**Basic Information**

Please fill in the information below. Cells will expand as needed.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Principal Investigator (PI) Name:** | (Last) | (First) | (MI) | (Highest Degree Earned) |
| **PI Contact Info:** | (Email) | (Phone) | (Address) |
| **PI Status:** | [ ] Faculty or Staff [ ]  Student |
| **PI Title:** | (e.g., Doctoral Student)  |
| **Faculty Advisor or Committee Chair:** | (if applicable) |
| **Co-Investigator(s):** | (if applicable)  |
| **Division/Department:** |  |
| **Research Background of PI and/or Faculty Advisor:** | (e.g., research courses, professional experience, etc) |
| **Proposed Title:** |  |
| **Key Words:** | 1.  | 2.  | 3.  |
| **Research Site(s):** | (Indicated expected site(s) of investigation or location(s) of potential participants) |
| **Funding Source:** | (if applicable)  |
| **Grant, Contract, or Protocol #** | (if applicable; provide a copy of the grant application or sponsor’s protocol as an appendix)  |

1. **Exemption Screening Questions**

**Research activities in which the *only* involvement of human participants falls under one or more of the categories identified in 45 CFR 46.104 qualify as exempt. Even if your study may qualify as exempt, you must complete and submit this application to the IRB. The final determination of exemption may only be made by the IRB, not the principal investigator (PI). Exempt studies do not require continued IRB monitoring, however, any changes made to research must be submitted and approved by the IRB before implemented. Please submit all application materials to** **IRB@mobap.edu****.**

* 1. **Exemption Checklist**

Please complete the following items to indicate if your study qualifies as exempt or non-exempt. Mark **Y** for Yes and **N** for No. If the question is not applicable, mark **N/A** (specific questions only).

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Y** | **N** | **N/A** |
| **a.)** Does your research involve prisoners? |[ ] [ ]   |
| **b.)** Does your research involve pregnant women? |[ ] [ ]   |
| **c.)** Does your study involve deception of participants? |[ ] [ ]   |
| **d.)** Are you collecting or recording data from anyone under the age of 18? (Mark N if archival data or data accrued through normal classroom procedures). |[ ] [ ]   |
| **e.)** Are you collecting or recording data from anyone 90 years or older? |[ ] [ ]   |
| **f.)** Does your research involve survey or interview procedures with children as participants? \* |[ ] [ ]   |
| **g.)** Does your research involve observation of children in settings that would not be considered normal or typical educational activities **and** where investigator(s) will participate in the activities? \* |[ ] [ ]   |
| **h.)** Does your research involve participants from an economically disadvantaged area? |[ ] [ ]   |
| **i.)** If participants are identifiable either by name or through demographic data, are there potential risks of criminal or civil liability or of damage to the subjects’ financial standing, employability, educational advancement, or reputation to participants if the information is revealed or disclosed? |[ ] [ ]   |
| **j.)** Would the disclosure of data to be collected place the participants at risk (risks may be psychological, social, physical, economic, or legal)? |[ ] [ ]   |
| **k.)** If participants are identifiable (e.g., by name or through demographic data), would the collection of information include sensitive data (e.g., illegal activities or sensitive issues such as sexual orientation, sexual behavior, undesirable work behavior, or other embarrassing information)? |[ ] [ ]   |
| **l.)** Has the data (documents, records, or specimens) previously been collected for a purpose other than the proposed research study? If yes, answer a.) and b.). If no, mark NA for a.) and b.). |[ ] [ ] [ ]
| 1. Will any data (documents, records, or specimens) be collected from participants after IRB approval?
 |[ ] [ ] [ ]
| 1. If the existing data (documents, records, or specimens) are originally labeled with identifiers and are not publicly available, will the investigator de-identify the data?
 |[ ] [ ] [ ]
| **m.)** Please indicate the type of information to be collected or recorded:[ ]  **No** health information[ ]  Health information **without** identifiers. (Please complete the De-Identification Certification form.)[ ]  Health information **with** identifiers. (This constitutes protected health information (PHI) and HIPAA applies. Your study **does not** qualify as exempt)**If any health information is collected or recorded, Section 2.3 Risk and Benefit must be answered completely.** |

