Application for IRB Approval of Proposed Research

General Information

Project Title:

_____

Has this research project been reviewed by the IRB at another institution? If yes, which institution and what was the outcome of this review?

Anticipated start date: _____

Anticipated end date: _____

Is this research supported, in whole or part, by a grant or contract?

☐ Yes
☐ No

If yes, briefly describe the grant or contract, including the source of funding.

Investigators

Principal Investigator Name:

_____

Check one:

☐ Columbia College Faculty
☐ Columbia College Adjunct Faculty
☐ Columbia College Staff
☐ Columbia College Administrator
☐ Other _____

PI email: _____

PI phone: _____

PI department: _____

☐ Check this box to certify that the PI completed the training as described in the instructions on the Columbia College IRB webpage.

Co-Investigators: List names, email address, phone, department, affiliation of any co-investigators (defined as anyone other than PI who will interact with subjects or identifiable data). All co-investigators must complete the training as described in the instructions.

Research Category
Complete the following checklist. This information is used to determine the type of review the proposed research requires.

Vulnerable populations are defined by federal regulation. Research using these populations may have additional requirements. It is recommended that you contact the IRB to discuss the details of your research if you plan to conduct research using any of these groups.

Check if any of the following that apply to your proposed research:
☐ The research involves pregnant people, human fetuses, or neonates. [Subpart B]

☐ The research involves prisoners. [Subpart C]

☐ The research involves minors (participants under 18 years of age). [Subpart D]

☐ The research involves individuals with impaired decision-making capacity.

☐ The research involves economically or educationally disadvantaged persons.

☐ I am not using any of these populations in my research.

"Exempt" Categories

This is a category defined by federal regulation. Investigators must submit a proposal to the IRB even if their research falls into one of these categories. Determination that a project is exempt can only be made by the IRB.

The following checklist is for guidance only, the full regulations can be found here: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html. It is the PIs responsibility to understand the requirements for exempt research and document in this application that the proposed research meets the criteria.

There are some additional exempt categories that are not included here as they are unlikely to be relevant to the Columbia College context. If you believe your research falls under an exempt category not included on this form, please contact the IRB.

☐ (1) Research done in educational settings using only "normal educational practices." This category is referring to the everyday assessment, comparison, and adjustment of teaching and classroom management methods and strategies that occurs in educational settings. If any additional data collection tools (like surveys) are used, this category does not apply.

☐ (2) Research that only includes educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior. At least one of the following criteria must also be met: a) the information is recorded in such a way that the participant is not identifiable, or b) disclosure of information collected would not place the participant at risk of criminal or civil liability or be damaging to their financial standing, employability, educational advancement, or reputation.

☐ (3) Research involves "benign behavioral interventions" and collection of data from an adult. The participant must agree to the intervention and information collection. At least one of the following criteria must also be met: a) the information is recorded in such a way that the participant is not identifiable, or b) disclosure of information collected would not place the participant at risk of criminal or civil liability or be damaging to their financial standing, employability, educational advancement, or reputation.

- Benign behavioral intervention means interventions that "are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subject will find the interventions offensive or embarrassing".
- If the research involves deceiving the subject about the nature or purpose of the research, this category does not apply.

☐ (4) Secondary research using identifiable information or identifiable biospecimens, if at least one of the following criteria is met:

- The information or biospecimens used are publicly available;
- Information is recorded by the investigator in way that is not identifiable, the investigator does not contact the subjects, the investigator will not re-identify the subjects;
- The research is for the purposes of "health care operations" and "public health activities and purposes" as defined and regulated by 45 CFR parts 160 and 164.

- The research is conducted on behalf of a federal department or agency using government-generated or government-collected information obtained for non-research activities (note: additional regulations apply in this situation).

☐ (5) Research is supported by a federal department or agency and is designed to study public benefit or service programs (note: additional regulations apply to this situation).

☐ (6) Research consists of consumer evaluation of food quality and/or taste. Food must be "wholesome" and without additives, or ingredients must be at or below safe levels established by FDA or EPA or USDA.

Expedited Categories

This is a category defined by federal regulation. Investigators must submit a proposal to the IRB even if their research falls into one of these categories. If a project is determined to meet the expedited criteria, it goes through a less intensive review process than research that does not meet these criteria.

The following checklist is for guidance only, the full regulations can be found here: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html. It is the PIs responsibility to understand the requirements for expedited research and document in this application that the proposed research meets the criteria.

There are some additional expedited categories that are not included here as they are unlikely to be relevant to the Columbia College context. If you believe your research falls under an expedited category not included on this form, please contact the IRB.

To be eligible for expedited review, research must present no more than minimal risk to human subjects and meet one of the following sets of criteria.

☐ (1) Clinical studies of drugs and medical devices when this research does not require an investigational new drug application (21 CFR Part 312), or does not require an investigational device exemption application (21 CFR Part 812), or the medical device is cleared/approved for marketing and is being used in the research in accordance with cleared/approved labeling.

