BECKER COLLEGE

Becker College Institutional Review Board (IRB) Initial Application Form

Instructions: Complete this form to request an **initial IRB review of research involving human participants**. The application for study renewal and the request for study modification may be found on the IRB webpage at: http://www.becker.edu/irb. The checklist below is for general guidance to help researchers submit complete application materials and facilitate the review process. Incomplete or illegible applications will **extend** the IRB review process. If you are collecting data at a hospital, please seek hospital IRB approval prior to Becker College IRB approval. Please submit an electronic application and all research materials (consent form, surveys, interview guides, etc.) irb@becker.edu.

A Complete Application Packet Should Include:

- ☐ A cover letter or memo that inventories all materials submitted
- ☐ An electronic copy of the IRB initial application form, research summary, and research instruments. Types of research instruments that should be attached include:
  - Recruitment materials: emails, letters, recruitment scripts, flyers, posters, brochures, etc.
  - Data collection materials: questionnaires, surveys, data collection forms, focus group scripts, interview scripts, etc.
- ☐ Signature page with faculty advisor and student signatures (Approval will be withheld without signatures.)
- ☐ Copies of NIH PRHP training certificate or Becker College course and training certificate **for all key research personnel who will interact with subjects or collect data**
- ☐ **Consent forms(s)—You must use the Becker College IRB Informed Consent Template found on the Becker College IRB website** http://www.becker.edu/irb when creating your informed consent form(s).
- ☐ **If minors (under 18) will be research participants, you must create a Child Assent Form and a Debriefing Form using the templates found on the Becker College IRB website** http://www.becker.edu/irb.
- ☐ **Principal Investigator's C.V.**

Student Researchers:

☐ Faculty research advisor was consulted in the study design and has reviewed and signed the application.

Research in Hospitals or HIPAA-Covered Entities

☐ Submit copies of the IRB approval letter and IRB approved consent form(s) from the participating institution(s).

Research in Public Schools:

☐ Review Protection of Pupil Rights Amendment requirements at: http://www.ed.gov/policy/gen/guid/fpco/ppra/index.html

☐ Submit copies of the permission letter to perform research from each school principal via fax or email.

☐ Submit copies of IRB approval if the school has an IRB.

Research at sites other than Becker College:

☐ Submit copies of the site permission letter to perform research from administrator via fax or email.

☐ Submit copies of IRB approval if research is initiated from the other site.

Federally funded research: Wait until you have been funded before submitting an IRB Application.

☐ Submit documentation of funding status with this protocol application.

☐ Submit a complete copy of the federal grant/contract proposal including face page.

BECKER COLLEGE

IRB Initial Application Form

For Initial IRB Review Only

Becker College Institutional Review Board
Office of Academic Affairs
61 Sever Street
Worcester, MA 01609
508-373-9500
email: irb@Beckercollege.edu

I. Study Title: (If funded, the study title must match the sponsored title.)		**Today's Date:**
II. Principal Investigator Information		B. Are You? (Please check)
Name:		☐ Faculty
Mailing Address:		☐ Staff
		☐ Undergraduate Student
Department:		☐ Graduate Student
		☐ Postdoctoral fellow
		☐ Other:
E: Email Address:		
F: Primary Phone Number:	G. Alternate Phone:	
H. Faculty Advisor's Name:	I. Faculty Advisor's Phone:	
J. Faculty Advisor's E-mail:		

III. Funding

A. ☐ **None or self-funded (Go on to Section IV)**

Do you plan to apply for funding in the future? ☐ Yes ☐ No If yes, please explain:

B. ☐ **University Funded:** List source:

C. ☐ **External, non-federal***: List source and grant number:

D. ☐ **Federal***: List agency, department, and sponsor's award number:

*Wait until you have been notified that your project will be funded before seeking IRB approval unless otherwise instructed by the funding source. If federal funding is involved, submit documentation of funding status with a complete copy of the funding proposal with this form.

E. Is Becker College the primary awardee for the grant? ☐ Yes ☐ No If no, please list primary awardee:

F. Are there subcontracts? ☐ Yes ☐ No If yes please list sub-contractors:

IV. General Study Information

A. Anticipated number of participants
Females: Males: Transgender:

B. Participant Ages (please check)
- ☐ 0-7 (requires written parental informed consent and oral child assent)
- ☐ 7-17 (requires written parental informed consent and child written assent)
- ☐ 18-65 (requires written informed consent)
- ☐ 65+ (requires written informed consent)

C. Estimated Project Duration
***Anticipated Start Date:** **End Date:**

D. Why is this project being conducted?
- ☐ Faculty/Staff Research
- ☐ Undergraduate Coursework
- ☐ Master's Thesis
- ☐ Doctoral Dissertation
- ☐ Other:

*Project cannot start without IRB approval.