**\*** *This refers to research conducted in settings other than established or commonly accepted settings, involving normal educational practices.*

* 1. **Exemption Categories**

Review and select the appropriate Exempt Category for your research. Then complete the questions in the corresponding Exempt Category.

|  |
| --- |
| **Exemption Categories** |
| Principal Investigators (PIs) need only complete the section below that might apply to their research.* [Category 1](#EXEMPT_CATEGORY_1): Research conducted in established or commonly accepted educational settings involving normal educational practices.
* [Category 2](#EXEMPT_CATEGORY_2): Research involving educational tests, survey procedures, interview procedures, or observation of public behavior.
* [Category 3](#EXEMPT_CATEGORY_3): Research involving benign behavioral interventions.
* [Category 4](#EXEMPT_CATEGORY_4): Secondary research uses of identifiable private information or identifiable biospecimens.
* [Category 5](#EXEMPT_CATEGORY_5): Research and demonstration projects that are conducted, supported by, or otherwise subject to the approval of a federal department or agency on public benefit or service programs.
* [Category 6](#EXEMPT_CATEGORY_6): Research on food taste and food quality evaluation and consumer acceptance studies.
 |
| [ ]  **EXEMPT CATEGORY 1 [§46.104(d)(1)]:** Research conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies and research on the effectiveness or the comparison among instructional techniques, curricula, or classroom management methods. |
| **EC1a.)** What is the common educational setting for your study (e.g., MBU School of Nursing BSN program, adult care classes, secondary school, etc.) |  |
| **EC1b.)** What is the educational practice to be evaluated (e.g. team-based learning, diabetes education, implementation of new accreditation standards into course, etc.)? Provide justification that it is a normal educational practice that reasonably occurs within the setting. | 1. Educational Practice:
 |
| 1. Justification:
 |
| **EC1c.)** Will your research involve obtaining and analyzing data from secondary sources including, but not limited to, online educational sources; student records; local, state, or federal datasets? | [ ]  NO – Skip to Item EC1e.)[ ]  YES – Continue to EC1d.)*If YES, include documentation of permission to use the data from the source, when applicable (does not apply to publicly available data sets)* |
| **EC1d.)** Describe in detail each data set including the source of the data, type of data (ordinal, nominal, interval, ratio), the number of data points expected, and how you have access. Provide specific information, including an IRB protocol number if using data from a previous MBU study. |  |
| **EC1e.)** Family Educational Rights and Privacy Act (FERPA): Does data to be collected or obtained include any identifiable student records (e.g., grades, test scores, class assignments, class evaluations) beyond standard directory type data? | [ ]  NO[ ]  YES – Indicate which of the following you will do to ensure FERPA regulations are followed: [ ]  Obtain documented permission to use this information from the adult student (18 and older) or their parent/guardian, which can be obtained through the informed consent process. **-OR-**[ ] Obtain and submit a copy of a documented FERPA exception from the educational site’s registrar. For records obtained at MBU, request this document from the MBU Registrar, email FERPA@mobap.edu. |
| **EC1f.)** Provide justification that your study will not adversely impact any student’s ability to learn. |  |
| **EC1g.)** Provide justification that your research will not adversely impact the assessment or evaluation of educators who provide instruction. |  |
| End of Category 1. [Click here to continue to Section 1.3 Description of Research](#Description_of_Research). |
| [ ]  **EXEMPT CATEGORY 2 [§46.104(d)(2)]:** Research that only includes interactions involving education tests (e.g., cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording), AND at least one of the following criteria is met:1. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
2. Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or
3. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

NOTE: there are restrictions of Category 2 when research will involve children. |
| **EC2a.)** Does the research involve children younger than 18? | [ ]  NO – Skip to Item EC2b.)[ ]  YES – If YES – does research with children involve any of the following:* Survey procedures
* Interview procedures
* Observation of public behavior when the investigator(s) will participate in the activities being observed

