Columbia
COLLEGE CHICAGO

INSTITUTIONAL REVIEW BOARD

Office of Academic Affairs
600 S. Michigan Avenue
Chicago, IL 60605
IRB@colum.edu

APPLICATION FOR SOCIAL SCIENCE AND BEHAVIORAL RESEARCH

Complete all sections of this application and attach all required supporting materials. E-mail the completed form and attachments to IRB@colum.edu.

SECTION 1: OVERVIEW

Research project title:	

Principal investigator's name:	

Anticipated research start date:	Anticipated completion date:

Allow time to obtain IRB approval. Research cannot begin before IRB approval.

Do research subjects include any special populations? (See list in Section 3: Human Participants)	No ☐	Yes ☐	Special population(s):

Do research subjects include Columbia College Chicago students or employees?	No ☐	Yes ☐	Students ☐ Employees ☐

Date submitted:	

Requesting:	Full board review ☐	Expedited review ☐	From the expedited review questionnaire, reason number(s):

If requesting expedited review, attach Request for Expedited Review Screening Questionnaire.

Project Summary – 300 word maximum.

SECTION 2: INVESTIGATORS AND LOCATIONS

Principal investigator information

Name:				
CCC:	Faculty ☐	Student ☐	Staff ☐	Other CCC specify:
CCC department:				

OR:

External investigator ☐	Institution/position:		
Email:		Phone number:	
Mailing address:			

For CCC Students: Faculty advisor information Does not apply ☐

Name:		Department:	
Email:		Phone number:	

Additional investigators/Study personnel information Does not apply: ☐

Name	Institution/Title	Role in the research project

Add table rows as needed. Place cursor in last row. In Table Tools: Layout click on insert below.

Collaborating Institutions Does not apply: ☐

Institution/City, state, country	Nature of collaboration	IRB Approved?	
		Yes ☐	No ☐
		Yes ☐	No ☐
		Yes ☐	No ☐
		Yes ☐	No ☐

For each participating institution, attach: 1) a letter of determination from that institution's IRB; 2) an application to that institution's IRB; or 3) documentation that an IRB review is not required by that institution.

Research Location(s)

Location /Description	City, state, country

1. Attach written permission for recruitment or research procedures taking place in controlled facilities such as schools, clinics, nursing homes, etc.
2. If any locations are outside of the United States, you may need to obtain IRB approval in the country where the research is taking place. Attach documentation of approvals needed for human subject research and if you have applied for or secured any required approvals.

SECTION 3: HUMAN PARTICIPANTS

Special Populations

Identify any of these special populations that the research project will specifically target. Check all that apply.

☐	Minors (under 18)	☐	Economically/educationally disadvantaged
☐	Prisoners	☐	Members of the Armed Forces
☐	Pregnant women/infants	☐	Individuals living with AIDS/HIV
☐	Decisionally impaired	☐	LGBTQ individuals
☐	Non-English speaking	☐	Other (Please identify):

Columbia Students and Employees

Are you recruiting any Columbia College Chicago students?	Yes ☐ No ☐
Are any of those students in classes you teach, or students for whom you have responsibility, e.g., as an advisor, internship or thesis supervisor, or as the supervisor for a student worker?	Yes ☐ No ☐
If you answered "yes" to the last question, explain why this population is necessary to the study:	

Are you recruiting Columbia College Chicago employees?	Yes ☐ No ☐
Do you have supervisory authority for any of those employees?	Yes ☐ No ☐
If you answered "yes" to the last question, explain why this population is necessary to the study:	

Populations/number of participants

Identify: 1) each group or population of subjects who will participate in the research project; 2) the sex, gender, ethnicity and age range of each group that you intend to recruit; and 3) the planned total enrollment of each group. Generally, participants who have given written or oral consent are counted as enrolled. Therefore, account for attrition in your enrollment numbers.

Group/population	Planned demographic mix	Planned enrollment

Recruitment

Describe how you will recruit each group of research participants.

Group/population	Recruitment methods

1. Attach copies of all recruitment materials such as ads, flyers, e-mails, etc.
2. As noted before at the section on locations, you will need written permission to recruit participants at facilities with controlled access.
3. At open locations, as a courtesy check to see if there are policies and procedures for recruiting human subjects including posting recruitment materials.

