|  |  |
| --- | --- |
| **Berkshire community college****Institutional Review Board - HUMAN SUBJECTS****APPLICATION FOR a Project Involving Human Subjects** | **Irb NO.**  |
|  |

This document is to be completed by the Principal Investigator (PI), who is the individual primarily responsible for conducting the research project. However, for student projects, a Faculty Supervisor must also take responsibility for this research project and sign this form. The application should be completed following review of the IRB Application Guidelines, which can be found on the shared drive (in the “Institutional Review Board (IRB) @ BCC” folder).

Following completion of this form, please submit: 1) the ORIGINAL HARD COPY (with signatures); 2) an ELECTRONIC COPY of this form; and 3) all supporting documents (e.g. consent forms, questionnaires, etc.), to the IRB as one or more Word file(s) at irb@berkshirecc.edu. For questions regarding this application, please contact the IRB Chair, Margaret Stephenson at 413-236-2117.

|  |
| --- |
| **SECTION A: Researcher Information** |
| **1.** | **Project Title:**  |
| **2.** | **Submission Date:**   |
| **3.**  | **Funding Source (if applicable) and Grant Number (if assigned):**  |
| **4a.** | **Principal Investigator (PI):**  **Email: Non-BCC-Affiliated?** [ ]  |
| **4b.** | **If PI is a student, Faculty Supervisor:**  **Email:** |
| **4c.** | **Other Co-Investigator(s):** **Email: Non-BCC-Affiliated?** [ ]  |
| **5.** | **Department or Course:**  |
| **6. Attach IRB Training of Researchers:** Forfederally-funded research, attach Certificate of Completion from the NIH Protecting Human Research Participants tutorial at <https://phrp.nihtraining.com> |

|  |
| --- |
| **SECTION B: PURPOSE AND SIGNIFICANCE** |
| 1. **Briefly state the background of the study, describing previous work that provides a basis for the proposed research and demonstrates the need for the project, and describe how the results will be used (limit 250 words).**
 |
|  |
| 1. **Clearly state your research question(s), including the hypothesis or goal(s) of the project (limit 250 words).**
 |
|  |
| 1. **Explain the importance or significance of the knowledge to be gained from the study (limit 150 words).**
 |
|  |

|  |
| --- |
| **SECTION C: SUBJECT CHARACTERISTICS AND RECRUITMENT** |
| **1a. Description of the proposed subject population** (check all that apply) |
| [ ]  Adults (>18 years)  | [ ]  School-aged Children and Adolescents (<18 years) | [ ]  Senior Citizens (65+ years) |
| [ ]  Fetuses | [ ]  Pregnant Women | [ ]  Hospitalized Patients |
| [ ]  Institutionalized Persons | [ ]  Prisoners | [ ]  Incarcerated Youth |
| [ ]  Parolees | [ ]  Cognitively or Developmentally Disabled Persons | [ ]  Individuals with Mental or Physical Illness or Disability |
| [ ]  Physically Disabled Persons | [ ]  Substance Abusers | [ ]  Homeless Persons |
| [ ]  International Persons | [ ]  Undocumented Immigrants | [ ]  Limited English-Speaking Persons |
| [ ]  Other (please describe): |
| Estimated Number of Subjects: | Estimated Ages or Age Range**:**  | Estimated Gender Distribution: |
| Desired Racial/Ethnic Background of Sample (if applicable): | Desired Physical and Mental Health Status of Sample (if applicable):  |
| Other (please describe):  |
| **1b. If applicable, explain the rationale for the inclusion of special classes of subjects, especially vulnerable populations (e.g., minor children, cognitively or developmentally disabled prisoners, undocumented immigrants)** (Limit 125 words):  |
| **1c. If applicable, list criteria for exclusion of potential subjects from the study, and the method and rationale for doing so. Explain the screening process:** (Limit 125 words) |
| **2a. Recruitment** (check all that apply) |
| [ ]  In-person | [ ]  Email or other electronic messaging | [ ]  US Mail |
| [ ]  Telephone | [ ]  Flyer/Posting/Advertisement (including web-based) | [ ]  Network/Social Media/Snowball |
| [ ]  Other (please describe)  |
| **2b. List the specific location(s) where subjects will be recruited (e.g., names of schools, agencies):** |
| **2c. Describe how potential subjects will be identified and recruited:** |
| **2d. If online Flyer/Posting/Advertisement/Email or other electronic messaging are used, include screen shots or links, as well as a list of websites where such tools will be linked.** |