E. Will this study involve long-term follow-up with participants? ☐ Yes ☐ No If yes, please describe:

F. Special Study Populations (Check if applicable.) ***Research involving any of these populations require full IRB review.***
- ☐ Minors (under 18 years)
- ☐ Pregnant women/fetuses or products of labor & delivery
- ☐ Prisoners
- ☐ Physically or mentally challenged
- ☐ Diminished capacity for consent

V. Research Risk

Research must present no more than minimal risk to human participants in order to qualify for expedited review. 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." (45 CFR 46.102)

A. Does the research propose greater than minimal risk to participants? ☐ **Yes** ☐ **No**

B. Check all procedures that apply to the research:

☐ (1) Clinical studies of drugs and medical devices.

☐ (2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.

☐ (3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples: hair and nail clippings; saliva; deciduous teeth at time of exfoliation or extracted during routine care; excreta and external secretions (including sweat); un-cannulated mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; sputum collected after saline mist nebulization.

☐ (4) Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Examples: 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 participant or an invasion of the participant'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.

☐ (5) 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).

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

☐ (7) 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.

☐ (8) Continuing review of research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new participants, (ii) all participants have completed all research-related interventions, and (iii) the research remains active only for long-term follow-up of participants; or (b) where no participants have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.

☐ None of the above categories apply.

For a comprehensive list of expedited categories see **http://www.hhs.gov/ohrp/policy/expedited98.html**

C. Does this study involve any of the following? (Check all that apply.)

☐ Deception

☐ Punishment

☐ Use of drugs

☐ Covert observation

☐ Induction of mental and/or physical stress

☐ Procedures which may risk physical/mental harm to the participant

☐ Materials/issues commonly regarded as socially unacceptable

☐ Information relating to sexual attitudes, sexual orientation, or practices

☐ Information relating to the use of alcohol, drugs, or other addictive products

☐ Procedures that might be regarded as an invasion of privacy

☐ Information pertaining to illegal conduct

☐ Genetic information that may be linked to a participant's health status, such as genetic markers for cancer, heart disease, etc.

☐ Information normally recorded in a patient's medical record, which if disclosed could reasonably lead to social stigmatization or discrimination

☐ Information pertaining to an individual's psychological wellbeing or mental health

☐ Information that if released could reasonably damage an individual's financial standing, employability, or reputation within the community

Please provide details on all procedures checked above: How are they integral to the study?

VI. Research Summary:

Please attach a 4-5 page research summary using the topic headers **A-H** below. Be sure to dedicate 1-2 pages to the review of literature. Please use simple language and avoid technical jargon. **Be sure to address each item.**

Note: Grant, thesis, dissertation or course work proposals may **not** be submitted in lieu of the Research Summary because traditional proposals do not include specific information on risks, benefits and detailed informed consent procedures.

A. Introduction and Background (literature review):

1. State the problem and hypothesis.
2. Provide the key scientific or scholarly literature for this study and background on the topic.

B. Specific Aims/Study Objectives:

1. List the purpose(s) of the study (What you are hoping to learn or discover as a result of the study?).

C. Materials, Methods, and Analysis (quantitative and qualitative):

1. Describe data collection methods (procedures)—Be specific.
2. Describe the specific materials or tools that will be used to collect the data—Be specific. For established instruments include reliability and validity information. If instruments are changed from the original form, provide explanation.
3. Describe timeline of the procedures and an estimate of how long each procedure will last.
4. Describe how you will analyze your data; describe the analysis type and procedures including statistics and scientific or scholarly justification for the use of these analyses—be specific.

D. Research Population & Recruitment Methods:

Describe:

1. Inclusion and exclusion criteria (What participant traits are needed to be included? What traits exclude participants?)
2. What is the scientific or scholarly justification for the number, gender, age, or race of the population you intend to recruit?
3. How did you choose the source of participants or data? (Census records, Becker students, Mass General Hospital records, etc.)
4. Recruitment procedure (if applicable) including who will recruit participants
5. Tools that will be used to recruit (payment, advertisements and flyers—Attach copies to this application.)
   (**Note**: participant payment beyond $600 must be reported to the IRS, and this requirement must be added to the consent form.)

