1. PURPOSE

1.1. The University of Georgia Institutional Review Board (UGA IRB) requires that all activities involving the use of human participants in research receive prior review and approval. Under certain circumstances, human research activities may qualify for exempt review.

1.2. The purpose of this policy is to provide: (1) information to researchers about what human research activities are considered exempt; (2) the responsibilities of the researchers in the ethical conduct of human participant research; (3) the application and review process for research that is exempt, and (4) information about changes made to the research study that would require IRB review.

2. DEFINITIONS

2.1. **Exempt Research** is a category of IRB review. It does not mean that a study can be conducted without, or is exempted from, IRB review. Exempt studies are so named because these are exempt from meeting the requirements of the federal human subjects regulations, such as the requirement for continuing review.

2.2. **Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

2.3. **Federally Funded** means projects with any funding or support from a US federal agency, including subawards or contracts, no cost extensions, projects where any research team member (such as a student) is paid/supported from a federal award, or otherwise paid/supported directly from the Faculty Advisor’s federal funds, federal sponsorship, including federal training grants and center grants, and contractual obligations to follow federal research requirements.

2.4. **Existing** or “on-the-shelf” means data, documents, records, biological specimens, or diagnostic specimens are already existing or on the shelf at the time of IRB submission.

3. POLICY

3.1. Research qualifies for exempt review only if it involves no more than minimal risk or no risk to participants and fall within one or more of the exemption categories listed in the federal regulations (DHHS) or UGA’s flexibility criteria (FLEX). The categories are listed below. For certain conditions and examples, see table at end of document.

3.2. Exempt status does not, however, lessen the ethical obligations to human participants as articulated in the Belmont Report and in disciplinary codes of professional conduct.
3.3. Principal investigator and all individuals engaged in the conduct of the research should have successfully completed the IRB training at the time of initial application or submission of modification request to add new research team members.

3.4. There are additional protections when vulnerable populations are specifically targeted for research. As a result, there are certain restrictions on their involvement in exempt research which are as follows:

3.4.1. Exempt review does not apply to research involving prisoners.

3.4.2. Research that involves children may be exempt in all categories with the exception of Categories 2 and 7. Regarding Category 2: Research involving survey or interview procedures, or observation of public behavior, does not apply to research involving children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

3.5. Research that is subject to FDA regulations may be exempt only under category 6.

3.6. Researchers are required to submit an application for exempt review through the IRB’s electronic application system. The submission is reviewed on an ongoing basis; there are no submission deadlines.

3.7. Research subjects are informed of the research through a documented or undocumented consent process, if appropriate.

3.8. Because all research activities involved in a project must fit into at least one of the exempt categories in order to be considered exempt, if any part of a project does not fit an exempt category then the entire study must be reviewed by an IRB through an expedited or full board review.

3.9. OHRP’s longstanding guidance recommends that exempt determinations be made by a knowledgeable and appropriately trained individual designated by the institution, and that investigators not be given the authority to determine that their own research is exempt, due to conflict of interest concerns. At UGA, exempt studies are reviewed by a qualified IRB staff who has no conflict of interest and is not affiliated with the research activities to be conducted.

3.10. The research may not begin until the investigator has received notification from the IRB that the research qualifies for exemption.

3.11. An exempt study is typically given an end date of five years. A new submission is required if the study will continue after five years. If the research is completed before the end date, the PI should submit a Continuing Review for Study Closure.

3.12. Research is compliant with other applicable federal and state laws and institutional policies. Applicable federal laws include, but are not limited to Family Educational Rights and Privacy Act (FERPA), Protection of Pupil Rights Amendment (PPRA), and Children's Online Privacy Protection (COPPA).

3.13. Research initially determined to qualify for FLEX-Exempt Category 7 or 8 and later becomes federally funded, supported, or regulated, must be reported by the researcher immediately to the IRB and any research activities that will be supported by the federal funding cannot commence until IRB approval is obtained.

3.14. Modifications to an approved exempt study that would require prior IRB review and approval include changes in study population and/or risk assessment that may not qualify for exempt review, and changes to study team personnel.
4. **DHHS Categories for Exempt Research (§46.101).** DHHS-Exempt 1: Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research (a) on regular and special education instructional strategies, or (b) to evaluate the effectiveness of or to compare instructional techniques, curricula, or classroom management methods.

4.1. DHHS-Exempt 2: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability, or loss of insurability, or be damaging to the subjects' financial standing, employability, or reputation.

4.2. DHHS-Exempt 3: 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 category 2, if (a) the human subjects are elected or appointed public officials or candidates for public office; or (b) Federal statutes require without exception that the confidentiality of the personally identifiable information is maintained throughout the research and thereafter.

