BARNARD COLLEGE
Application for the Review of a Human Subjects Research Protocol in a New Project

Project Title:	

Principal Investigator:

Name and highest earned degree:			
Office Phone:		Department Phone:	
Email Address:		Facsimile Phone:	
Department:		Building & Room:	
Institution:	☐ Barnard ☐ Columbia Other:		
Mailing Address:			

List any Co-Investigator working on this project. Include any individual who will have responsibility for the consent process, direct data collection from subjects, or follow-up. If there are more than three Co-investigators, please attach additional pages listing all.

Co-Investigator #1

Name and highest earned degree:			
Office Phone:		Department Phone:	
Email Address:		Facsimile Phone:	
Department:		Building & Room:	
Institution:	☐ Barnard ☐ Columbia Other:		
Mailing Address:			

Co-Investigator #2

Name and highest earned degree:			
Office Phone:		Department Phone:	
Email Address:		Facsimile Phone:	
Department:		Building & Room:	
Institution:	☐ Barnard ☐ Columbia Other:		
Mailing Address:			

Co-Investigator #3

Name and highest earned degree:			
Office Phone:		Department Phone:	
Email Address:		Facsimile Phone:	
Department:		Building & Room:	
Institution:	☐ Barnard ☐ Columbia Other:		
Mailing Address:			

Research Staff

Research Staff includes any personnel to be included in correspondence related to this study. Use attachment pages for additional staff.

Name and highest earned degree:			
Office Phone:		Department Phone:	
Email Address:		Facsimile Phone:	
Department:		Building & Room:	
Institution:	☐ Barnard ☐ Columbia Other:		
Mailing Address:			

Project Period

How many months will this study last? (No research may begin until you have obtained IRB approval.)

Number of Months:				
Inclusive dates (mm/dd/yy)	Start:		End:	

Financial Conflict of Interest

Before federally funded research projects may obtain approval from the IRB, investigators must complete Barnard College's Financial Conflict of Interest form available on the website for Institutional Support.

1. Is this research project funded by an award, contract, or agreement with a U.S. Federal Government agency?
   ◉ Yes ○ No
2. Are you responsible for the design, conduct, or reporting of the research project?
   ◉ Yes ○ No
3. If you answered YES to questions #1 and #2 above, you must complete Barnard College's Financial Interest Report. Have you completed this form?
   ◉ Yes ○ No

4. Has Barnard College concluded that you have a Financial Conflict of Interest?

(●) Yes ( ) No

If you answered YES to question #4, you must notify subjects/participants about the financial conflict of interest in the letter of informed consent.

Project Sponsorship

How will your project be funded?

☐ Internal department funds

☐ Corporate sponsors/private foundation

☐ Federal grant

☐ Other

☐ Non-funded research

If your project is supported externally, please provide contact information with this IRB application and include a PDF copy of your sponsored project proposal for IRB review:

Agency:				
Address:				
Contact Name & Title:				
Telephone Number:				
Fax Number:				
E-mail:				
Proposal ID #:				
Funding:	☐	Decision is pending	☐	Funds have been awarded
If awarded, please provide agency-assigned award number:				

Office of Sponsored Research (Human Subjects Research Training Certification):

Before the IRB can approve your protocol, you are required to complete an online educational module at the website of the Collaborative Institutional Training Initiative (https://www.citiprogram.org/) and to request the transfer of information about your certification to RASCAL, the Columbia University Research Compliance and Administration System (http://www.rascal.columbia.edu/). All project personnel involved in human subjects research must be certified. Please list applicable personnel and give their certification dates. If certification is pending, please type "pending" in the space.