[ ]  NO – proceed to Item b.)[ ]  YES – **Exemption 2 does not apply to your study.**  |
| **EC2b.)** Does the research include any intervention (e.g., physical procedures by which data are gathered [for example, venipuncture]) and manipulations of the subject or the subject’s environment that are performed for research purposes and are intended to *change* the participant’s behavior, thoughts, perceptions, or knowledge level)? | [ ]  NO[ ]  YES – **Exemption 2 does not apply to your study**.  |
| **EC2c.)** Exemption Category 2 does not allow linkage of other data sources to the information collected through the educational tests, survey procedures, interview procedures, or observations of public behavior. Will your study involve linkage of any other data sources? | [ ]  NO[ ]  YES – **Exemption 2 does not apply to your study.**  |
| End of Category 2. [Click here to continue to Section 1.3 Description of Research](#Description_of_Research). |
| [ ]  **EXEMPT CATEGORY 3 [§46.104(d)(3)]:** Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection, and at least one of the following criteria is met:1. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
2. Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or
3. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).
 |
| **EC3a.)** Does your research involve one or more benign behavioral intervention(s)? (*Item EC3c.) below provides assistance on determining whether an intervention meets the definition of a benign behavioral intervention.)* | [ ]  YES[ ]  NO – **Exemption 3 does not apply to your study.**  |
| **EC3b.)** Are all research participants adults (aged 18 and older for MBU and affiliates except Veterans Affairs [VA], which is 19 and older)? | [ ]  YES[ ]  NO – **Exemption 3 does not apply to your study.** |
| **(i.)** What is the maximum amount of time the intervention(s) could take for any single participant? (*To qualify for Exempt Category 3, the intervention[s] must be brief in duration, which the MBU IRB has defined as taking “NO more than a five [5] hours in a single day.”*) |  |
| **(ii.)** Is the intervention(s) harmless? | [ ]  YES[ ]  NO – **Exemption 3 does not apply to your study.** |
| **(iii.)** Is the intervention(s) painless? | [ ]  YES[ ]  NO – **Exemption 3 does not apply to your study.** |
| **(iv.)** Is the intervention(s) physically invasive? | [ ]  YES – **Exemption 3 does not apply to your study.**[ ]  NO |
| **(v.)** Is the intervention(s) likely to have a significant adverse lasting impact on the participants? | [ ]  YES – **Exemption 3 does not apply to your study.**[ ]  NO |
|  **(vi.)** Does the investigator have any reason to think the participants will find the intervention(s) offensive or embarrassing? | [ ]  YES – **Exemption 3 does not apply to your study.**[ ]  NO |
| **EC3c.)** Does the research involve deception or partial disclosure of the purpose or activities involved in the research, including not disclosing the research title? | [ ]  YES – to be eligible for Exempt Category 3, participants must prospectively agree to the deception through an agreement in which they are informed that they will be unaware of or misled regarding the nature of purposes of the research. Describe how you will obtain participant’s agreement to the deception in Item **2.2 Participants, Question f.)**. |
| **EC3d.)** Is information from participants recorded through verbal or written responses (including data entry) or audiovisual recording only? (*NOTE: data collection via physical procedures such as blood pressure monitoring, activity trackers, and eye trackers are not allowed in Exempt Category 3*). | [ ]  YES[ ]  NO - **Exemption 3 does not apply to your study.** |
| End of Category 3. [Click here to continue to Section 1.3 Description of Research](#Description_of_Research). |
| [ ]  **EXEMPT CATEGORY 4 [§46.104(d)(4)]:** Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:1. The identifiable private information or identifiable biospecimens are publicly available;
2. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
3. The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or
4. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq. [§46.104(d)(4)]
 |
