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| **BELLARMINE UNIVERSITY IRB: Application Form for New Human Subjects Research** |
| The IRB reviews all **research**involving **human subjects**. The Code of Federal Regulations [45 CFR 46.102] defines *research*as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. *Human subject*means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. [See <https://www.ecfr.gov/on/2018-07-19/title-45/subtitle-A/subchapter-A/part-46> for more information.]  |
| **INSTRUCTIONS**: Submit your full IRB proposal package, including this completed form and required supporting documents, in a single email to irb@bellarmine.edu. Submitting pieces of a proposal package in multiple emails may delay the review process.  |
| **PROJECT TITLE** |  |
| **\*Anticipated START Date:** |  | **Anticipated END Date:** |  |
| \*Remember, it may take up to two weeks to review your proposal after submission. Participant recruitment and data collection may not begin prior to approval or exemption from the IRB. |
| **SECTION I: INVESTIGATOR INFORMATION** |
|  | **Name** | **Email** | **Department/Affiliation** | **Status\*** |
| **Principal Investigator (PI)** |  |  |  |  |
| **Co-investigator (CoPI)** |  |  |  |  |
| **Co-investigator (CoPI)** |  |  |  |  |
| **Co-investigator (CoPI)** |  |  |  |  |
| \*Please indicate faculty, staff, student – graduate (G) or undergraduate (UG), or other (please specify). You may insert additional rows for CoPIs as necessary. |
| The following items must be **SUBMITTED** with the IRB proposal package for **each** investigator listed on this application: * (1) Resume/curriculum vitae
* (2) CITI Human Subjects Training Certification (<https://about.citiprogram.org/>); expires after three years
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| **SECTION II: PROJECT OVERVIEW** |
| 1. **Is this project being funded by a source external to BU?** (Check “X” the box for Yes or No)
 | **Yes** |  | **No** |  |
| *If YES, list the funding source and/or sponsor name:*NOTE: A *Conflict-of-Interest Form* may be required. Contact IRB for guidance. |  |
| 1. **Do you intend to publish/present the results of this study?**
 | **Yes** |  | **No** |  |
| *If YES, please describe where you anticipate publishing or presenting this work:* |  |
| 1. **List the site(s) where the research will be conducted:**
 |  |
| NOTE:If systematic recruitment is occurring at an external institution, you are required to follow the recruitment procedures for that institution. If external institutions are "engaged" in the research, a "single IRB" reliance agreement may be required. Contact IRB for guidance.  |
| **SECTION III: RISK ANALYSIS**  |
| Human subjects may be exposed to short- and long-term risks by participation in research. Examples of potential risk categories include physical, psychological, social, financial, or legal. A minimal risk study is one where the probability and magnitude of harm or discomfort is not greater than that ordinarily encountered in daily life or during performance of routine physical or psychological examinations or tests. |
| **In your opinion, does this study involve *no more than minimal risk* or *more than minimal risk*?** (Check “X” one) |
|  | No more than minimal risk |
|  | More than minimal risk; please EXPLAIN: [ ] |
|  | Not sure |
| **SECTION IV: COERCION AND VULNERABLE POPULATIONS** |
| As a BU faculty or staff member, the Principal Investigator (PI) holds a special trust and may not exert undue influence when recruiting students and University employees as potential research subjects. Other potential research participants are considered vulnerable and entitled to increased protection, including minors, prisoners, or the cognitively impaired. A full review by the convened IRB may be required.  |
| **Will any of the following potentially be participants in your research project?** (Check “X” all that apply) |
|  | Student under your supervision at BU |  | Pregnant women, fetuses, or neonates |
|  | Employee under your supervision at BU |  | Cognitively or decisionally impaired |
|  | Minors (less than 18 years of age) |  | Other potentially vulnerable populations |
|  | Prisoners |  | No, none of these |
| *If YES to vulnerable participants, please explain:* |  |
| **SECTION V: PARTICIPANT RECRUITMENT AND INDUCEMENTS** |
| 1. **What is the desired sample size or approximate number of participants to be recruited?**
 |  |
| 1. **Will participants be paid/compensated for their participation in this study?**
 | **Yes** |  | **No** |  |
| *If YES to payment, please explain the amount to be paid, how the amount will be pro-rated if the participant withdraws before study completion, and/or if there is any other type of compensation for participation, (e.g., coupons, raffles, etc.).* NOTE: Research participant incentive procedures may be required. Contact IRB for guidance. |  |
| 1. **How will participants be recruited?** (Check all that apply)
 |
|  | Recruitment emails |  | Oral scripts |
|  | Direct solicitation |  | Snowball/word of mouth |
|  | Flyers/posters |  | Advertisements |
|  | Social media |  | Other (please specify): [ ] |
| * Please **SUBMIT** all recruitment materials along with your completed proposal application.