4.3. DHHS-Exempt 4: 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.

4.4. DHHS-Exempt 5: Research and demonstration projects which are conducted by or subject to the approval of Federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.

4.5. DHHS-Exempt 6: Taste and food quality evaluation and consumer acceptance studies if (a) wholesome foods without additives are consumed; or (b) a food is consumed that contains a food ingredient or agricultural chemical or environmental contaminant which is or below the level and for a use found to be safe by the FDA, or approved by the EPA or Food Safety and Inspection Service of the USDA.

5. **UGA-FLEX Categories for Exempt Research**

5.1. FLEX-Exempt 7: *Non-federally funded*, when the research activities do not conform to one of the six DHHS exempt categories, and involves research of individual or group characteristics or behavior using established qualitative data collection procedures which includes performance of non-physically invasive tasks and physical actions by a subject, presentation of stimuli, or manipulations.
5.2. **FLEX-Exempt 8: Non-federally funded**, when the research activities do not conform to one of the six DHHS exempt categories research and is limited to analysis of existing or prospective materials (data, documents, records, or specimens) and information may be recorded by the investigator in such a manner that subjects can be identified, directly or through identifiers linked to the subjects.

6. **PROCEDURES: Researchers**

6.1. A researcher submits a complete IRB application for exempt review through the IRB’s electronic application system. Researcher makes a preliminary assessment that the submission is eligible for exempt review, proposing that it falls into one or more of the applicable exempt categories. An IRB staff reviews the submission and makes the final determination if the submission is eligible for exemption.

6.2. If there are interactions or intervention with subjects, there should be an appropriate consent process [except in limited cases where a consent process would not be a natural part of the data collection process (e.g., in ethnographic observations/interviews)]. See Exempt Consent Guidance.

6.3. Report any complaints and unanticipated problems involving risks to subjects or others to the IRB.

6.4. Modifications to Exempt Studies

6.4.1. **For exempt research, only significant modifications and changes that that will disqualify study for exempt review must be submitted to the IRB. Researchers can implement minor changes to an approved exempt study without prior IRB review and approval.** The list of examples below is intended for purposes of general guidance only since it is not possible to include examples of all possible modifications. If there is any question if a modification requires review and approval, the PI should consult the IRB Office.

6.4.2. **Submit to IRB: Significant modifications and changes that make the study no longer eligible for exempt review** include, but are not limited to:

6.4.2.1. Receipt of new or additional federal funding or support for the human research activities (include the grant with the submission)

6.4.2.2. New knowledge, information or research question that increases the risk level and/or significantly changes the overall research design

6.4.2.3. Changes to, or additions of, conflicts of interest disclosures for study team members

6.4.2.4. Add a new group of participants that does not have the identical inclusion/exclusion criteria as the previously approved group (e.g., including children to a study previously approved for adults only; add prisoners)

6.4.2.5. Add data collection instrument, survey, etc. from which information obtained is recorded in such a manner that (i) human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) 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 (e.g., add to a non-anonymous survey questions about
sensitive aspects of the subjects’ behavior such as illegal conduct, drug use, sexual behavior, or alcohol use)

6.4.2.6. Survey, interview procedures, or observation of children that involves participation by the researcher that do not fall under exempt category 1

6.4.2.7. Use of any methods described in the expedited review categories that do not meet the exempt criteria (e.g., blood draws); for information about Expedited review categories, see [http://www.hhs.gov/ohrp/policy/expedited98.html](http://www.hhs.gov/ohrp/policy/expedited98.html)

6.4.2.8. Research subject to FDA regulations (except if exempt category 6 applies)

6.4.2.9. Change in PI and/or to other members of the study team

6.4.3. Do Not Submit to IRB: Minor changes include, but are not limited to:

6.4.3.1. Editorial or administrative revisions to consent documents, data collection materials, or other study documents (such as fixing typos/grammatical errors, restating the same questions for clarity, reordering or reformatting the questions, splitting one question into multiple questions)

6.4.3.2. Add or revise questions to a survey, interview or focus group, if the questions are similar in nature or follow the same theme/topic (e.g., to ask follow-up questions or seek clarification)

6.4.3.3. Add or revise recruitment procedures and/or materials, if consistent with UGA’s policy for recruitment and advertisements

6.4.3.4. Add a new group of participants that have the identical inclusion/exclusion criteria as the previously approved group (e.g., include a new Biology class to a study approved to target other Biology classes)

6.4.3.5. Increase or decrease the number of subjects, unless a new group of participants that does not have the identical inclusion/exclusion criteria as the previously approved group will be added

6.4.3.6. Add or revise research incentive that does influence a participant’s voluntary participation (i.e., does not unduly influence an individual into participation)

6.4.3.7. Change in data collection procedure that will not significantly change the overall research design (e.g., switch from a paper-and-pencil to an online survey or vice-versa)

6.4.3.8. Change in study title

6.4.3.9. Any change to recruitment material and/or consent document as a result of a minor study modification that will not require IRB review (e.g., change in incentive, data collection procedure, or title)

7. PROCEDURES: Institutional Review Board

7.1. The IRB staff applies the policy described in Section 3 to determine whether submission qualifies for exempt review. If necessary, additional information or clarification is requested from the investigator.

