1 Level of Review and Committee Assignment:			
❑Expedited Review ❑Exempt ❑Full Committee Review			
❑North (College of Letters & Science OR Professional Schools)			
❑ South (Nursing, Public Health, NPI or Medicine (not biomedical or clinical research)			

2. 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 and information 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.*	❑	❑	❑

3. Surveys, Interview Protocols, Instruments/Measures, etc.	YES	NO	N/A
10.1 includes all instruments attached. (1) Instruments may include: surveys, questionnaires, interview protocols, instruments/measures, focus group protocols, etc. (2) *Sections 10.1 item 4.0 should identify study procedures supported by instruments.*	❑	❑	❑

Recruitment Materials	YES	NO	N/A
18.3 includes all necessary recruitment materials attached. (1) Recruitment materials may include: contact letters, flyers, advertisements, scripts *(2) Section 18.1 should identify proposed recruitment methods.*	❑	❑	❑

Informed Consent Documents	YES	NO	N/A
20.3 includes all consent documents attached. (1) Consent documents may include: adult consent, parental permission, child/youth assent, information sheets, scripts, and/or letters. *(2) Section 20.1 should indicate* the plan for obtaining informed consent*.*	❑	❑	❑

Regulatory Issues – Populations	YES	NO	N/A
a. 11.2: Minors	❑	❑	❑
b. 11.2: Pregnant Women, Human Fetuses, and Neonates	❑	❑	❑
c. 11.2: Prisoners *(See DOJ checklist for additional requirements)*	❑	❑	❑
d. 11.2: Wards (45 CFR 46.209) - Applicable if research falls under 45 CFR 46.406	❑	❑	❑
e. 11.2: Non-emergency proxy consent	❑	❑	❑
f. 11.2: Minors in schools or UCLA students *(See ED checklists for required considerations)*	❑	❑	❑

Regulatory Issues - Consent/HIPAA Authorization	YES	NO	N/A
a. 20.1: 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	❑	❑	❑

d.	20.2: Waiver of signed informed consent for the study (or a component of the study)	❑	❑	❑
e.	20.1: 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.	9.2: Suicide Plan	❑	❑	❑

2. 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 certification (as applicable) completed for PI and faculty sponsor	❑	❑	❑
g. Research involving drugs & investigational devices is not reviewed by GIRB; transfer to MIRB	❑	❑	❑
h. External scientific or scholarly review has been completed	❑	❑	❑
i. PI assurances and FS assurances (as applicable) completed	❑	❑	❑
j. PI is affiliated with UCLA	❑	❑	❑

3. Deception / Withholding Information Section 8.1	YES	NO	N/A
a. 8.4: Justification provided	❑	❑	❑
b. Deception language in consent document(s)	❑	❑	❑
c. Section 8.4 item 3.0: Debriefing	❑	❑	❑

4. Screening, Recruitment Sections 18.1-19.2 (as applicable)	YES	NO	N/A
a. 18.1: Recruitment process described for all identified populations (by whom, when, where)	❑	❑	❑
b. 19.1: Screening procedures to select/identify subjects described	❑	❑	❑
c. 19.2: Recruitment and screening documents for all identified populations	❑	❑	❑

5. Informed Consent – Overview Sections 20.1-20.3 (as applicable)	YES	NO	N/A
a. 20.3: Consent/assent process described for all identified populations (by whom, when, where)	❑	❑	❑
b. 20.2: Consent/assent waivers identified and justified	❑	❑	❑
c. Language level appropriate to study population(s)	❑	❑	❑
d. 20.3: Consent/parental perm./assent for all identified populations (unless waivers justified)	❑	❑	❑
e. UCLA template format or reasonably acceptable variation	❑	❑	❑

6. Informed Consent - Specific Language	YES	NO	N/A
a. Focus groups - disclose limits to confidentiality	❑	❑	❑
b. 8.1: Certificate of Confidentiality - ensure no remaining reference to "if required by law"	❑	❑	❑
c. 8.1 and 8.8: Audio/video recording one-on-one research activities - right to review, edit, erase	❑	❑	❑
d. 9.2: Mandated reporting language (child abuse, elder abuse, harm to self)	❑	❑	❑
e. Local IRB/investigator contact information, when applicable	❑	❑	❑