**EXEMPT RESEARCH PROTOCOL TEMPLATE**

**INSTRUCTIONS:**

* Use HRP-503a – TEMPLATE - Exempt Protocol to prepare a document with the information from following sections. HRP-503a should be used for exempt level research. HRP-503 should be used for expedited and full board protocols. 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 the full board/expedited research template (HRP-503). To determine if your research falls under an exemption category, please consult HRP-312 WORKSHEET: Exemption Determination and/or the HHS decision chart for exemption determination.
* For research involving secondary use of data, documents, records, or specimens, please complete HRP-900 – APPENDIX – Secondary Use of Data and upload it under ‘Local Site Documents’. This applies to research falling in Exempt category 4.
* Depending on the nature of your study, some sections may not be applicable to your research. If so mark as “NA”.
* Delete all orange italicized instructional/help text prior to submitting (or use the version without instructions).
* While you will be able to download a copy of the protocol from the system, you should always keep an electronic copy. When making changes, we strongly recommend that you download the most recent copy of your protocol directly from Endeavor. This will allow you to make changes that will be detected by Endeavor for ease of reviewing. Failure to do so may delay the review process.
* As you are writing the protocol, remove all instructions in orange italics so that they are not contained in the final version of your protocol (or use the version without instructions available on the IRB website, the Endeavor IRB Canvas site, or through Endeavor) and use this copy as a guide).

**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>  \*\*If your research ONLY involves secondary use of data, please complete HRP 900 – APPENDIX – SECONDARY USE OF DATA. However, if your research involves any activities other than secondary use of data, documents, records, or specimens, continue with this form. |
|  | 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. |
|  | Exempt 7: Storage or Maintenance of Secondary Research | Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts limited IRB review (see HRP-319 - WORKSHEET - Limited IRB Review and Broad Consent). For research involving secondary use of data, documents, records, or specimens, please attach the completed HRP-900 -APPENDIX – Secondary Use of Data under ‘Local Site Documents’. Please note that at this time, AU does not have the institutional infrastructure to support this category of research. |
|  | Exempt 8: Secondary Research | Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use (see HRP-319 - WORKSHEET - Limited IRB Review and Broad Consent). For research involving secondary use of data, documents, records, or specimens, please complete and attach HRP-900 under ‘Local Site Documents’. Please note that at this time, AU does not have the institutional infrastructure to support this category of research. |

**NOTES:**

* Prisoners may not be included in exempt research, except for research aimed at involving a broader subject population that only incidentally includes prisoners.
* Exemption categories 7 and 8 require broad consent. The AU IRB has determined the regulatory requirements for legally effective broad consent are not feasible within the current institutional infrastructure. Exempt categories 7 and 8 will not be implemented at this time.

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

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

**ANTICIPATED START DATE:** *MM/DD/YYYY*

**ANTICIPATED END DATE:** *MM/DD/YYYY*

**PRINCIPAL INVESTIGATOR:**

**Name:**

**Department:**

**Email address:**

PI is not a student.

I have read the PI eligibility statement in HRP 103 – INVESTIGATOR MANUAL and confirm that the above named PI meets criteria to be a PI on an IRB protocol at AU.

***\*\*BOTH BOXES MUST BE CHECKED\*\****

***\*\*ALL KEY PERSONNEL MUST BE ADDED THROUGH ‘LOCAL STUDY TEAM MEMBERS’ IN ENDEAVOR. PLEASE ENSURE THAT ALL PERSONNEL HAVE COMPLETED THE NECESSARY MODULES TO CONDUCT RESEARCH AS SPECIFIED IN HRP-103 – INVESTIGATOR MANUAL. YOU CAN CHECK THE STATUS OF CITI TRAINING BY CLICKING ON THE ‘TRAINING’ TAB IN ENDEAVOR. TRAINING THAT OCCURS OUTSIDE OF CITI MUST BE UPLOADED UNDER THE ‘LOCAL SITE DOCUMENTS’ SECTION OF YOUR PROTOCOL.\*\****

**DEPARTMENT HEAD/CHAIR:**

**Name:**

**Email address:**

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| --- |
| ***Please Note:*** Undergraduate and graduate students are not allowed to be the Principal Investigator on a research study. For further information on who is eligible to serve as a Principal Investigator, see HRP-103 – INVESTIGATOR MANUAL. |