|  |
| --- |
| **SECTION D: CONSENT PROCESS**(For description of requirements, see IRB Application Guidelines, Section 4) |
| **1. State whether a consent form will be used or if a waiver is being requested** (choose a or b): |
| [ ]  **a**. **I will obtain written informed consent, with signature.** (Attach a copy of the informed consent form) |
|  |
| [ ]  **b.** **I am requesting a waiver of the informed consent process**. If you are requesting a waiver or alteration of the informed consent process, describe below the rationale: [ ]  (i) The consent document would be the only record linking the subject and the research; potential harm could result from a breach of confidentiality.  [ ]  (ii) The research involves no more than minimal risk to the subjects. [ ]  (iii) The waiver or alteration will not adversely affect the rights and welfare of the subjects. [ ]  (iv) The research could not practically be carried out without the waiver or alteration. [ ]  (v) Whenever appropriate, the subjects will be provided with additional pertinent information after participation. [ ]  (vi) Other (please explain): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **2. Describe the detailed consent procedures to be followed. Note: Subjects must be given a blank copy of the consent form and/or informational cover letter.** |
| 1. **Under what circumstances will consent be sought and obtained (e.g., location, time of day, mode of interaction)?**
 |
| 1. **Who will seek consent?**
 |
| 1. **Will consent be provided by the subject, or someone other than the subject (e.g., for a minor, cognitively impaired person)? If the latter, explain and indicate who will provide consent, and the relationship to the subject.**
 |
| **3. Attach informational cover letter, or script you plan to use. These should be written in language appropriate to the population being addressed and reveal as much as possible of the goals of the study without biasing subject performance. For BCC consent form templates, see “Examples” folder on shared drive.** |
|  |
| **SECTION E: RESEARCH SETTING** |
| **1. Setting(s) Where the Research Will Be Conducted** (check all that apply) |
| [ ]  BCC Campus (check all that apply)⏵ | [ ]  In Class | [ ]  Out of Class |
| [ ]  Other College Campus (check all that apply)⏵ | [ ]  In Class | [ ]  Out of Class |
| [ ]  K-12 Schools (check all that apply)⏵ | [ ]  In Class | [ ]  Out of Class |
| [ ]  Hospital | [ ]  Correctional Facility | [ ]  Store or Mall |
| [ ]  Outpatient/Community Clinic | [ ]  Shelter | [ ]  Conference/Professional Organization |
| [ ]  Community Organization | [ ]  Sports Setting | [ ]  Government Agency |
| [ ]  Email | [ ]  Internet (e.g., web-based, social networking, etc.) |
| [ ]  Other (please describe):  |
| **2. List the specific location(s) where the study will take place (e.g., names of schools, agencies):**The investigator must include information regarding the location from which subjects will be recruited (e.g., schools, college campuses, fitness facilities, hospitals, government agencies, nonprofit organizations, places of business, places of worship). Also included should be a confirmation that permission has been obtained from the institution to conduct this protocol, in the form of a letter from an authorized official, on the organization’s official letterhead. |
|  |

