

Application #	
Name	A B
Title	
Reviewer Decision	<input type="checkbox"/> Approved <input type="checkbox"/> Approved with Provisions <input type="checkbox"/> Denied
Committee Decision	<input type="checkbox"/> Approved <input type="checkbox"/> Approved with Provisions <input type="checkbox"/> Denied
IRB sections	If “Approved with Provisions” or “Denied” indicate required modifications
1. Purpose	Clearly state the goals of the study. Provide detailed literature review and research citations to support purpose and rationale for study.
2. Subjects	Provide detailed information in regards to participants (<u>number of participants, age group etc.</u>). Number of participants and age must be indicated (if applicable). This information needs to be consistent throughout the application and must also be mentioned in the summary section on the first page. Subject selection must be equitable. PI must describe rationale for invitation to specific subjects. If applicable, clearly describe in what capacity he/she is employed at the site.
3. Recruiting	If applicable, clearly describe in what capacity he/she is employed at the site. If the PI is not related to the facility, include a statement that PI does not have any relationship with the research site. In case they do, PI should clearly describe their relationship with the site. Must clarify how subject pool will be selected. Must provide copy of all recruitment material (letter, flyer, emails, script etc.). Provide site permission letter on letterhead or approval email from official email. Applicants should use the template (On the website, there is a template for use in regards to research in schools) for the content of their permission letter. Follow the guidelines provided on IRB website in regards to “Research in Classroom” and “Research in Workplace”. Review checklist for consent/assent forms and include all required language (e.g. participation is voluntary, refusal to participate involves no penalty or loss of educational benefits, deciding to participate/withdraw will not have any affect etc.) Clearly describe in the protocol and consistently state on informed consent and debriefing form the safeguards PI will use to minimize unintended coercion/undue influence.
4. Duration	Specify duration of study/survey/interview etc. Information should be consistent throughout the application. This information should also be provided in the summary section.
5. Location	Specify where research activities will take place. IRB prefers a neutral location to minimize coercion. Also, PI should state how the privacy of the subject will be protected.
6. Obtaining Consent	Describe in detail the informed consent process. The consent process should be explained clearly. It should state the required order, e.g.: “After IRB approval, a flyer will be sent to subjects. If subjects are interested, they will contact PI and sign two copies of consent form. One copy will be returned to the PI with signature and one they will keep for their own

	record". Consent process should be explained in detail in age appropriate language. The form should include reminder to participants that they can withdraw anytime, referral information for appropriate agencies (e.g. counseling center etc.) and contact information if they have questions about the study.
7. Benefits	Describe the benefits to the subject or to others. If there is no direct benefit, PI should indicate that the participants may not directly benefit from participating in this study. State that, this study will help PI better understand the topic of the research. They may also include a statement stating that the participants and the general population may benefit in the future from the information found from this study.
8. Risks	Address risk factor. State the specific steps that will be taken to minimize the risk identified. Risk factor on application and ICF must be consistent.
9. Privacy	Please refer to KU IRB procedures under administration of online surveys. Clearly outline the steps taken to ensure that there are no links between identity of the subject and the results of the work. Explain how the data will be kept secured and how the subject's privacy will be maintained. Who else will have access to the data collected?
10. Storage	Paper files/Electronic files: Describe password protection of computers, databases and protection of hard copies. Include location of computers/ file cabinets or other location where data will be stored. Always include a statement that access will be given to IRB representative, if requested.
11. Disposal	Clearly describe what will happen to informed consent forms. Explain how data collected will be destroyed.
12. Measures	If applicable, indicate the scales that will be used for measure. Include permission to use the measure/scale. If the scale is available for public use, then include a statement that it is in the public domain.
ICF, Assent, Debrief Forms	<p>All forms must have Kean logo on top (see the website for template). All forms must have <u>Kean phone</u> numbers of PI and IRB, in case subjects want to contact with questions. Provide contact information of counseling services or appropriate agencies for advisement. Confidentiality section on ICF should clarify storage location and date/method of data disposal. Assent forms (If applicable) should include age-appropriate language.</p> <p>In case of audio or video recording, a separate paragraph and a separate signature line is required. Subjects must be fully aware and should provide an additional signature to consent to digital recordings.</p> <p>Debriefing form should be in past tense and should capture benefits, risks, compensation and correct wording of people to contact.</p>