Name:		Date:	
Name:		Date:	
Name:		Date:	
Name:		Date:	
Name:		Date:	
Name:		Date:	
Name:		Date:	
Name:		Date:	

Peer Review

Is this research subject to review by another College Committee? (If so, provide the requested information.) It is the responsibility of the PI to secure the appropriate approval from these Committees and to document that approval to the IRB/Human Subjects Review Committee

	Committee		Date of Submission (mm/dd/yy)
☐	Institutional Animal Care and Use Committee (IACUC)		
☐	Departmental Committee		
☐	Environmental Health and Safety		
☐	Clinical Trials Office		
☐	Other IRB Approval		
☐	Other Entity (Please specify):		

Lay Summary

Please answer these questions in lay language or language understandable by a person unfamiliar with your topic of research. Jargon should be avoided. Do not direct the reader to the protocol described in the Research Plan.

1. What is your research question?

2. What research methods will you use? (How do you ask the question?) Attach a protocol if applicable.

3. What will you ask the subjects to do?

Subject Populations

A. Number of Subjects: How many subjects will you enroll?

Male:		Female:		Total:	0

If this is a clinical trial, how many people do you estimate will need to take through the consent process (but not necessarily enroll) to get the data sets you need? Not Applicable

Male:		Female:		Total:	0

B. Age Ranges (check all that apply)

☐	0-7 (Submit parental consent form and Appendix B.)
☐	8-17 (Submit child's assent form, parental consent form, and Appendix B.)
☐	18-64
☐	65 and older

C. Location of Subjects during Research Data Collection (check all that apply)

☐	Barnard College	Department:	
☐	Elementary or Secondary Schools	School:	
☐	Community Clinic	Specify:	
☐	Prisons/Halfway Houses	Specify:	
☐	New York State Psychiatric Institute	Specify:	
☐	Columbia Morningside Campus	Specify:	
☐	Columbia Presbyterian Hospital	Specify:	
☐	Babies and Children's Hospital	Specify:	
☐	Other Community Organizations	Specify:	
☐	Other University Facilities	Specify:	
☐	Other Hospitals	Specify:	
☐	Other Universities	Specify:	
☐	Other Special Institutions	Specify:	
☐	Non-US Site/Institution	Specify:	

D. Subject Characteristics (check all that apply)

☐	Normal Volunteers (competent adults)		
☐	Normal Volunteers (competent children)		
☐	Inpatients		
☐	Outpatients		
☐	Secondary Data with Identifiers/No Subject Contact		
☐	Secondary Data with Identifiers/Subject Contact		
☐	Normal Volunteers Drawn from Subject Pool	Specify Subject Pool:	

E. Inclusion and Exclusion of Subjects in this Research Study

It is necessary to justify the inclusion and exclusion of minors. Provide justification in Appendix C.

Inclusion Criteria:

Exclusion Criteria:

F. Special Populations to be Included in this Study (check all that apply)

Some groups are considered vulnerable, requiring special consideration by federal regulatory agencies and by the IRB. Suggestion: Researchers should not select subjects on the basis of discriminatory criteria. Criteria that exclude participants on the basis of sex or race require a clear scientific rationale for the exclusion (See Appendix C).

☐	Minors (under age 18) Appendix B must be attached		
☐	Patients		
☐	Mentally/Emotionally/Developmentally Disabled People		
☐	Minority Group(s) and Non-English Speakers	Specify	
☐	Pregnant Women Appendix C must be attached		
☐	Fetuses/Fetal Tissue		
☐	Elderly Subjects (65 and over)		

Provide Rationale for Using Special Populations

RECRUITMENT OF SUBJECTS

A. Describe how subjects will be identified and recruited.

Attach a copy of any and all recruitment materials to be used, e.g. advertisements, bulletin board notices, e-mail messages, letters, or phone scripts. Note that only the IRB approved, stamped versions of these forms may be used for your project.

B. Initial Contact

Describe who will make initial contact, and how it will be made. If subjects are chosen from records, indicate who gave approval for use of the records. Written documentation for the cooperation/permission from the holder or custodian of the records should be attached. (Initial contact of subjects identified through records search must be made by the official holder of the record, i.e. primary physician, therapist, or public school official.)