|  |
| --- |
| **SECTION F: METHODS AND PROCEDURES** |
| **METHOD(S)** (check all that apply) | **NUMBER** | **DURATION** | **DESCRIPTION** |
| 1a. | [ ]  Review of Records |  |  |  |
| 1b. | [ ]  Observations |  |  |  |
| 1c. | [ ]  Surveys/Questionnaires |  |  |  |
| 1d. | [ ]  Individual Interview |  |  |  |
| 1e. | [ ]  Focus Group Interview |  |  |  |
| 1f. | [ ]  Audio/Video Recording |  |  |  |
| 1g. | [ ]  Secondary Data Analysis  |  |  |  |
| 1h. | [ ]  Other (please describe): |  |  |  |
| 1. **Identify the instrumentation used in obtaining data (e.g., questionnaire, interview, etc.). If questionnaires are used, indicate if they are modifications of standard scales (cite references) or self-developed, and attach copies. If online surveys/questionnaires are used, include screen shots or links**.
 |
|  |
| 1. **Briefly explain and justify if there is less than full disclosure of the study’s purpose to subjects.** (For more information, see IRB Application Guidelines Section 3.4.3.) **If deception as to the purpose of the study is involved, explain what deception is being used and justify its usage. Attach a debriefing sheet or script** **to be used** **to ultimately inform subjects about the study’s true purpose, or justification for not debriefing** (limit 250 words).
 |
|  |
| 1. **Describe how data will be recorded (e.g., audio, video, field notes, database or other electronic file). Indicate if the data will be anonymous (there will be no association between responses and respondents) or confidential (data are associated with personal identifiers or coded to protect personal privacy). (For description of anonymity and confidentiality, see IRB Application Guidelines Section 3.4.8.1.) (Limit 300 words)**
 |
|  |
| 1. **Select the procedures that ensure that anonymity or confidentiality will be maintained during data collection:**
 |
| [ ]  Responses will be placed into individual, unlabeled, sealable envelopes, and collected in person.[ ]  Respondents will place surveys in a box with slot or into a large envelope, face down.[ ]  Questionnaires will be mailed in postage-prepaid envelopes, with a reminder not to place identifiers on the envelope.[ ]  Web-based surveys (e.g., SurveyMonkey) will not collect IP addresses.[ ]  Web-based survey sites will contain the following security and firewall protection (please describe): |
| [ ]  Data collection will be done in a location that affords privacy.[ ]  Subjects in a group setting will be reminded not to share what is discussed beyond the group.[ ]  Audio recordings will not contain identifiers.[ ]  Researcher will record data anonymously.[ ]  Researcher will code the data.[ ]  Other (please describe): |
| 1. **Describe any incentives or payment used, the amount, and the process by which it will be disbursed:**
 |
| **Cash**  | **Check or Money Order**  |
| **Gift Card**  | **Lottery** (indicate chances of winning:) |
| **Course Credit**  | **Extra Credit**  |
| **Refreshments/Meals**  | **Other (please describe):** |
| 1. **Briefly describe how you plan to analyze your data, including detail or statistical methods to be used, where applicable** (250 word limit):
 |
|  |