7.2. The IRB staff determines that the research meets UGA’s ethical standards as listed in the Exempt Checklist.
8. MATERIALS
   8.1. Exempt Checklist

9. REFERENCES
         http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
Exempt Consent Guidance

Any consent process and/or materials for exempt research are reviewed by the UGA IRB. The consent process should provide sufficient opportunity for subjects to consider whether to participate. Any information that will be disclosed to subjects to make a decision is presented in understandable language and should include the following:

1. The identity/affiliation and contact information of the Principal Investigator (PI) and student co-PI (if this is a student’s project).
2. A statement that indicates that the activity is research.
3. A statement that describes that participation is voluntary.
4. A statement that subjects can refuse to participate or withdraw their participation at any time.
5. A brief but complete description of the study procedures.
6. Anticipated duration of participation.
7. A description of any risks or discomforts to study participants. If none, the investigators should indicate so.
8. A description of any benefits to participants or society.
9. Name and contact information of individual to contact for answers to pertinent questions about the research. [This is usually the PI and/or the student co-PI (if this is a student’s project).]
10. Contact information for IRB, to respond to questions or concerns about subject rights.
11. The following additional information, only if applicable:
   i. A statement that individually identifiable results will be disclosed outside the research team (such as, use of direct quotes that will be attributed to an individual in presentations/publications; data will be shared with the classroom teacher or the school administrators).
   ii. A statement that refusal to participate or withdrawal from the study at any time will not affect their grades or class standing (if subjects are students in a class), or their employment or employment evaluations (if subjects are employees at a workplace).
   iii. A description of any incentives, compensation, or reimbursement for research participation.
   iv. For funded studies, name of the sponsor funding the research.
## Exemption Categories, Conditions and Examples

<table>
<thead>
<tr>
<th>Category</th>
<th>Definition</th>
<th>Conditions and Examples</th>
</tr>
</thead>
</table>
| **DHHS-Exempt 1** | Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research (a) on regular and special education instructional strategies, or (b) to evaluate the effectiveness of or to compare instructional techniques, curricula, or classroom management methods. | **Commonly accepted educational settings include but are not limited to K-12 schools and college classrooms. They may also include after-school programs, preschools, vocational schools, alternative education programs, adult education programs, 4H and cooperative extension programs, and other sites where educational activities regularly occur.**

**Normal educational practices include established or innovative teaching methods or curriculum, and commonly accepted classroom management techniques that are planned and implemented by the classroom teacher and/or adopted by the school as a classroom/teaching practice. Normal educational practices are activities that would occur regardless of whether the research is conducted and will be offered to all individuals whether they participate in the research or not.**

**Surveys, interviews, and participant observations are acceptable if they are about the curriculum or educational activity that is being studied. Studies that involve interactions or interventions with minors that are outside of “normal educational practices” do not qualify for this category of exemption. In comparison, in studies using between group design, the scope of the research must be relevant to the curriculum/educational activities to which each group would normally be exposed to outside the context of the research.**

*Example 1*: A study comparing two curricula that are currently being implemented in a school. The researchers will observe classroom instruction and ask the student participants to complete a pre-test and post-test at the beginning and end of the year to measure growth.

*Example 2*: A study evaluating the effectiveness of a commonly accepted special education intervention. The researchers will observe classroom instruction and make copies of the student participants’ Individualize Education Plan (IEP) and coursework to include in the research analysis. For the study, the researchers must obtain documented parental permission as the school records are protected by FERPA.

| **DHHS-Exempt 2** | Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through **Research involving children does not qualify for Category 2 exempt review when it involves:**

**Surveys or interview of children, or that involve children as third party subjects, that do not fall into Category 1.**

**Observation of the public behavior of children when the investigator participates in the activities or manipulates the environment in order to elicit certain kinds of behavior.**

**The research involves a task (except when the task is part of an educational test such as an intelligence test). For example, most intelligence (“IQ”) tests have the individual perform visual-spatial tasks.**
Identifiers linked to the subjects; and (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability, or loss of insurability, or be damaging to the subjects' financial standing, employability, or reputation.

**This “identifiability” criterion means that no identifiers are associated with the data, either directly or through a coding system. It is also possible that multiple pieces of information, none of which are identifiable on its own, may identify a person when brought together. Under such circumstances, the data would be considered identifiable.**

Any data collection that involves audio-recordings, video-recordings, or photographs of subjects would be considered identifiable.