| **EC4a.)** Are the data and/or biospecimens to be evaluated considered private and identifiable? Review the options below and select **ONE [1]** of the following: |
| [ ]  **YES** – The proposed study involves the collection of identifiable, private information from materials that were collected and maintained subject to HIPAA regulations (e.g., electronic medical record, another study). (*NOTE: this subsection is for the use of data only; obtaining and/or analyzing biospecimens is not allowed, although information about biospecimens may be collected*.)[ ]  **YES** – Research members of this study have access to identifiers (data only; biospecimens are not allowed in this exemption subsection) through primary material collection (e.g., they are research members on the source study, they were involved in the collection and maintenance of QI data) and as such, have access to identifying information; however, no identifiers will be recorded for *this* proposed research study.[ ]  **YES** – The identifiable private information or identifiable biospecimens contain identifiers (e.g., zip codes) and are publicly available – Cite Source (e.g., URL, web address): ***HERE***[ ]  **YES** – The proposed study involves the collection of identifiable, private information that was collected by or on behalf of the federal government using government-generated or collected information obtained for non-research activities.[ ]  **YES** – Other (e.g., the data contain identifiers, do not qualify for any of the above criteria, but the PI can justify why they are not readily identifiable, either directly or indirectly). Justify your choice: ***HERE***[ ]  **YES** – The proposed study involves the collection of identifiable, private information but does not fit any of the above criteria. **Exemption 4 does not apply to your study.** Consider whether other exemptions apply.[ ]  **NO** – The data contain no identifying information and cannot be indirectly identified. **Exemption 4 does not apply to your study**. Consider whether other exemptions apply. |
| **EC4b.)** Does your research **only** involve the evaluation of secondary (retrospective or prospective) information or biospecimens for which consent is not required? | [ ]  NO – some or all of the information or biospecimens will be collected directly from the participant by me or by someone else specifically for my research. **Exemption 4 does not apply to your study**.Consider whether other exemptions apply.[ ]  YES |
| **EC4c.)** Does your research involve *establishing* a data registry or a biospecimen repository for future studies? | [ ]  NO[ ]  YES – **Exemption 4 does not apply to your study.** |
| End of Category 4. [Click here to continue to Section 1.3 Description of Research](#Description_of_Research). |
| [ ]  **EXEMPT CATEGORY 5 [§46.104(d)(5)]:** Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.1. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects as collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq. [§46.104(d)(4)]
 |
| **EC5a.)** Does your study **only** involve research on a public benefit program (e.g., Social Security) conducted by or subject to the approval of the federal government? | [ ]  NO – **Exemption 5 does not apply to your study.**[ ]  YES – Provide the publicly accessible Federal website on which this study is listed: ***HERE*** |
| End of Category 5. [Click here to continue to Section 1.3 Description of Research](#Description_of_Research). |
| [ ]  **EXEMPT CATEGORY 6 [§46.104(d)(6)]:** Taste and food quality evaluation and consumer acceptance studies:1. If wholesome foods without additives are consumed, or
2. 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 Department of Agriculture.
 |
| **EC6a.)** Which **ONE [1]** of the following applies to your study? | [ ]  Wholesome foods without additives | Describe the foods: |
| [ ]  Food that contains a food ingredient, agricultural chemical, or environmental contaminant found to be safe. | Describe the food(s), food ingredient(s), agricultural chemical(s), and/or environmental contaminant(s): |
| [ ]  None of the above – **Exemption 6 does not apply to your study.**  |  |
| End of Category 6. [Click here to continue to Section 1.3 Description of Research.](#Description_of_Research) |