|  |
| --- |
| **SECTION G: RISKS AND RISK REDUCTION** |
| 1. **What level of risk will subjects be exposed to?** (For more information about risk level, see IRB Application Guidelines, Section 3.4.7.)
 |
| [ ]  Minimal | [ ]  Moderate | [ ]  > Moderate |
| 1. **Safeguards that Apply to All Research**
 |
| **Voluntary Nature of the Research** (choose a or b): |
| [ ]  a. Subjects will be informed that their participation is voluntary, and that they may withdraw at any time with no consequences or penalty.[ ]  b. The subjects’ participation in the activity is not voluntary (e.g., classes engaging in certain curriculum or intervention), but the subjects’ permission to collect and use data from such activity will be obtained, and they will be informed that they may withdraw this permission at any time, with no consequence or penalty. |
| **Anonymity or Confidentiality (check all that apply).** The study is anonymous if no one, including the researcher, will know who participates in the study; the study is confidential if anyone involved in data collection will know the identity of the participants (in-person data collection is never anonymous). |
|         | [ ]  Subjects will be informed by what measures their anonymity will be protected.[ ]  Subjects will be informed by what measures their confidentiality will be protected.[ ]  Data will not contain identifiers. [ ]  Data will be stripped of identifiers.[ ]  Audio/video recordings will not contain identifiers.[ ]  Subjects will be referred to by sequential number only.[ ]  Subjects will choose or be given a pseudonym.[ ]  Results will be reported anonymously and/or in aggregate form.[ ]  Results will be reported through the use of first name only or pseudonyms.[ ]  Results will be reported using names or other identifiers, but consent will be obtained.[ ]  Other (please specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. **Identify all the risk(s) to the subjects by responding to the following items, as well as adding any foreseeable risks not covered (check all that apply). Assess their likelihood and seriousness. For each risk category with “yes” checked off, identify the appropriate safeguards that will be implemented to minimize the corresponding risk. Indicate any circumstances under which the researcher may withdraw subjects from the study entirely, or from a particular session, and the criteria that will be used to determine such withdrawal.**
 |
| [ ]  Yes[ ]  No | 1. **Will subjects be exposed to any stimuli or asked any questions that might be physically or psychologically harmful, or cause stress, distress, or physical or psychological discomfort?**
 |
| **If Yes, Describe Specific Risks:** |
| **If Yes, Describe Corresponding Safeguards** (check all that apply): |
| [ ]  Subjects will be told that they may refrain from answering any question that makes them uncomfortable.[ ]  All prospective subjects will be given a resource sheet of referrals and resources (e.g., hotlines, agencies, etc.).[ ]  Subjects will be informed that they may choose not to be audio/video recorded.[ ]  Subjects will be given the opportunity to destroy audio/video recordings if they withdraw from the study.[ ]  Subjects will be allowed to take breaks.[ ]  Subjects will be informed about the results of their testing, and that they might want to seek further information or care from a professional (a diagnosis should not be made).[ ]  For care beyond the scope of BCC services, subjects will be asked to seek care from their personal/outside health care provider. In all cases of need for emergency care, 911 will be called.[ ]  Other (please describe): |
| [ ]  Yes[ ]  No | 1. **Might the information gathered expose the subjects to criminal or civil liability, discrimination, or embarrassment if revealed (e.g., concerning child abuse, sexual behavior, drug abuse, or other sensitive issues)? Are there any limits to your ability to maintain confidentiality (e.g., mandatory requirements to report child or elder abuse, intent to harm self or others, disclosure of criminal behavior that has not been prosecuted, etc.)?**
 |
| If Yes, Describe Specific Risks: |
| If Yes, Describe Corresponding Safeguards: (check all that apply)[ ]  Subjects will choose or be given a pseudonym.[ ]  Subjects will be referred to by sequential number only.[ ]  Conversation will be steered away from disclosures that will trigger mandatory reporting or information that could be subpoenaed.[ ]  Subjects will be reminded about the consequences of further disclosure of information that could be subpoenaed or that will trigger mandatory reporting.[ ]  Researcher has obtained a Certificate of Confidentiality (For description, see IRB Application Guidelines, sec. 3.4.8.8).[ ]  Subjects will be told that they may refrain from answering any question that makes them uncomfortable.[ ]  Subjects will be informed about the results of their testing, and that they might want to seek further information or care from a professional (a diagnosis should not be made).[ ]  Subjects will be informed that they may choose not to be audio or video recorded.[ ]  Audio or video recordings will not contain any identifiers.[ ]  Subjects will be given the opportunity to destroy audio or video recordings if they withdraw from the study.[ ]  Subjects will be given the choice of declining documentation of informed consent (see Consent/Assent section above).[ ]  Other: (please describe) |
| [ ]  Yes[ ]  No | 1. **Will the subjects be involved in any physical activities?**
 |
| If Yes, Describe the Activity and Potential Risks: |
| [ ]  Subjects will be told that they may refrain from answering any question that makes them uncomfortable.[ ]  All prospective subjects will be given a resource sheet of referrals and resources (e.g., hotlines, agencies, etc.).[ ]  Subjects will be informed that they may choose not to be audio/video recorded.[ ]  Subjects will be given the opportunity to destroy audio/video recordings if they withdraw from the study.[ ]  Subjects will be allowed to take breaks.[ ]  Subjects will be informed that for care beyond the scope of BCC services, subjects should seek care from their personal/outside health care provider. In all cases of need for emergency care, 911 will be called.[ ]  Other (please describe): |
| [ ]  Yes[ ]  No | 1. **Will any equipment or apparatus be used on the subjects?**
 |
| If Yes, List Specific Risks: |
| If Yes, Describe Corresponding Safeguards: |
| [ ]  Yes[ ]  No | 1. **Could information containing the identity of subjects become known or accessible to outside parties, or will the information be used in public presentations or publications, etc.?**
 |
| If Yes, List Specific Risks: |
| If Yes, Describe Corresponding Safeguards: |
| [ ]  Yes[ ]  No | 1. **Might subjects feel pressured or coerced to participate in the study (e.g., subjects are researcher’s students, or significant payment or incentive is offered by researcher)?**
 |
| If Yes, Describe Specific Risks: |
| If Yes, Describe Corresponding Safeguards: (check all that apply) [ ]  Subjects will be informed that their participation will have no effect on their grades or the services they are receiving.[ ]  Subjects will be informed that partial or full credit/extra credit or payment will be given even if they withdraw from the study.[ ]  Other: (please describe) |
| [ ]  Yes[ ]  No | 1. **Will deception or less than full disclosure be employed?**
 |
| If Yes, Describe Specific Risks: |
| If Yes, Describe Corresponding Safeguards: (check all that apply)[ ]  Subjects will be debriefed immediately (in cases where deception or less than full disclosure is employed).[ ]  Subjects will be debriefed at the end of the study (in cases where deception or less than full disclosure is employed).[ ]  Other: (please describe) |
| [ ]  Yes[ ]  No | 1. **Will others be present during data collection (e.g., research assistants, on-site foreign/sign language translators, fellow subjects), thereby potentially compromising anonymity or confidentiality?**
 |
| If Yes, Describe Specific Risks: |
| If Yes, Describe Corresponding Safeguards:  |
| [ ]  Yes[ ]  No | 1. **Are there other risks (please describe)?**
 |
| If Yes, Describe Specific Risks: |
| If Yes, Describe Corresponding Safeguards:  |
| **SECTION H: BENEFITS** |
| **Describe any anticipated benefits to subjects and/or the importance of the knowledge that may be gained:** |
| **SECTION I: STORAGE PROCEDURES AND DISPOSITION OF DATA** |
| **1. Who will have access to the data/codes?** |
|  |
| [ ]  Yes[ ]  No | **2. Will audio/video recordings be inserted in publications or presentation (e.g. reports, articles, theses or PowerPoints)? If yes, please describe.**  |
| Indicate which of the following items will be kept securely and separately from each other, the location of storage, and the length of time that item will be kept. **Note: Identifiable data should not be kept at home. The PI is responsible for storing data.** |
| **Item** | **Length of Time\*** | **Location\*\*** |
| [ ]  Consent Forms |  |  |
| [ ]  Questionnaires |  |  |
| [ ]  Interview Transcripts |  |  |
| [ ]  Observation Checklists |  |  |
| [ ]  Coded List of Subjects |  |  |
| [ ]  Audio/Video Recordings |  |  |
| [ ]  Field Notes/Notes |  |  |
| [ ]  Electronic Data Files |  |  |
| [ ]  Other: (please describe) |  |  |
| \* Data must be kept for a **minimum of three years** following completion of study, with the exception of audio recordings, which may be deleted immediately following transcription.\*\*For students: make arrangements with professor regarding storage of data.  |

