

Columbia University, Morningside Institutional Review Board
Human Subjects Research
Undergraduate Study Approval Request Form

1. **Title of project**
2. **Name and UNI**
3. **School**
4. **Class standing**
5. **IRB Protocol Number**
6. **IRB Category requested**
7. **Date of Human Subjects Information Session attended**
8. **Date of IRB Submission Workshop(s), if attended**
9. **Name of Columbia University Faculty PI**

10. Study Purpose and Rationale.

Include a background description which includes a statement of the research problem, how your research project will address this, and how your chosen methodology is most appropriate. The background and description of the project that you will have submitted to your faculty adviser will most probably be sufficient.

11. Study Procedures

Describe the procedures in sufficient detail so that a reviewer who is not familiar with them can comprehend what is to be done. Include what subjects will be required to do, or what is done to them, and how long you anticipate participation to take for each subject.

12. Study Instruments

Describe any study instruments that will be used and identify which are standardized instruments. This includes surveys, interview guide, focus group guide, etc. Attach a copy of each to your RASCAL submission. If subjects will be deceived in any way, describe the nature of the deception, why the deception is necessary to the research, why you are not utilizing alternative methods of researching the problem without deception, and how you will explain to subjects following their participation the deception the research involved.

13. Study Subjects.

Identify how many research subjects you anticipate recruiting, including what criteria will be used to include or exclude individuals from your project. Make clear whether or not your project will include minors and other members of federally-identified vulnerable populations.

14. Recruitment

Describe in detail how and where participants will be recruited including type (e.g., word of mouth, leaflets, letters, posters). Describe any payment or other inducements for participation that subjects will receive. Attach a copy of each written advertisement, letter, or poster, if any as well as verbal recruitment script.

15. Informed and Voluntary Consent Process

Describe how consent will be obtained, including by whom, when, where, and by what method (e.g., use of consent form requiring signature, verbally in-person, verbally by telephone). Attach copies of all relevant informed consent forms.

If relevant to your research, include the following:

- a) Describe means of communicating if non-English speaking, illiterate, or other vulnerable persons will be included among study subjects.
- b) Describe any visual aids or devices that may be used to help explain a complicated procedure or process.
- c) If subjects are deemed 'vulnerable', describe the steps you will take to minimize the risk of coercion or undue influence and how you will ensure subjects understand that participation is voluntary.
- d) If subjects are children, mentally infirm or otherwise not legally competent to consent, describe how their assent will be obtained and who consents on their behalf.

Alternatively, explain why a consent waiver applies in this case.

16. Potential Risks

Describe possible risks of harm (physical, psychological, legal, and/or social) to participants, specifically whether or not risk is greater than that which would be encountered in subjects' daily life.

If you anticipate there to be risks of harm to the participants, include the following:

- a) Describe why the risks are necessary
- b) Describe your plan for minimizing the risks
- c) Explain why alternative ways of conducting the research either do not reduce risk or do not address the research problem
- d) Where possible, include data on risks that have been encountered in past studies. If the occurrence of a certain adverse event was 20% or more, include those data in this description.
- e) Describe your plans in the event that a research subject is harmed.

17. Potential Benefits

Provide a description of what benefits are expected, based on current knowledge. Identify direct benefits to individual study subjects and/or indirect benefits to this field of study.

18. Confidentiality of Study Data

Describe how data will be recorded and stored (and for how long), specifically indicating whether data will contain direct or indirect identifiers. In addition, describe how data-security will be maintained (e.g. if the data is stored on a lap top that is stolen, how will the data be protected?).

19. Privacy Protections

Describe how subjects' expectations for privacy will be established, how their privacy will be protected, and what limits to protection will operate. For example, in the recruitment and data collection stages, how will you ensure that subjects can talk freely, discuss the research, and ask questions about participation without being heard and/or seen by others?

20. Non-CU Research Sites

If you will be conducting research at another institution or organization (e.g. school, hospital, prison, corporation) describe how permission has been obtained and include letters of approval in your RASCAL submission.

In addition, if you will be conducting research in another country you are required to submit a letter of approval from an expert in the locality and can attest to the appropriateness of your study design. This expert may be another member of the CU faculty or another qualified expert. Discuss with your faculty PI who can be asked to provide this statement.