SECTION 4: RESEARCH PLAN

Research purpose

Describe the purpose of this research project: • What is the research hypothesis or question? • What are the research goals; what questions do you intend to answer? • Why did you choose this topic? • Did personal experience influence your choice of topic?

Research methods

Describe: • The research project design and procedures, including the participants, setting, timing and sequence of all activities. • Any interventions, procedures, or equipment that are innovative, unusual or experimental. • Any use of audio or videotape and why such use is justified. Attach all related research process materials such as protocols and scripts.

Data collection and analysis

Describe: • The proposed sample size. • How data will be collected, compiled, and analyzed. • How data will be stored and for how long it will be retained. • If the research involves using existing data, how authorization for access to the data will be obtained.

Confidentiality

Describe: • Any identifiable private or sensitive information that will be obtained about participants or other living individuals. • Provisions to protect the privacy of participants and to maintain the confidentiality of the data, e.g., by keeping data in a locked file cabinet, whether or not such information is obtained.

Inclusion/exclusion criteria for participants

Describe: • All major criteria for including or excluding participants. • Any proposed criteria for exclusion that is based on gender, age, race, religion or sexual orientation. Provide justification for such exclusions. • Conditions under which participants may be removed from the study, e.g., non-compliance with study rules, study termination, etc.

Risks and inconveniences

Describe: • Potential risks to participants and steps you will take to minimize those risks. Types of potential risk include physical, psychological, social, legal, employment, and financial. • Any anticipated inconveniences the participants may experience. • Monitoring procedures you will use to mitigate risks and inconveniences and to ensure the safety of all participants.

Benefits

Describe: • Anticipated benefits to the individual participants. Clearly state if participants will not benefit directly. • Anticipated benefits to specific groups of individuals, such as athletes or autistic children. • Anticipated benefits to society, i.e., added knowledge to the field of study.

Economic considerations

Describe: • Any costs to the participants. • Amount and method of any compensation for the participants. • If participants will be compensated, explain how the amount and method was determined.

Definitions

List and define words, phrases, etc. in your proposal that are common terminology in the field of study, but may not be readily understood by the general public.

SECTION 5: INFORMED CONSENT

Principal investigators are responsible for taking reasonable steps to assure that participants are fully informed about and understand the research project and that they have obtained all required informed consent from participants. Informing participants and obtaining consent may vary by populations of participants.

Do you anticipate any of the following? Check all that apply (if none apply, complete A below).

☐	Minor children participants.	Complete B below
☐	Participants with limited decision-making capacity.	Complete C below
☐	Participants with communication barriers such as language or hearing difficulties.	Complete C below
☐	Requesting a waiver of signed consent (i.e., when participants give verbal consent after being presented either verbally or in writing with the same information required in a signed consent form).	Complete D below

A - General consent procedures

Describe:

- The consent process including who will obtain consent, where and when it will be obtained, and how much time participants will have to make a decision.
- How an assessment of consent materials will be made to assure that participants understand the information, particularly in research projects with complicated study procedures, extensive time commitments, or that expose participants to more than minimal risk.

Attach all consent documents that will be used including consent forms, information sheets, etc.

B – Minor children

If the research project will include minor children participants, describe:

- If and how the children's assent will be obtained, including if that assent will be written or verbal.
- How you will assess if the language used in the communications with the children is appropriate for their age and comprehension.
- How you will obtain the consent of the children's parent(s) or legal guardians, including if you intend to, or are required to, obtain consent from more than one person, for example from both parents.

Attach all assent and consent documents for both children and parents/guardians, including consent forms, information sheets, scripts for obtaining verbal consent, etc.

C – Limits on capacity to consent

If the research project will include participants with limited capacity to consent, describe:

- How you will assess capacity to consent, and assess appropriateness of consent materials for the population.
- Whether and how you will obtain assent, including how you will assess if language used in communications with the participants is appropriate for them, in the event the participant is not capable of providing their own consent.
- Whether and how you will obtain consent from the participants' legal guardians, including if you intend to, or are required to, obtain consent from more than one person.

If the research project will include participants with communication barriers such as language or hearing difficulties, describe:

- What accommodations you will make to ensure that the participants fully understand the consent process.

Attach all assent and consent documents for participants with limited capacity to consent and their guardians, or for participants with communication barriers. Include consent forms, information sheets, scripts for obtaining verbal communication, etc.

