**EXEMPT RESEARCH PROTOCOL**

*(v.27JAN25)*

Your research involving human subjects ***must*** fall into one or more of the categories listed in the table below to meet the exemption criteria. Otherwise, please use either the *Social and Behavioral* or *Biomedical* research templates.

**Exempt Categories**

|  |  |  |
| --- | --- | --- |
| Please select the exempt category that best describes your research: | | |
|  | **Exempt Category** | **Criteria** |
|  | Exempt 1: Normal Educational Practices | 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 of or the comparison among instructional techniques, curricula, or classroom management methods. |
|  | Exempt 2: Educational Tests, Surveys or Interviews, or Public Observation | Research that only includes interactions (*may not include interventions*) involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) ***if at least one of the following criteria is met***:  (i) 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;  (ii) 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  (iii) 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)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.111(a)(7)).  *Children may participate in Exemption 2 (i) and (ii) if the research is limited to educational tests or the investigator(s) do not participate in the activities being observed during observation of public behavior.* |
|  | Exempt 3: Benign Behavioral Intervention | 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***:  (i) 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;  (ii) 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  (iii) 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)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.111(a)(7)).  The benign behavioral interventions ***must be*** brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.  NOTE: If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.  *Children are not eligible for Exempt 3 research.* |
|  | Exempt 4: Secondary Use of Data or Specimens | 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:  (i) The identifiable private information or identifiable biospecimens are publicly available;  (ii) 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;  For criteria (iii) and (iv), please visit <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-a-46104/index.html> |
|  | Exempt 5: Federal Research and Demonstration Projects | 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. For additional criteria please visit <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-a-46104/index.html> |
|  | Exempt 6: Taste and Food Quality | Taste and food quality evaluation and consumer acceptance studies:  (i) If wholesome foods without additives are consumed, or  (ii) 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 U.S. Department of Agriculture. |

**NOTE: Prisoners may not be included in exempt research, except for research aimed at involving a broader subject population that only incidentally includes prisoners.**

**PROTOCOL TITLE:** *<< Include the full study title>>*

**VERSION DATE:** *MM/DD/YYYY*

**PRINCIPAL INVESTIGATOR**

Name:

Department:

Email address:

|  |
| --- |
| ***Please note*** that undergraduate and graduate students are not allowed to be the Principal Investigator on a research study (see [University Policy 4012](https://universitypolicy.gmu.edu/policies/principal-investigators/)). Adjunct faculty members, affiliate faculty members, part-time, fixed-term faculty, and post-doctoral fellows may only serve as Principal Investigator with the permission of their Dean or Department Head on a case by case basis. Please contact the IRB for more information. |

**Is this study part of a dissertation or thesis?**  Yes  No

**Is this study part of a capstone project?**   Yes  No

**Is this study an assignment for a class?**   Yes  No

**If yes, what class?** <<Insert course number>>

Please complete the table below and identify all the study procedures that will be conducted in this study:

|  |  |
| --- | --- |
| Check any **applicable** boxes: | |
| Normal Educational Practices | Taste and Food Quality |
| Surveys | Educational Tests |
| Interviews | Benign Behavioral Interventions |
| Observation of Public Behavior | Secondary Use of Data or Specimens |
| Deception | Focus Groups |

**1. Purpose and rationale of the study:**

<< Describe the purpose of your study. Include a description of your objectives, aims, and/or research question/hypothesis being tested. >>

**2. Study procedures:**

<< Describe the study procedures **in detail**. Identify all study procedures the participants will be asked to complete during the study, and how long the participants will be engaged in the research completing each procedure. >>

**3. Study population:**

<< Provide the inclusion and exclusion criteria for the study populations that will be targeted for enrollment or data collection. >>

**Does your study population involve children under the age of 18?**

Yes  No

1. **How many participants will be enrolled?** << Provide numerical response >>
2. **If obtaining pre-existing records for secondary analysis, how many subject records will be obtained or received?** << Provide numerical response >>
3. **If obtaining pre-existing biological specimens for secondary analysis, how many subject specimens will you receive?** << Provide numerical response >>

**4. Recruitment:**

<< Describe when, where, and how potential participants will be recruited. Describe the types of strategies and materials that will be used to recruit participants. >>

**5. Study Location:**

<< List the locations where the research will take place. >>

**Will this research occur at an external or non-GMU entity?**   Yes  No

*You will need to provide a site authorization or permission document if the research is taking place in an external or non-GMU location.*

**6. Potential Risks to Participants**

<< *Describe the reasonably foreseeable risks, discomforts, hazards, or inconveniences related to the participant's participation in the research. Describe the probability, magnitude, duration, and reversibility of the risks.*

*Consider physical, psychological, social, legal, and economic risks as well as community or group harms. Note: a breach of confidentiality is a common risk in social and behavioral research.* >>

**7. Benefits to Participants**

<< *Describe any benefits to the participant. Do not include incentives or compensation as a benefit. >>*

**8. Consent Process**

<< *Describe the process you will use to obtain informed consent (written, verbal, online, etc.) from participants, including where and when the consent process will occur. If you will obtain consent in different ways for different participant groups or study phases, describe the consent process that you will be using for each participant group or study phase.>>*

**Will participants be asked to sign the consent document?**   Yes  No

**Will you use an electronic consent document?**   Yes  No

**9. Participant Compensation**

<< *Describe any compensation or extra credit that will be provided to participants >>*

**10. Personally Identifiable Information**

<< Please complete the table below. If you have a data collection document or spreadsheet that includes the variables you will collect, it should be provided as a Word or PDF document with your online submission. >>

|  |  |
| --- | --- |
| Identify all personally identifiable information (PII) or protected health information (PHI) you will receive, collect, or record ***even if you plan to anonymize the data or specimens***.  Check any **applicable** boxes. | |
| None | IP addresses |
| Names | Date of births |
| Email addresses | Zip Codes |
| Phone numbers | Social security numbers |
| Medical record numbers | Student or employee numbers |
| PHI | Web URL |
| Other <*< describe >>* | |

**11. Provisions to Protect Participant Privacy and Data Confidentiality**

*<< Describe the process for protecting the privacy of the participants and the confidentiality of participant data. Include where and how the data will be stored (specific servers, encryption, password protection, individuals with access). Note: data must be kept a minimum of 5 years (or 6 years for studies involving HIPAA regulated PHI) after study completion or as required by study sponsor. >>*

**12. Generalize findings**

*<<Generalizable knowledge: The information gained from the research is expected to expand the knowledge base of a scientific discipline or other scholarly field of study and yield one or both of the following:*

* *Results that are applicable to a larger population beyond the site of data collection or the specific subjects studied*
* *Results that are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.>>*

**There is an intent to generalize the findings of this research to others beyond this study?**

Yes  No