C. Will subjects receive inducements before or rewards after the study?

(●) Yes ( ) No

If yes, please describe. Note that this information must be included in the consent form, under the heading "Compensation," and not in the "Benefits" section. Also, payments for multiple visits should be prorated.

D. Will subjects be charged for research related procedures?

(●) Yes ( ) No

If yes, explain charges, including estimated amounts. This information must be specified in the consent document.

RISKS AND BENEFITS

A. Does the research involve any of the following? (Check all that apply)

☐	Any surgical process		
☐	Administration of drugs, chemical, or biological agents, or devices. Attach Appendix E.		
☐	Use of controlled substances		
☐	Use of radioisotopes or other sources of ionizing radiation (including X-rays)		
☐	Administration of physical stimuli		
☐	Major changes in diet or exercise		
☐	Use of private records:	☐ Medical records	☐ Educational Records
☐	Possible invasion of privacy of subject or family		
☐	Deprivation physiological requirements such as nutrition or sleep		
☐	Manipulation of psychological or social variables such as sensory deprivation, social isolation, or psychological stresses		
☐	Any probing for personal or sensitive information in surveys or interviews		
☐	Use of a deceptive technique (placebo, double blind, etc). If deception is part of the experimental design, the protocol must include a debriefing procedure, which will be followed upon completion of the study or upon withdrawal of a subject. Attach a description of the debriefing protocol and any related materials.		
☐	Presentation of materials which subjects might consider offensive, threatening, or degrading		
☐	Other risks Specify:		

B. Describe the precautions that will be taken to minimize the risk to the subjects.

C. Why are the above-mentioned risks and inconveniences reasonable?
What is the expected scientific yield from the project? Please justify the risks in relation to the anticipated benefits to the subjects, and in relation to the importance of the knowledge that may reasonably be expected to result from the research.

D. Benefits of Participation:
List any anticipated direct benefits to participation in this research project. If none, state that fact here and in the consent form. The benefit of receiving treatment is not necessarily a benefit to participation in the research project. This distinction is central to informed consent.

BIOLOGICAL SAMPLES

A. Blood drawing, marrow biopsy sampling, biopsy of other tissues, etc.
If samples of body fluids or tissues are taken as part of this research project, state how much and how often the samples are taken. The consent form must include lay term equivalents for the amounts, teaspoons, etc. Please distinguish procedures that are diagnostic from procedures that are performed solely for research. Any known side effects, possible pain or injuries that may occur from such procedures should be noted in the risks section above as well as in your consent form.

B. Will DNA be collected?

◉ Yes ○ No If "yes," attach Appendix D.

C. Will issue/blood samples be stored with identifiers?

◉ Yes ○ No If "yes," attach Appendix D.

RESEARCH-RELATED INJURY

Research-related injury (physical, social, financial, or otherwise) that is more than minimal risk is possible in research; an explanation must be given if voluntary compensation and treatment will be provided. Note that the regulations do not limit injury to "physical injury," a common misinterpretation.

CONFIDENTIALITY OF DATA

A. Describe provisions that will be made to maintain confidentiality of the data.

B. Where will the data be kept and for how long? Please explain below and in the consent form.

C. What security provisions will be used? Who will have access to the collected data? Please explain below and in the consent form.

D. Will data identifying the subjects be made available to anyone other than the Principal Investigator, for example, the FDA, study sponsor, etc.?

(●) Yes ( ) No If yes, please explain below and in the consent form.

E. Will the data be part of a medical chart or other permanent record?

(●) Yes ( ) No If yes, please explain below and in the consent form.

INFORMED CONSENT

A. Prepare and attach a consent form for IRB review.
A date should also be noted on each page to ensure that only the most recently approved version is used.

B. Describe the method by which you will introduce the research to the subjects.
Write the explanation in lay language. If you are using telephone surveys, telephone scripts are required. Type the explanation in the box, and do not refer the reader to an attachment.