* 1. **Description of Research**

|  |
| --- |
| **(NOTE: This is where you tell the IRB everything you are doing. Record your narrative in the box below.)**Points to consider in your description (this is not intended to be a comprehensive list nor is it required to be presented in this order):* Fully describe what you plan to do.
* Fully describe the materials (data, specimens) to be utilized.
* Describe the source of any data/specimens.
* Describe whether any dataset/biospecimen will be linked to another set of data.
* Describe whether any data/biospecimens will be sent to another entity (regardless or identifiers).
* Describe whether any other entities are involved and how (e.g., analysis, coordinating center, receipt of data).

NOTE: Include data collection forms as an appendix to your application to the IRB. |
|  |

1. **Study Methodology**
	1. **Description of the Study**

Using lay language, briefly describe:

|  |  |
| --- | --- |
| **a.)** Problem statement |  |
| **b.)** Purpose statement |  |
| **c.)** Research Question(s) |  |
| **d.)** Please provide a description of research methods (quantitative, qualitative, or mixed-methods) **and** how research will be conducted (e.g., sampling technique, independent and dependent variables, intervention, method design, data collection). |  |

* 1. **Participants**

Describe:

|  |  |
| --- | --- |
| **a.)** Please give total number of the population that you will be studying, a rationale to the anticipated response rate, and the expected number of participants for each attempt and requesting participation in your study. |  |
| **b.)** Role of Participants |  |
| **c.)** Participant recruitment (e.g., letters, media ads, posters, etc.) and how it will be carried out |  |
| **d.)** If participant incentives are offered, describe and justify; otherwise, state not applicable |  |
| **e.)** The composition of the proposed study population in terms of gender and racial/ethnic group, and provide a rationale for participant selection |  |
| **f.)** How participants will be informed about the study (e.g., through a cover letter, statement from the investigator, and/or informed consent form) Also, describe any use of deception and debriefing needed to complete the research.(*Applicable to all Exempt Categories except Category 4*) |  |

NOTE: Recruitment materials (e.g., letters, media ads, posters, etc.), cover letters, statements from the investigator, and informed consent forms should be included as an appendix.

* 1. **Risk and Benefit**

Specify:

|  |  |
| --- | --- |
| **a.)** Risks to the participants *and* the steps you will take to minimize each risk |  |
| **b.)** Benefits to the Participants and/ or Society.  |  |
| **c.)** Give rationale as to why the benefits outweigh the risks. |  |

1. **Data Management**
	1. **Anonymous or Confidential**

Select **one [1]** from the left column and justify your answer in the corresponding box in the right column.

|  |  |
| --- | --- |
| [ ]  Anonymous (Name and unique identifiers of participants are never attached to the data.)Describe the steps you will take to ensure anonymity |  |
| [ ]  Confidential (Access to private data about a person is limited.)Describe the steps you will take to protect confidentiality, including the identity of the participants, their responses, and any data that you obtain from private records and/or capture on audiotape or videotape:Describe the disposition of the data and/or the tapes once the study has been completed: |  |

* 1. **Data Security**

All information must be stored using at least **two [2]** of the following safeguards in accordance with NIH best practices. If you are using both electronic data and hardcopy data, you will need **two [2]** safeguards of each type.

|  |  |
| --- | --- |
| Electronic Data[ ]  Secure network (e.g. firewall)[ ]  Password access[ ]  Data de-identified by PI or research team[ ]  Coded, with master list kept as a hardcopy or on a secure network[ ]  Other – please specify: | Hardcopy data[ ]  Locked suite[ ]  Locked office[ ]  Locked file cabinet[ ]  Data de-identified by PI or research team[ ]  Data coded by PI or research team with a master list secured and kept separately[ ]  24-hour personnel supervision[ ]  Other – please specify: |

**NOTE: Data must be kept for three [3] years after completion of the study.**

1. **Conflict of Interest**
	1. **Access to Study Population**

Describe:

|  |  |
| --- | --- |
| **a.)** How do you have access to this study population (e.g., superintendent at the school, instructor of a class, gatekeeper, etc.) |  |
| **b.)** Your and any co-investigator’s authorization to review existing data, documents, records, or specimens(*Item b.) is only applicable to Category 4*). |  |

**NOTE: Letters of agreement from cooperating research sites should be included as an appendix.**

* 1. **Role of Investigator (and Co-Investigators)**

Describe:

|  |  |
| --- | --- |
| **a.)** The role of the investigator (and co-investigators) with the participants |  |
| **b.)** If there any conflicts of interest between the researcher and the participants (e.g., supervisory or evaluative role over participants, power differential in title or position, etc) |  |
| **c.)** Steps taken to mitigate any potential conflict of interest |  |

* 1. **Financial Conflict of Interest**

Indicate whether you, your spouse or dependent children, or any investigator participating in the study have, or anticipate having, any income from or financial interest in the sponsor of the protocol, the supporting organization, or a company that owns or licenses the technology being studied that may reasonably affect the outcome of the research. Financial interest includes but is not limited to consulting, speaking, or other fees; honoraria; gifts; licensing revenues; other research agreements; equity interests (including stock, stock options, warrants, partnership, and other equitable ownership interests).