E. Informed Consent Procedure:

Describe:

1. Who will perform the informed consent procedure?
2. How will that person be trained? (previous related coursework, previous experience, one-on-one training with PI or faculty, etc.)
3. How will the prospective participant's competence or understanding of the procedures be assessed? Will participants be asked questions about the procedures or encouraged to ask questions?

F. Confidentiality and Anonymity:

Describe the provisions for participant and data confidentiality:

1. Where will the data be stored, and who will have access to the data and the area?
2. How and in what format (hard or electronic copy, identifiable or de-identified) will the data be stored?
3. Will the participants' identities be coded? Will the codes to identify participants be stored with the data? (**Note:** If you are working with a hospital or clinic, please see information on HIPAA and research at http://privacyruleandresearch.nih.gov/)

G. Potential Research Risks or Discomforts to Participants:

1. Indicate the type of risk that may result from participation. Consider psychological or emotional risks, social stigma, change in status or employment, physical risks or harms, information risks including breach of confidentiality and any effect loss of confidentiality may have on status, employment, or insurability. If the protocol involves treatment, what are the risks compared to other treatments in terms of "standard of care"?
2. Consider the likelihood and magnitude of the risks or discomforts occurring? Are they unlikely or likely to occur, and what effect would the discomforts or risks have on the individual should they occur?
3. How will you minimize risks? Some examples include informed consent, adequate staff training and experience, debriefing, and monitoring adverse effects on participants.

H. Potential Research Benefits to Participants:

1. Indicate the type of benefit that may result from participation. Consider psychological or emotional benefits, learning benefits, physical benefits and discuss if participant will benefit directly or if the benefit is largely to gather generalizable knowledge or provide scientific or social information on a topic that may benefit society. DO NOT OVERSTATE the benefit.
2. Consider the likelihood of the benefits. Will all or some participants benefit?
   (Note: Monetary compensation is not a benefit of participation; it is a recruitment tool.)

VII. Informed Consent

A. The informed consent document should include all required elements of consent (See the Becker IRB informed consent template at http://www.becker.edu/irb). **Confirm that each element is included in your consent form:**

- ☐ A statement that the study involves research
- ☐ A statement that they are being asked to participate in research and how they were selected to participate
- ☐ The purpose of the research in lay terms (in language understandable to the participants)
- ☐ The expected duration of the participants' participation (e.g., "You will be asked to complete a survey every month for 1 year.")
- ☐ The total time commitment of participation in the procedures (e.g., "The survey will take 20 minutes to complete.")
- ☐ A brief but complete description of all procedures to be followed (Invasive biological, clinical, or behavioral interventions require specific descriptions of the procedure. If research includes treatment, describe which procedures are experimental and alternatives to those procedures.)
- ☐ The benefits to the participant or others that are reasonably expected from the research
- ☐ The risks or discomforts that are reasonably expected from the research and a statement that "There may be unknown risks."
- ☐ A statement describing any payments for being in the study or that there is no payment for being in the study
- ☐ A statement indicating that there is no cost to the participant for being in the study
- ☐ A statement that participation is entirely voluntary and may be discontinued at any time
- ☐ A statement that withdrawal from participation will not result in denial of entitled benefits or harm the participant's academic status, employment status, or relationship with Becker.
- ☐ A statement of confidentiality describing how the participants' personal information will be kept private
- ☐ A statement that provides the participants with a contact at the institution who may be reached if injury occurs or confidentiality is breached
- ☐ The consent form must be signed and dated, or oral consent must be witnessed and signed and dated by the witness.

Note: Individuals with added protections require both permission of a legal representative and assent of the individual.

B. The comprehension level of the consent document must be verified to ensure it is consistent with the comprehension level of the participants. Please use the Flesch-Kincaid Grade Level score to verify the comprehension level and insert it below. To determine the Flesch-Kincaid Grade Level score go to www.readability-score.com and paste your text into the text box. After pasting the text in the box, place the curser at the end of the text and hit "Enter" or you will not get a reading from the website.

Flesch-Kincaid Grade Level Score:

VIII. Research Staff (e.g., PI, Co-PI, Research Assistant, etc.)

Please attach a list and submit educational certificates for all personnel who will interact or collect data.