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

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

**FUNDING INFORMATION:**

**Check all that apply.**

|  |
| --- |
| Not funded by any source. |
| Internal funding. Provide the source/mechanism of internal support: |
| U.S. Federal government funding (i.e., DoD, NIH, NSF, etc.) via one or more direct awards or a sub-award. Provide the source of federal support: |
| Other sources of funding (please specify): |

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 | Other (specify): |

**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. If applicable, include gender, sex, race, and ethnicity of the participant population.*

1. **How many participants will be enrolled?** *Provide numerical response.*
2. **How many subject records will be obtained or received?** *Provide numerical response.*
3. **How many subject specimens will you receive?** *Provide numerical response.*

**Does the study target any of these special populations (check all that apply):**

|  |  |  |  |
| --- | --- | --- | --- |
| Pregnant people/fetuses | Known interpersonal relationships | At risk for/Experiencing substance use disorder | LBGTQIA+ |
| Minors | At risk of/Experiencing homelessness | Refugees | American Indian/Alaskan Native |
| Prisoners/Justice-Involved | Persons with economic disadvantages | Disabled people/People with disabilities | AU faculty, staff, students |
| Persons with educational disadvantages | Decisionally or intellectually impaired | Unauthorized immigrants | Non-AU Students |

**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.* *Please keep in mind that recruitment materials must follow the University distribution policies as well as individual building policies. Please refer to HRP-315 – WORKSHEET –ADVERTISEMENTS for guidance.*

**5. Study Location(s):**

*List the locations where the research will take place.*

**Will this research occur at an external or non-AU 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-AU location. If you are conducting research at schools, please make use of the School Site Authorization template to obtain permission. Permission templates can be found here: <insert link>*

**If your research involves AU students’ records, do you have permission from the AU Registrar to conduct the research?**

This research does not include AU students’ records

Yes *(Provide the approval correspondence from the Registrar’s office as an attachment)*

No

*Please note: If you intend to use your student’s grades for research purposes, you must obtain written informed consent and explicitly indicate how the grades will be used and that their participation will have no bearing on their grade in the course. Please be sure to consult HRP-331 to ensure compliance with FERPA.*

**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. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research is not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or test. 45 CFR 46.102(j)*

*Note: A breach of confidentiality is a common risk in social and behavioral research. All exempt research is required to be no more than minimal risk.*

**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. Consent templates can be found on the IRB website, the Endeavor IRB Canvas site, and within Endeavor. Please* refer to HRP-411 – CHECKLIST – Waiver of Written Documentation of Consent and/or HRP-410 – CHECKLIST – Waiver or Alteration of Consent Process.

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

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

|  |  |
| --- | --- |
|  | Waiver of Consent (Including existing de-identified data) |
|  | Waiver of Documentation of Consent (Use of Information Letter, rather than consent form requiring signatures) |
|  | Waiver of Parental Permission (in Alabama, 18 years-olds may be considered adults for research purposes) |

**Provide the rationale for the waiver request:**

**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 3 years after study completion or as required by sponsor. AU IRB recommends AU Box. If a data collection form will be used, submit a copy of the form. If applicable, submit a copy of the data management plan or data use agreement. Attach HRP-902 – APPENDIX – Anonymous Data Collection Assurance under Local Site Documents 🡪 Other Attachments when you will be collecting anonymous data that is sensitive in nature or could be considered more than minimal risk if it were to be identifiable.*

**12. Describe how the results of this study will be used.**

*Is there is an intent to generalize the findings of this research to others beyond this study; or to publish the findings; or to present the findings at professional conferences? Describe how the results will be disseminated.*

**As a reminder, please upload all additional materials supporting your protocol to ‘Local Site Documents’ in Endeavor. This may include, but is not limited to:**

• Data collection instruments

• Letters of support/permission

• Debriefing forms

• Vendor vetting documentation

• Scripts

• Data use agreements

• Conflict of Interest (COI) management plans

• Referral lists

• Emergency Action Plans (EAPs)

• Data Safety Monitoring Board (DSMB) plans

• Data security plans

• Recruitment materials (i.e., flyers, social media posts, etc.)

• Additional training certificates that are external to CITI (i.e., phlebotomy certificates, youth protection training, etc.)

• Clinical trial registration confirmation

• Relevant appendices (i.e., mental health safety plan, MRI appendix (HRP-901), anonymous data collection assurance (HRP-902), etc.)