|  |
| --- |
| **IMPORTANT NOTES****The use of human subjects may commence only after you have received a final approval memo from the IRB. IRB approval is good for the specified time stated in your approval memo (maximum one year).** Should you need to modify the approved application during the approval period, additional approval must be granted prior to the implementation of such modification. If the use of human subjects or use of identifiable data is required past the approval period, additional approval must be granted to continue the study before the approval period has expired. *By signing below, the Principal Investigator (PI), who is responsible for the safe conduct of this project, is assuring the Institutional Review Board—Human Subjects that all procedures performed under the protocol will be conducted by individuals legally and responsibly entitled to do so.* If the PI is a student, the Faculty Supervisor is assuring that the student researcher is competent to conduct the activity described in this form and that the design meets the ethical and scientific standards of the field and the College. The Faculty Supervisor will provide appropriate direction and supervision to ensure the safety of the research subjects. If the PI is a campus sponsor for an unaffiliated researcher, the PI will likewise provide appropriate oversight to ensure the safety of the research subjects.The study must be conducted in the manner described in this form. The PI will notify the Institutional Review Board–-Human Subjects immediately, in writing, to request approval to change any procedures, prior to implementation, or to report any problems that may put subjects at risk. This includes any adverse reaction or risk associated with the study.  |
| **I understand that if the information in this application is unclear or incomplete, the application will be returned without review.** |
| **Signature** of Principal Investigator | Date |
| **Name** of Principal Investigator (please print) |
| **Signature** of Faculty Supervisor | Date |
| **Name** of Faculty Supervisor (please print) |
| **Signature** of Co-Investigator(s) | Date |
| **Name** of Co-Investigator(s) (please print) |