C. What questions will be asked to assess a subject's understanding?
Please explain how you will assess a subject's understanding of the consent process. Please ask subjects to explain the purpose of the study to you, along with the risks and benefits to themselves as participants. Their answers to these questions should allow you to determine if they understand the study and their part in it. If they do not understand, informed consent has not been achieved even if the subjects signed the consent document.

D. In relation to the actual data gathering, when will consent be discussed and documentation obtained? (pre-operatively, or several days before?) Be specific.

E. Will the investigator(s) be securing informed consent?

(●) Yes ( ) No

If no, please name the specific individuals who will obtain informed consent and include their job title and a brief description of your plans to train these individuals to obtain consent and answer subjects' questions.

Relevant Research Categories *Eligible* for Expedited Review

To be considered for an expedited review, your project must fit one if the expedited review categories authorized by 45 CFR 46.110. Note that most research will not fit the categories for expedited review. The decision to route the study via expedited review will be determined upon review of the complete application by the IRB.

Please indicate by checking the pertinent box whether your application is likely to meet the criteria an expedited review by the IRB.

- ☐ Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves, including:
  - ☐ physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
  - ☐ weighing or testing sensory acuity;
  - ☐ magnetic resonance imaging;
  - ☐ electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
  - ☐ moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
- ☐ Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
- ☐ Collection of data from voice, video, digital, or image recordings made for research purposes.
- ☐ Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
- ☐ Continuing review of research previously approved by the convened IRB as follows:
  - ☐ where the research is permanently closed to the enrollment of new subjects; and, all subjects have completed all research-related interventions; and, the research remains active only for long-term follow-up of subjects; or
  - ☐ where no subjects have been enrolled and no additional risks have been identified; or
  - ☐ where the remaining research activities are limited to data analysis.
- ☐ Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories set forth above do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Relevant Research Categories *Eligible* for Exemption from Review

The guidelines of 45 CFR 46 identify categories of subject participation that qualify a research proposal for an exemption from review by the IRB.

Please indicate by checking the pertinent box whether your application is likely to meet the criteria an expedited review by the IRB.

- ☐ Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- ☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
  (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
  (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- ☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under the preceding exemption, if:
  - ☐ the human subjects are elected or appointed public officials or candidates for public office; or
  - ☐ federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- ☐ Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- ☐ Taste and food quality evaluation and consumer acceptance studies:
  - ☐ if wholesome foods without additives are consumed or
  - ☐ if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical, or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

INVESTIGATOR'S AGREEMENT

As Principal Investigator of this study, I assure the Human Subjects Review Committee that the following statements are true:

The information that is provided in this form is correct. I will seek and obtain prior written approval from the IRB for any substantive modifications in the proposal, including changes in procedures, co-investigators, funding agencies, etc. I will promptly report any unexpected or otherwise significant adverse events that occur in the course of this study. I will report in writing any new findings that develop during the course of this study that may affect the risks and benefits to participation. I will not begin my research until I have received written notification of IRB approval. I will comply with all IRB requests to report on the status of the study. I will maintain records of this research according to IRB guidelines If I am seeking IRB approval for a sponsored project, I hereby certify that the application that I have submitted to my funding agency accurately and completely reflects what is contained in this application.

Original Signature of PI	Title of PI	Date (mm/dd/yy)
Original Signature of Co-PI	Title of Co-PI	Date (mm/dd/yy)
Original Signature of Co-PI	Title of Co-PI	Date (mm/dd/yy)

FACULTY SPONSOR AGREEMENT

Student research requires the approval of an Academic Advisor.
As Academic Advisor to the Student Investigator, I assume responsibility for ensuring that the student complies with University and Federal Regulations regarding the use of Human Subjects in research.

Check here if not applicable

Advisor's Name:	
University Department:	
Institution:	☐ Barnard ☐ Columbia Other:
Address:	
Telephone :	
E-mail:	

Signature of Faculty Sponsor	Date (mm/dd/yy)

DEPARTMENTAL APPROVAL

If Principal Investigator is faculty or staff, a Department Head signature is required.
As Department Head, I acknowledge that this research is in keeping with the standards set by my department and I assure that the Principal Investigator has met all departmental requirements for review and approval of this research.
Name of Department Head, or Chair of Departmental Committee:

Signature	Date (mm/dd/yy)

You have reached the end of this form. Please make sure that you have responded to every question, even if your response is "not applicable." Please review the checklist below to insure that you have included all of the declarations required in your application.

