Lesley University IRB Application Review Checklist

General Considerations When Reviewing:

1. Are there any potentially unethical practices?
2. Does the application feature any contradictions between sections?
3. Do all sections feature sufficient information?

Applicant Information			
Yes	No	N/A	Faculty Supervisor is correctly identified (for student applicant)
Yes	No	N/A	title of project listed?
Yes	No	N/A	project dates listed?
Yes	No		type of project listed?
Section I: Foundational Project Information			
Clear	Unclear	N/A	1.1 the purpose of the study
Clear	Unclear	N/A	1.2 approximate number of subjects
Clear	Unclear	N/A	1.3 design & methods clearly described
Clear	Unclear	N/A	1.6 potential risks with anticipated likelihood and severity ******If mental health supports are listed, free resources are identified to reduce cost burden on participants seeking support following research activities**
Clear	Unclear	N/A	1.6 measures to minimize risk included
Clear	Unclear	N/A	1.8 measures to maintain confidentiality or anonymity present?
Clear	Unclear	N/A	are the subjects a protected group? (e.g., children, pregnant women, prisoners)
Clear	Unclear	N/A	measures to ensure subjects from protected groups are sufficiently protected?
Section II: Affiliations, Collaborations, and Funding			
Yes	No	N/A	2.1 PI is correctly identified (note: for student applicant, advisor is PI)

Yes	No	N/A	2.2 collaboration with personnel outside Lesley is identified; affiliated institution is listed
Yes	No	N/A	2.3 funding sources are listed, and details provided
Yes	No	N/A	2.4 collaboration with another institution is listed; collaborating IRB information is provided
Section III: Procedures, Sample, and Data			
Clear	Unclear	N/A	3.1 sufficient details on potential subject pool
Clear	Unclear	N/A	3.2 subject selection (how are subjects selected)
Clear	Unclear	N/A	3.3 methods completely explained
Clear	Unclear	N/A	3.4 qualifications of interviewer described?
Yes	No	N/A	3.5 is an intervention planned?
Section IV: Ethical Considerations for Participants			
Clear	Unclear	N/A	4.1 explanation of research procedures to subjects, including informed consent and 4.3 withdrawal
Clear	Unclear	N/A	4.2 explanation of assent process for minors
Clear	Unclear	N/A	4.4 account for potential coercion?
Clear	Unclear	N/A	4.5 account for deception?
Clear	Unclear	N/A	4.6 explanation of benefits of study
Clear	Unclear	N/A	4.7 procedures for delivery of summarized results to participants if planned?
Section V: Measures for Ethical Research Practice			
Clear	Unclear	N/A	5.1measures to maintain confidentiality?
Clear	Unclear	N/A	5.1 measures to maintain anonymity?
Section VI: Appendices			
Yes	No	N/A	informed consent provided? (see checklist below)
Yes	No	N/A	informed assent provided?
Yes	No	N/A	recruitment letters/flyers provided?

Yes	No	N/A	interview guide provided?
Yes	No	N/A	compensation information provided?
Yes	No	N/A	data collection instrument(s) provided?
Yes	No	N/A	description of any experimental manipulation provided?
Yes	No	N/A	letters of IRB approval from cooperating institutions provided?
Yes	No	N/A	letters of correspondence from cooperating institutions that authorize this research within their setting(s) provided?

Examine the Informed Consent form for the following items:

Clearly Stated	Not Stated	N/A	a. explanation (brief) of the purpose of the study
Clearly Stated	Not Stated	N/A	b. expected length of time and what participation entails
Clearly Stated	Not Stated	N/A	c. statement of confidentiality of records, who will have access to records
Clearly Stated	Not Stated	N/A	d. reason for subject's selection (NOT required for survey)
Clearly Stated	Not Stated	N/A	e. description of what subject will be asked to do
Clearly Stated	Not Stated	N/A	h. description of expected benefits to subject/others

Clearly Stated	Not Stated	N/A	i. anticipated circumstances for termination of subject's participation
Clearly Stated	Not Stated	N/A	j. statement that participation is voluntary; refusal results in no penalty
Clearly Stated	Not Stated	N/A	k. offer to answer any questions
Clearly Stated	Not Stated	N/A	l. identification of contact person/phone number for questions about study
Clearly Stated	Not Stated	N/A	m. statement that copy of consent will be given
Clearly Stated	Not Stated	N/A	n. contact information for the Lesley IRB stated*
Clearly Stated	Not Stated	N/A	o. if subject is a minor or unable to give consent, how will assent be determined?

Please double check for the following in the consent form:

- Statement provided at the **bottom of the consent form and worded exactly**:
    - *There is a Standing Committee for Human Subjects in Research at Lesley University to which complaints or problems concerning any research project may, and should, be reported if they arise. Contact the Committee Chairpersons at irb@lesley.edu*
- Spaces for names, signatures, and date of signing for both the participant and the researcher in the standard consent form.
- Refer to example Survey Consent form on the Lesley website in policies document. Consent forms for survey research are part of survey and include the IRB statement. The IRB statement may say: "*Participation in this online questionnaire by clicking 'next' will constitute consent*"
- Refer to example Assent Forms on the Lesley website. Separate assent forms for underage subjects also need spaces for names, signatures, and date of signing and need to be simple and written at a level accessible by the target age group. NOTE that even if parents give consent, children do not have to give assent and may refuse participation; for authorization of a minor to participate, consent and assent must both be attained.
- When an incentive is given to subjects it cannot be reserved only for those who "complete" the study. "A*ll participants who begin the study will be given a $25 Amazon gift card.*"