**Auburn University at Montgomery**

**Institutional Review Board (IRB)**

**109 Administration Bldg,**

[**dtomblin@aum.edu**](mailto:dtomblin@aum.edu)

**Request for Exemption**

IRB #\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Directions:** All research conducted at AUM involving human subjects must be reviewed by the AUM IRB prior to the beginning of the project. If you feel that your project may qualify for exemption, please complete this form. Researchers themselves cannot determine the status of their research projects. The IRB must determine which research projects are exempt from IRB review and which projects are not. *This form must be typed*.

Please refer to the end of this document for definition of terms and Federal Regulations.

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| **Section A: Information Regarding Principal Investigator (PI)** | |
| PI Name:  School/Dept:  Email:  Phone: | Title (check one):  Faculty  Graduate Student  Undergraduate Student  Other, describe: |
| Please include a copy of your CITI ([www.citiprogram.org](http://www.citiprogram.org)) on-line training completion report.  CITI report attached: Yes No | |

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| **Section B: Research Information** | |
| Title of Project:  Proposed dates of project: | |
| 1. **Special Populations**   **(check all that apply):**  Minors (under 19)  Prisoners  Pregnant Women  Physically or mentally Challenged  Diminished Capacity to give informed consent | 1. **Categories of Sensitive Information (check all that apply):**   Information relating to sexual attitudes, preferences or practices.  Information relating to the use of alcohol, drugs, or other addictive products.  Information pertaining to illegal conduct.  Information that if released could reasonably damage an individual’s financial standing, employability, or reputation within the community.  Information that would normally be recorded in a patient’s medical record and the disclosure of which could reasonably lead to social stigmatization or discrimination  Information pertaining to an individual’s psychological well being or mental health |
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| **Section C: Research Risks & Methodology** | |
| 1. **Risks to Participants Identify all risks that may be reasonably expected as a result of participating in this research:**   Breach of confidentiality  Deception  Psychological  Coercion  Physical  Social  Other, describe: | 1. **Identify the descriptors that best apply to the research methodology (check all that apply):**   Prospective data  Retrospective data  Educational test (Cognitive, diagnostic, aptitude, achievement)  Surveys/questionnaires  Private records/files  Interviews  Observations  Audiotaping  Videotaping  Photographs  Physical/physiologic measurements or specimens  Other, explain: |
| 1. **Is any of the research conducted at a location other than AUM?** Yes No   If “yes”, give location/s: | |
| 1. **Will the results of the research be published or presented** (including thesis/dissertation) ?   Yes No | |

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| **Section D: Summary of Proposed Research** |
| 1. Describe the purpose of the research project: |
| 1. Describe how research subjects (participants) will be recruited. |
| 1. Explain what the research subjects will be asked to do (including sequence, amount of time required, location, etc): |
| 1. How will the risks (identified in Section C.3) be addressed? |
| 1. List all data collection instruments and techniques you plan to use (e.g. questionnaires, surveys, scripts, etc) |

For IRB use only:

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| --- |
| Date received by IRB:  Date assigned review:  Review type: Exempt  Referral to IRB for review  Date of determination:  Notes: |

**Additional Information:**

**Definitions of terms**

1. **Coercion:** persuading an otherwise unwilling person to do something by using force or threats
2. **Competency:**  Technically, a legal term, used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. (*See also: Incompetence, Incapacity*.)
3. **Confidentiality:** Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others, in ways that are inconsistent with the understanding of the original disclosure, without permission.
4. **Deception:** giving the appearance or perception different from the true one.
5. **Human subject:** A living individual about whom an investigator (professional or student) conducting research obtains: a) data through intervention or interaction with the individual, or b) identifiable, private information.
6. **Institutional Review Board:** A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research [Federal Policy 46.102(g), 46.108, 46.109].
7. **Minimal risk:** Probability and magnitude of physical or psychological harm that does not exceed those encountered in ordinary, everyday life or in the performance of routine medical or psychological examinations.
8. **Principal Investigator:** The scientist or scholar with primary responsibility for the design and conduct of a research project.
9. **Private Information:** Behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or information, provided for specific purposes by an individual, which that individual can reasonably expect will not be made public, (i.e., a medical record.)
10. **Research:** Systematic investigation designed to develop or contribute to general knowledge.

Under this definition some demonstration, service, and training projects may be considered to include research activities.

1. **Prospective Studies**: Studies designed to observe outcomes or events that occur subsequent to the identification of the group of subjects to be studied. Prospective studies need not involve manipulation or intervention but may be purely observational or involve only the collection of data. IRBs should note that prospective studies do *not* qualify for exemption under Federal Policy §45 CFR 46.101(b)(4) because the data or specimens in prospective studies are not extant at the time the study begins
2. **Retrospective Studies:** Research conducted by reviewing records from the past (*e.g*., birth and death certificates, medical records, school records, or employment records) or by obtaining information about past events elicited through interviews or surveys. Case control studies are an example of this type of research.

**LIST OF EXEMPT CATEGORIES**

**[As listed in *Code of Federal Regulations*, Title 45, Part 46.101(b)]**

1. Educational Research Conducted in Educational Settings: Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
   1. research on regular and special education instructional strategies, or
   2. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Survey/Interview/Observational Research: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior unless
   1. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; *and*
   2. any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3. Survey/Interview Research Not Exempted in (2) Above: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if

1. human subjects are elected or appointed public officials or candidates for public office; *or*
2. federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
3. Secondary Use of Existing Data: Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are *publicly available* or if the information is recorded by the investigator in such a manner that *subjects cannot be identified,* directly or through identifiers linked to the subjects.
4. Evaluation and Demonstration Projects of Federal Programs: Research and demonstration projects that are conducted by or subject to the approval of department or agency heads, and that are designed to study, evaluate, or otherwise examine
   1. public benefit or service programs;
   2. procedures for obtaining benefits or services under those programs;
   3. possible changes in or alternatives to those programs or procedures; or
   4. possible changes in methods or levels of payment for benefits or services under those programs.
5. Taste and Food Quality Studies: 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 ([FDA](http://www.fda.gov)) or approved by the Environmental Protection Agency ([EPA](http://www.epa.gov)) or the Food Safety and Inspection Service of the US Department of Agriculture ([USDA](http://www.usda.gov)).

# LIMITATIONS TO EXEMPT CATEGORIES

* Exemption 2 does not apply to the following types of research involving [children](http://www.irb.uiuc.edu/ihb/glossary.asp#child): surveys, interviews, and observations of public behavior when the investigator is a participant in the activities being observed.
* Research involving prisoners, pregnant women, people not competent to provide informed consent, or fetuses cannot be exempt.
* Research involving use of personal records such as health care information, drug and alcohol treatment records, psychiatric treatment records, educational records, and other records protected by the Federal Privacy Act and other federal and state laws cannot be exempt.