 |
| **SECTION VI: METHODOLOGY** |
| 1. **Research protocol:** Describe in detail how your research will be conducted. Provide a brief background rationale for your project, then be sure to address how participants will be identified, contacted, and recruited; what will they be told about the study; what they will be expected to do, including all questionnaire items or stimulus materials as appropriate; how informed consent will be obtained; identify steps for data storage, security, and destruction. You may type in the space provided below **OR SUBMIT** a separate document via email.
 |
|  |
| 1. **Data collection methods:** (Check all that apply)
 |
|  | In-person/face-to-face |  | Computer-based task data collection |
|  | Virtual/on-line |  | App collected task data |
|  | Questionnaire/survey |  | Intervention |
|  | Interview |  | Testing/evaluation |
|  | Focus group |  | Instruction/education curriculum |
|  | Observation |  | Physical tasks |
|  | Video or audio recording |  | Physiological measurement |
|  | Web or internet research (e.g., social media sites) |  | Other (please specify): [ ] |
| **SECTION VII: INFORMED CONSENT** |
| See the consent form templates on the IRB website as a guide and/or refer to 45 CFR 46.116(b) and (c) for the general requirements for informed consent.  |
| **Type of informed consent to be obtained (check all that apply):** |
|  | Adult consent – consent process with documentation (i.e., signature) |
|  | Adult consent – survey consent process without documentation; waiver of documentation requested |
|  | Consent from an adult’s legally authorized representative |
|  | Parent/guardian permission |
|  | Waiver of informed consent process will be requested (contact IRB for guidance) |
| * Please **SUBMIT** all applicable consent and assent materials with your completed proposal application via email.
* NOTE: For expedited and full review studies, please also submit the Consent Form Checklist with each item location in the consent appropriately referenced.
 |
| **SECTION VIII: REVIEW LEVEL** |
| 1. **Please select the review level which you believe best reflects your proposed research (check “X” one):**
 |
|  | Exempt (no more than minimal risk and fits one or more of the exempt categories) |
|  | Expedited (no more than minimal risk and fits one or more of the expedited categories) |
|  | Convened Board (more than minimal risk or does not fit one of the exempt or expedited categories) |
|  | Please evaluate my study as a potential quality improvement project (QIP) |
|  | Not sure |
| 1. **If EXEMPT, which of the following categories is most appropriate for your proposed research? (Check all that apply):**
 |
| **“X”** | **Category** | **Description** |
|  | N/A | My proposal does not qualify for exemption |
|  | 1 | Research conducted in established or commonly accepted educational settings |
|  | 2 | Research only includes interactions involving educational tests, surveys, interviews, or public observation\*  |
|  | 3 | Research involving benign behavioral interventions (BBI)\*  |
|  | 4 | Secondary research for which consent is not required  |
|  | 5 | Research and demonstration projects supported by a Federal Agency/Department AND designed to study, improve, public benefit or service programs  |
|  | 6 | Taste and food quality evaluation  |
|  | ~ | I am not sure which exempt categories are appropriate. |
| \*Categories 2 and 3 may require a privacy and confidentiality review (i.e., Limited IRB Review) if information is identifiable (directly or indirectly linked) and potentially sensitive; A full description of the exemption category descriptions can be found in the Electronic Code of Federal Regulations, 45 CFR 46.104, here: <https://www.ecfr.gov/on/2018-07-19/title-45/subtitle-A/subchapter-A/part-46> |
| 1. **If EXPEDITED, which of the following categories is most appropriate for your proposed research? (Check all that apply):**
 |
| **“X”** | **Category** | **Description** |
|  | N/A | My project does not require or qualify for expedited review. |
|  | 1 | Clinical studies of drugs and medical devices  |
|  | 2 | Collection of blood samples  |
|  | 3 | Collection of biological specimens by noninvasive means  |
