Bellarmine University
Exempt Review Research Categories
(45 CFR 46.101b)

A. Principal Investigator: _____ Phone _____

Campus Address _____ Email _____

B. Project Collaborators:

Name _____ Dept or Off Campus Affiliation _____
Name _____ Dept or Off Campus Affiliation _____
Name _____ Dept or Off Campus Affiliation _____

C. Title of Project: _____

D. Type of Exemption Requested (one or more may apply). Research activities in which the ONLY involvement of human subjects will be in one or more of the categories specified below are eligible for exemption certification. If the research study involves a vulnerable population, such as children, prisoners, or pregnant women, refer to 46 CFR subparts B, C, and D for protections afforded these groups. In most cases, an expedited or full review will be required. If the protocol involves a biomedical intervention or a behavioral/physical intervention that does not fit the criteria of Category #3 below, then you must complete the full IRB application for your research.

Please check the appropriate category or categories for your research project and attach a copy of any survey and/or interview questions:

____ 1. Research in established or commonly accepted education settings that involves normal educational practices (Must not be likely to adversely impact students' opportunity to learn or assessment of educators providing instruction)

____ 2. Research only includes interactions involving educational tests, surveys, interviews, public observation if at least ONE of the following criteria met:
   i. Recorded information cannot readily identify the subject (directly or indirectly/linked);
   ii. Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation);
   iii. Information is recorded with identifiers or code linked to identifiers AND IRB conducts Limited Review (NO children)

   Notes: Data collection only; may include visual or auditory recording; may NOT include intervention, only interactions; for surveys and interviews, NO children; for educational tests or observation of public behavior, can only include children when investigators do not participate in activities being administered/observed.

____ 3. Research involving Benign Behavioral Interventions (BBI) through verbal, written responses, (including data entry or audiovisual recording) from adult subject who prospectively agrees and ONE of following met:
   i. Recorded information cannot readily identify the subject (directly or indirectly/linked);
   ii. Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation);
   iii. Information is recorded with identifiers or code linked to identifiers AND IRB conducts Limited Review

   Notes: (i) NO children; may not include medical interventions; subject must prospectively agree; (ii) BBI must be: Brief in duration, painless/harmless, not physically invasive, not likely to have a significant adverse lasting impact on subjects; unlikely that subjects will find interventions offensive or embarrassing; (iii) No deception unless participant is informed in the prospective agreement that he/she will be unaware of or misled regarding the true nature or purpose of the research

____ 4. Secondary research for which consent is not required: Use of identifiable information or identifiable biospecimen that have been or will be collected for some other 'primary' or 'initial' activity, if ONE of following criteria met:
   i. Biospecimens or information is publicly available;

ii. Information recorded so subject cannot readily be identified (directly or indirectly/linked); Investigator does not contact subjects and will not re-identify the subjects;
iii. Collection and analysis involving investigators use of identifiable health information when use is regulated by HIPAA "health care operations" or "research" or "public health activities and purposes" (HIPAA regulations still apply; HIPAA protections include authorization nor waiver of authorization; does not include biospecimens – only PHI; only covers "investigator's use"; does not indicate that sharing is permitted under this exemption)
iv. Research information collected by or on behalf of federal government using government generated or collected information obtained for non-research activities (if research generates identifiable private information it is subject to specified federal privacy laws)

____ 5. Research and demonstration projects supported by a Federal Agency/Dept. AND Designed to study…improve… public benefit or service programs. (Must be posted on Federal Web Site)

____ 6. Taste and Food Quality (wholesome food without additives; ingredient level and use found to be safe)

E. A brief explanation (3-4 sentences) of why you believe your research is exempt from IRB review. As part of the explanation, you will need to articulate clearly the rationale for the exemption and attach any relevant supporting documentation.

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F. Signatures. By signing this application for exempt status, the principal investigator and collaborators (if any) commit to ensuring that they will protect the interests and general welfare of all participants. Further, the researcher(s) will provide all participants with notification of their rights as it relates to informed consent and clearly indicate participation is voluntary using the standard informed consent template. Finally, the researcher(s) agree to submit a modification of the research protocol should it be subsequently determined that the research may not necessarily be exempt and/or a change in the protocol requires resubmission.

Principal Investigator _____ Date _____

Administrator (Dept Chair) _____ Date _____

G. Exemption Status: ____ Approved ___ Not Approved

If NOT approved, note rationale: _____

IRB CHAIR SIGNATURE OR DESIGNEE _____ Date_____