☐ (2) Collection of blood samples from healthy, nonpregnant adults who weigh at least 110 lbs (additional criteria apply regarding amounts drawn and frequency).

☐ (3) Collection of biological specimens by noninvasive means.

☐ (4) Collection of data through noninvasive procedures routinely employed in clinical practice. Procedures involving general anesthesia, sedation, x-rays, or microwaves are not eligible for this category.

☐ (5) Research involving materials (data, documents, records, or specimens) that have been collected only for non-research purposes.

☐ (6) Collection of data from voice, video, digital, or image recordings made for research purposes.

☐ (7) Research on individual or group characteristics or behavior or research using survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Research Design

Describe your proposed research. Your description should include the following information (if a section does not apply to your project, state that). You may type and submit your research design as a separate document if you prefer.

If you believe your research meets the criteria for exemption, you may choose not to answer all of the following questions and only submit as much information as is necessary to establish that the criteria are met. You may be asked submit additional information.

- **Purpose**
  - Describe the background and rationale for the study and the goals of the proposed study. Use language understood by a person unfamiliar with this area of research. Specific jargon should be avoided or explained. Include your research question(s) or a description of what you hope to learn through this research.

- **Participants**.
  - Describe any inclusion/exclusion criteria for research participants.
  - If the research involves any "vulnerable populations" describe which group(s), explain why this population is necessary to the study, and describe how you will ensure participants do not feel coerced to participate.
  - How will potential participants be recruited (e.g., flyers, emails, in-class announcements, etc)? Attach a template for any recruiting material including flyers, email announcements, social media posts, etc.
  - How many participants do you anticipate will be involved in the research?
  - If you anticipate recruiting more potential participants than you intend to include in the research, explain how you will select who participates.

- **Research procedures**
  - Describe the research procedure, include all steps from recruitment to completion of participation. A step-by-step list is recommended.
  - Describe what participants will be expected to do for the research.
    - How long will participation last?
    - Is participation a one-time activity or ongoing?
    - Include as an attachment any data collection tools (e.g., survey questionnaire, interview guide, etc)
  - Where will data collection take place (this could be physical locations or digital platforms).
  - Does the study involve research conducted at an external site? If yes, attach a letter or email indicating permission from this site/organization to conduct this research.
  - Will participants be audio and/or video recorded?
  - Will participants be offered incentives? If yes, please describe (this includes extra credit or class credit).

- Is any deception being used in this research? If yes, please describe.
- Describe any debriefing that participants will receive after completion of the research.

- **Risks and Benefits**
  - Does this research entail more than "minimal risk" to research participants?
    - *Minimal risk* means that "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."
  - Describe all risks of participation in the research. Include those that fall within scope of "minimal risks". Consider potential physical, psychological, emotional, financial, and reputational harms.
  - Describe how you will minimize these risks and their impact on participants.
  - What are the benefits of this research to the research participant? If there are no direct benefits to the participant, state this.
  - What are the potential benefits of this research to academia and/or society at large?

- **Informed Consent**
  - See detailed information about obtaining informed consent.
  - Describe how, when and where the informed consent process will take place.
  - Will consent be obtained in writing, verbally, or some other way? What will constitute consent (e.g., a signature, checking a box, a verbal "yes", etc)?
  - Attach consent form and/or any additional consent documentation. If information for informed consent will be given verbally, include script.
  - Will any of consent material be translated into a language other than English? If so, translation must be attached.

- **Protection of Participant Identity**
  - Does this research involve the collection of information that could be used to directly or indirectly identify the participants?
  - If yes, describe how you will maintain confidentiality of the data to prevent participants from being identified. Will data be stored with identifiable information included or will identifiable information will be removed? How long will identifiable information be protected from unauthorized access, how long will it be stored, when and how will it be destroyed? If identifiable information will be removed after collection and before storage or analysis, describe what process will be used.
  - If written consent forms with participant name and/or signature were used, how will these be protected from unauthorized access? How long will they be stored? How and when will they be destroyed?
  - How will participant identities be protected in any resulting publications or presentations?

Principal Investigator Assurance and Acknowledgement

- I certify that the information provided in this application is complete and accurate.
- As the principal investigator, I have ultimate responsibility for the conduct of this study, the ethical performance of the project, the protection of the rights and welfare of human participants, and strict adherence to any stipulations designated by the IRB.
- I accept and will conform to all federal, state, and institutional provisions concerning the protection of human participants in research. I will ensure all personnel involved in the research will be appropriately trained for all procedures used in this project.
- I agree to conduct the research involving human participants as presented in this protocol application as approved by the Columbia College Institutional Review Board (IRB), and am qualified to perform the procedures described herein.
- I will submit any proposed changes/modifications for review and approval before they are implemented.
- I agree to notify the IRB of any adverse events that may occur during the study.
- I will follow through with the storage and destruction of data as outlined in the protocol.
- If I am the Principal Investigator for a student's research project, I agree to be available and to personally supervise the student investigator in solving problems as they arise.
- I understand that data collection (including recruitment) is not permitted until final approval is granted by the IRB

Signature: _____

Date: _____