D – Waiver of signed consent

In some instances, the IRB may approve a waiver of signed consent, which allows you to obtain only verbal consent from participants after presenting them verbally or in writing with the same information required in a signed consent form. If you wish to request a waiver of signed consent, answer each of the following screening questions. The IRB will determine if a waiver is appropriate.

Is participation in the research project considered of minimal risk? If yes, explain.

Is breach of confidentiality the principal risk to participants? If yes, explain.

Would the signed consent form be the only record linking the participant to the research? If yes, explain.

Does the research include any activities that would require a signed consent in a non-research setting? If yes, explain.

SECTION 6: FUNDING

Funding source(s)

Identify all that apply.

Columbia College Chicago Funds		External grants/contracts		Other	
☐	Department funds	☐	Government	☐	Investigator(s) out of pocket
☐	Faculty grants	☐	Private	☐	Unfunded
☐	Graduate student research grant			☐	Other (specify)
☐	Undergraduate student research grant				

External funding information

For each external grant or contract provide the following information and attach a complete copy of the grant application and/or contract.

Funding Source:	
Principal investigator of contract/grant:	
Contract/grant title:	
Grant/ contract status (e.g. pending, awarded):	

Changes in funding

The Principal Investigator is responsible for notifying if the funding source changes in any way. Use the Amendment Review form to report funding changes; or if you are both applying for re-approval and submitting a funding source change, use the Re-Approval/Continuation form.

SECTION 7: CONFLICT OF INTEREST

All investigators must disclose all real, apparent, or potential significant financial interests to the IRB. In addition, all investigators must disclose any other relationships that might present an ethical conflict of interest or might affect the outcome of the research. ("Investigator": any person responsible for the research design, conduct, or reporting, including the principal investigator, faculty sponsor, co-investigators, collaborators, consultants, key research personnel, and any family members thereof.)

Do you have a conflict of interest?	No ☐	Yes ☐
If yes, explain.		

SECTION 8: INVESTIGATOR'S PLEDGE AND FACULTY ADVISOR CERTIFICATION

Investigator's pledge

I certify that the information provided in this application is complete and correct.

I understand that as Principal Investigator, I have ultimate responsibility for the protection of the rights and welfare of human participants, conduct of the study and the ethical performance of the project. I agree to comply with all IRB policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of human participants in research. I understand Columbia College Chicago's policies concerning research involving human participants and I agree:

1. To comply with all IRB policies, decisions, conditions, and requirements;
2. That this study has been designed, to the best of my knowledge, to protect human participants engaged in research in accordance with the standards set by Columbia College Chicago, the United States Department of Health and Human Services, and any other sponsoring agency;
3. To obtain prior approval from the IRB before amending the research protocol or the approved consent/assent form;
4. To report to the IRB in accordance with IRB policy, any adverse event(s) and/or unanticipated problem(s) involving risks to participants;
5. To submit the Re-Approval/Completion Form as needed and/or required;
6. That each individual listed as study personnel in this application a) has completed the required human subjects training, and b) is knowledgeable of the study procedures described in the protocol;
7. That each individual listed as study personnel in this application possesses the necessary training and experience for conducting research activities in the role described for them in this research study.
8. To obtain signed informed consent/assent from human participants if applicable.

Signature of Principal Investigator	Date

Faculty Advisor certification (Required for student initiated research)

By my signature as Faculty Advisor on this research application, I certify that the student investigator is knowledgeable about the regulations and policies governing research with human participants and has sufficient training and experience to conduct this particular study in accord with the approved protocol. In addition:

1. I agree to meet with the investigator on a regular basis to monitor study progress,
2. Should problems arise during the course of the study, I agree to be available, personally, to supervise the investigator in solving them, and
3. I agree to ensure that the investigator will promptly report significant or untoward adverse effects to the Columbia IRB in a timely manner.
4. If I will be unavailable, as when on sabbatical leave or vacation, I will arrange for an alternate Faculty Advisor to assume responsibility during my absence and will advise the Columbia IRB by letter of such arrangements.
5. I further certify that the proposed research is not currently underway and will not begin until approval has been obtained.

Signature of Faculty Advisor	Date

IRB office use only

Review Level:	Full ☐	Expedited ☐	Protocol No:

Date Submitted	Date Reviewed	Date Approved	Date Closed