Checklist for Investigators

(Application will be returned if not complete.)

1. This application includes a lay summary stating the purpose of the study.
2. The application describes the study population, inclusion/exclusion criteria, process of identifying subjects, etc.
3. The abstract includes a full description of anticipated risks and benefits of study participation.
4. The application includes a description of tasks the subjects will be asked to complete.
5. Provisions have been made to minimize risks and these are outlined on the form.
6. Provisions have been made and documented to care for subjects in case of accident or injury.
7. Procedures to maintain confidentiality have been described fully.
8. Provisions have been made to obtain informed consent from all individuals related to the study (parents, subjects, cooperating institutions, etc.).
9. All questions on the form have been completed.
10. All supporting documents have been attached, including proposal, survey instruments, interview schedules, solicitation letters, advertisements, etc.
11. A certificate of completion for the on-line educational module is included for all personnel involved in human subjects research.
12. If this study requires approval of another committee or cooperating agency, documentation of approval or notice of application has been attached.
13. Appropriate departmental signatures and signature of academic advisor for student research have been secured.
14. A copy of this application has been retained for the investigator's records.

If the PI plans to post flyers on the Columbia campus, and/or to recruit human subjects from Columbia University, or if any part of the study takes place on the Columbia campus, a separate protocol must be submitted to the Columbia University IRB via the RASCAL electronic grants management system.

Send an electronic version of the completed application as an attachment to an email message to:

IRB Coordinator
Barnard College
irb@barnard.edu

Appendix A
Sponsored Projects

If your research will be funded please answer these questions.

PROJECT TITLE:	
An application to seek sponsorship for this project	☐ has been ☐ will be submitted to the following funding agencies:
Agency 1	
Address:	
Telephone Number:	
Contact Person:	
Telephone Number:	
Proposal ID:	
Funding:	☐ decision is pending ☐ has been awarded
If awarded, please provide Agency-assigned award number:	

Agency 2	
Address:	
Telephone Number:	
Contact Person:	
Telephone Number:	
Proposal ID:	
Funding:	☐ decision is pending ☐ has been awarded
If awarded, please provide Agency-assigned award number:	

How is/will research be funded? Please check all that apply.

- ☐ Internal departmental funds (department administrative signature is required)
- ☐ External grant/contract
- ☐ Corporate sponsor: If funding is provided under a grant or contract agreement, the committee must review the agreement for compliance with Federal and University regulations governing the use of human subjects. Please provide a copy of the agreement with this application.
- ☐ Foundation: Submit a copy of the grant application with this application.
- ☐ Federal sponsor: Submit a copy of your proposal with this application.

If this study is part of a project or center grant, please provide the following information.

Principal Investigator:	
IRB assigned study code number:	
Title of Project or Center Grant:	

PI Certification/Signature

I hereby certify that the application that I have submitted to my funding agency accurately and completely reflects what is contained in the "Application for the Approval of the Use of Human Subjects in Research."

Original Signature of PI	Title of PI	Date (mm/dd/yy)

Table of Appendices

Appendix B
Use of Children as Subjects in Research

Project Title:	

Researchers planning to include a minor subject in a project which involves more than minimal risk* must provide:

1. Written explanation of the direct benefit that can be anticipated for a child who participates in the project. This statement should include information gathered on adults, if this exists, or an explanation about why it does not exist.

2. Parental Permission (consent) form.

I have attached the parental consent form to my application

3. Assent form for children who can read, generally thought to be 7-17 year-olds.

I have attached the assent form to my application

*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. The specific regulations governing children as research subjects are found under 45 CFR 46, Subpart D, Sections 46.401 through 46.409.