**Check one of the following:**

|  |  |  |
| --- | --- | --- |
| **a.)** [ ] No financial interest | **b.)** [ ] Financial interest UNDER $10,000 in aggregate | **c.)** [ ] Financial Interest OVER $10,000 in aggregate |
| *If you selected b.) or c.):*1. *You must submit a discloser document that describes the above financial relationship. NOTE: This information must be disclosed to the Missouri Baptist University IRB prior to enrolling participants in this study. If your current Financial Disclosure Statement does not contain this information, contact your research administration office to update your form.*
2. *Date discloser document was submitted to the IRB:*

*NOTE: You may not begin your study until your disclosure form has been reviewed and any requirement management plan has been approved by the CCI.* |

1. **Appendices**
	1. **Appendix Checklist**

Submit your application with the following materials, if applicable:

[ ]  Formal research protocol (e.g. grant application, sponsor protocol)

[ ]  Questionnaire, survey

[ ]  Interview questions

[ ]  Data collection sheets (e.g. a list or spreadsheet of the data elements to be collected or studied)

[ ]  Recruitment materials (email invitations, flyers, advertisements, telephone scripts)

[ ]  Cover letters or recruitment statement to participants

[ ]  Informed consent forms

[ ]  Site permission letters or site cooperation letters

[ ]  HIPAA related materials (e.g. De-Identification Certification Form)

[ ]  FERPA related materials

[ ]  Documentation of external IRB approval from other sites where research is conducted

[ ]  Documentation that all investigators have completed human subject research (HSR) participant protection training

* 1. **List of Appendices**

|  |  |
| --- | --- |
| Provide a complete list of the appendices you are including with your application. *When referencing an appendix throughout the application, cite the appendix by including “(See Appendix Number)” in your response.* | List: |

1. **Submission and Signatures**
	1. **Submission**

When you have completed the application and your faculty advisor or committee chair has reviewed and approved, submit the application (as a Word document) and all appendices (in the format best suited for the document) to IRB@mobap.edu.

* 1. **Signatures**

You will receive your full application via SignNow (a secure, electronic signature service). Your signature on the application indicates that you accept responsibility and have used the ethical guidelines set forth by the Belmont Report, Declaration of Helsinki, the Nuremberg Code, or the Ethical Principles of the American Psychological Association for the research described.

The signature of the Principal Investigator and Faculty Advisor or Committee Chair indicates that the Principal Investigator has the requisite credentials, training, and any necessary privileges to carry out all procedures involved in the protocol. It is expected that universal precautions will be used in handling all research specimens.

You may not begin your research (collect data) until you receive confirmation that the research has been approved via a signature from the IRB Chairperson or IRB Designee on your IRB application and an IRB Approval Letter with your IRB Approval Number.

NOTE: Any revision to the research protocol MUST be approved by the IRB BEFORE implementation to determine its effect of your study.

Please keep a copy of your materials and a copy of this application for your records.

**Approval**

**Principal Investigator (PI) Signature**

*­­­­­ Name Date*

**I will keep all data for three years after completion of the study. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

*Initials*

As Dissertation Committee Chair, I am signing that I have read and approve the submission of the IRB application for the above PI.

**Dissertation Committee Chair Signature**

*­­­­­ Name Date*

As IRB Chairperson, I am signing that this IRB application has been vetted and approved by the MBU Institutional Review Board.

**IRB Chairperson or IRB Designee Signature**

*Name Date*

The Principal Investigator has been given approval to collect data for one year from the approval date below. After one year, if any data collection is needed, the investigator must apply for an extension.

|  |
| --- |
| Stamp of IRB APPROVALIRB APPROVAL NUMBER: IRB APPROVAL DATE:  |

**This study meets the criteria for exemption. Y:\_\_\_\_\_\_\_ N:\_\_\_\_\_\_\_**

**Approval: Full:\_\_\_\_\_\_\_ OR Contingent Upon:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Disapproval:\_\_\_\_\_\_\_\_**