|  | 4 | Collection of data through noninvasive procedures  |
|  | 5 | Research involving materials that have been collected, or will be collected solely 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  |
|  | 8 | Continuing review of research previously approved by the convened IRB  |
|  | 9 | Continuing review of research, not conducted under an investigational new drug application or investigational device exemption  |
|  | ~ | I am not sure which expedited categories are appropriate. |
| NOTE: A full description of the expedited category descriptions can be found on the Office for Human Research Protections (OHRP) website here: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html> |
| **SECTION IX: COMMUNITY-ENGAGED RESEARCH** |
| Bellarmine's Community Engagement Task Force would like to gauge the amount of community engaged research occurring at the University at this time. We are inviting you to voluntarily report your community-engaged research activity below. Please note that your responses to these questions will not impact the IRB review processes. |
| 1. **Is your current project proposal based on community-engaged research, defined as an approach to conducting research with varying degrees of community engagement? This would include community-placed research, community-driven research, community-based research, and community-based participatory research (CITI definition).** (Check “X” one)
 |
|  | Yes |
|  | No |
|  | Not sure |
|  | Prefer not to respond |
| 1. **If you answered "YES" or "NOT SURE" to the question above, do you give permission for the IRB Office to send your name, contact information, and study title to the Bellarmine Center for Community Engagement to help track faculty involvement in community-engaged research endeavors and to offer resources in the research process?** (Check “X” one)
 |
|  | Yes |
|  | No |
|  | I said “NO” to the question above. |
|  | Prefer not to respond |
| **SECTION X: DEPARTMENT CHAIR APPROVAL & PRINCIPAL INVESTIGATOR SIGNATURES** |
| DEPARTMENT CHAIR APPROVAL |
| Department Chairs, through appropriate procedures established within their respective departments, are responsible for reviewing research proposals/protocols for ethical considerations as well as scientific merit. By providing my name in the box below, I, as Chairperson of the PI’s department, certify that I have reviewed this study protocol submitted to the IRB.  |
|  |  |
| **Department Chair Name and Signature** | **Date** |
|  |
| PRINCIPAL INVESTIGATOR SIGNATURE |
| By providing my name in the box below, I certify that I have read, and I understand Bellarmine University’s policies and procedures governing human subject research as described in Bellarmine IRB Handbook. I will fully comply with those policies and will not conduct any research activities without IRB approval. I further acknowledge my obligation to: (1) obtain written approval of deviations from the originally approved protocol BEFORE making those deviations; and (2) Immediately report all adverse events of the study to the Chairperson of the Institutional Review Board and the Research Sponsor, if applicable. This study will be conducted in a manner consistent with how it has been represented to the IRB and will follow any alterations in the procedures that may result from the IRB review process. |
|  |  |
| **Principal Investigator Signature & Today’s Date** | **CITI Training Completion Date** |
| **SECTION XI: IRB Submission Checklist** |
| **Please use this checklist as you prepare your human subjects research proposal package for IRB review. Your proposal submission should include the following sent via a single email to** **irb@bellarmine.edu****:**  |
| **“X”** | **Supporting Document** |
|  | This completed proposal application |
|  | Resume/Curriculum vitae for each investigator listed |
|  | Current CITI certification for each investigator listed |
|  | Research protocol (if not inserted into this application) |
|  | Data collection materials (e.g., assessments, survey items, stimulus materials, etc.) |
|  | Conflict of Interest Form (if applicable) |
|  | Participant recruitment materials |
|  | Informed consent form |
|  | Consent form checklist (if applicable) |