Name and Credentials	Date of IRB Training Certificate	Research Role	University/Department

IX. Performance Sites:

If the institution has an IRB, IRB approval may have to be received from that institution as well as Becker College. If the institution does not have an IRB, the institution must authorize or provide permission for the research activities (Please include a site permission letter from an institutional official.). If you are collecting data at a hospital with an IRB, seek hospital approval prior to submitting the Becker IRB initial application form.

Name of Institution:	Date of IRB Approval:

X. Acknowledgement

SUBMISSION OF A PROPOSAL TO THE BECKER COLLEGE IRB REQUIRES THAT THE PRINCIPAL INVESTIGATOR (AND FACULTY ADVISOR IF THE PI IS A STUDENT) READ THE DEFINITION OF "SCIENTIFIC MISCONDUCT" AND ANSWER ALL "CONFLICT OF INTEREST" QUESTIONS BELOW.

A. Scientific Misconduct

"Scientific Misconduct" shall be considered to include:

1. Fabrication, falsification, plagiarism or other unaccepted practices in proposing, carrying out, or reporting results from research;
2. Material failure to comply with federal requirements for the protection of human participants, researchers and/or the public;
3. Failure to meet other material legal requirements governing research;
4. Failure to comply with established standards regarding author names on publications;
5. Failure to adhere to issues of confidentiality as provided in the participant consent form, the study protocol, and as outlined in the Code of Federal Regulations (45 CFR 46).

B. Conflict of Interest

1. Are you or any member of your immediate family (spouse or domestic partner and/or dependent children) an officer, director, partner, trustee, employee, advisory board member, or agent of any of the following: (Check all that apply.)
   - ☐ An external organization funding this project
   - ☐ Any external organization from which goods and services will be obtained under this project (including those to which you may be subcontracting a portion of the project work)
   - ☐ Any external organization whose financial condition could benefit from the results of this project
   - ☐ Any external organization having business dealings in an area related to the work under this project

2. Are you or any immediate family member the actual or beneficial owner of more than five percent (5%) of the voting stock or controlling interest of (a) the external organization funding this project, (b) any external organization from which goods and services will be obtained under this project (including those to which you may be subcontracting a portion of the project work), (c) any external organization whose financial condition could benefit from the results of this project, or (d) any external organization having business dealings in an area related to the work under this project? ☐ **Yes** ☐ **No**

3. Have you or any member of your immediate family derived income within the past year, or do you or any member of your immediate family anticipate deriving income, exceeding $10,000 per year from: (Check all that apply.)
   - ☐ An external organization funding this project
   - ☐ Any external organization from which goods and services will be obtained under this project (including those to which you may be subcontracting a portion of the project work),
   - ☐ Any external organization whose financial condition could benefit from the results of this project
   - ☐ Any external organization having business dealings in an area related to the work under this project

   Do *not* include funds that would pay your university salary under a sponsored project budget.

*__If you checked any of the above, please specify the extent of involvement__:

4. For those projects funded by any external entities, do you have a current, up-to-date Conflict of Interest Disclosure on file with the Office of Academic Affairs that describes this financial relationship? ☐ **Yes** ☐ **No** (If no, you must submit an undated COI disclosure before IRB review.)

SIGNATURES			
SIGNATURE OF PRINCIPAL INVESTIGATOR			
The undersigned accept(s) responsibility for the study, including adherence to the ethical guidelines set forth in the Belmont Report, Declaration of Helsinki, the Nuremberg Code, the ethical principles of your discipline, the Common Rule and Becker policies regarding protections of the rights and welfare of human participants participating in this study. In the case of student protocols, the faculty supervisor and the student share responsibility for adherence to policies.			
Printed Name of Principal Investigator	Signature of Principal Investigator	Date	
SIGNATURE OF FACULTY RESEARCH ADVISOR~REQUIRED FOR STUDENT RESEARCH			
By signing this form, the faculty research advisor attests that s/he has read the attached protocol submitted for Becker IRB review, has completed the NIH training for protection of human research participants (https://phrp.nihtraining.com/users/login.php) and agrees to provide appropriate education and supervision of the student investigator and share the above Principal Investigator responsibilities.			
Printed Name of Faculty Research Advisor	Signature of Faculty Research Advisor	NIH Certificate Number	Date
SIGNATURE OF DEPARTMENT CHAIR OR DEAN~REQUIRED FOR FACULTY RESEARCH			
Your signature below affirms that you have been informed of the research.			
Printed Name of Department Chair or Dean	Signature of Department Chair or Dean	Date	