**This risk of disclosure criterion means that there would be no significant detrimental consequences to the subject if identifiable information were disclosed outside of the research. Whether “consequences” would be significant and detrimental depends in part on context. For example, including a question about sexual identity in an interview study that investigates adults’ plans to change careers could be non-controversial – and exempt – in some locales, but highly sensitive – and therefore non-exempt – in other places.**

<table>
<thead>
<tr>
<th>Example 1: A study involving an anonymous survey regarding workplace satisfaction at area firms. Example 2: A study involving interviews with college seniors (age 18 and older) about their plans after graduation. The answers to the questions would present no risks to subjects if divulged outside of the research.</th>
</tr>
</thead>
</table>

<p>| DHHS-Exempt 3 | 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 category 2, if (a) the human subjects are elected or appointed public officials or candidates for public office; or (b) Federal statutes require without exception that the confidentiality of the personally identifiable information is maintained throughout the research and thereafter. <strong>This category is for the same procedures as in Category 2, but holds public servants to a different privacy standard by not requiring that the collected data be anonymous and is not concerned with any risks that may result from disclosure of the data. This category does not apply to public employees such as managers and staff in public agencies or offices. Federal guidance provides the following non-inclusive list of examples of public officials: Mayors, governors, School superintendents, school board members, and Police chiefs.</strong> <strong>This category applies only to research on specific programs conducted or supported by the federal Department of Justice or the federal National Center for Education Statistics.</strong> |
| Example 1: A study that includes interviewing town mayors about their religious beliefs and views on the separation of church and state. Example 2: A study of candidates for the state legislature that includes interview questions about their finances and state employment. |</p>
<table>
<thead>
<tr>
<th><strong>DHHS-Exempt 4</strong></th>
<th>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.</th>
<th><strong>The materials or data to be used in the research must be existing at the time the research is proposed to the IRB. This category does not apply to the prospective collection of data or specimens. Research that involves the ongoing collection of specimens and/or data does not meet the criteria for Category 4, even if they were destined to be discarded.</strong> Research can qualify for this category of exemption if the investigators initially have access to identifiable private information, but abstract the data needed for the research in such a way that the information can no longer be connected to the identity of the subjects. This means that the abstracted data set does not include direct identifiers (names, social security numbers, addresses, phone numbers, etc.) or indirect identifiers (codes or pseudonyms that are linked to the subject’s identity). <strong>If information or specimens will be received/transferred from another institution, the researchers should determine if they need a Materials Transfer Agreement (MTA) or Data Use Agreement.</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Example 1:</strong> A researcher conducts a retrospective chart review -- that is, the researcher only reviews data that was already in the medical record when the submission entered the UGA IRB. When extracting the data, the investigator does not record any identifiers or any other information that could link data to individual subjects. <strong>Example 2:</strong> A researcher studies publicly available data sets that include identifiers, i.e., NCI SEER, (Surveillance Epidemiology and End Results), NHANES, DMV records.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| **DHHS-Exempt 5** | Research and demonstration projects which are conducted by or subject to the approval of Federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs. | **The program under study must deliver a public benefit (e.g., financial or medical benefits as provided by Social Security) or service (e.g., social, supportive or nutrition services as provided under the Older Americans Act).** The research may be designed to study, evaluate, or otherwise examine the program; procedures for obtaining benefits or services under those programs; possible changes in methods or alternatives to those programs or procedures; or possible changes in methods or levels or payment for benefits or services under those programs. **The research or demonstration project must be conducted pursuant to specific federal statutory authority. [That is, the research is required by a federal law or regulation.]** There must be no statutory requirement that the project be reviewed by an IRB. **The project must not involve significant physical invasions or intrusions upon the privacy of the subjects.** This category applies only to federally-supported projects examining federal public benefits programs. It is extremely rare for research to meet the criteria of this category. |
**Example 1:** A researcher sponsored by the Department of Agriculture-Food and Nutrition Service wants to compare the current use of the Supplemental Nutrition Assistance Program (i.e., food stamps) by Americans compared to twenty years ago.

**Example 2:** A researcher sponsored by DHHS wants to conduct a study analyzing the effectiveness of various government sponsored programs in decreasing obesity in the United States.

<table>
<thead>
<tr>
<th>DHHS-Exempt 6</th>
<th>Taste and food quality evaluation and consumer acceptance studies if (a) wholesome foods without additives are consumed; or (b) a food is consumed that contains a food ingredient or agricultural chemical or environmental contaminant which is or below the level and for a use found to be safe by the FDA, or approved by the EPA or Food Safety and Inspection Service of the USDA. <strong>Research will not qualify for exempt status under Category 6 if there have been food and color additives incorporated into the food product and these additives are used in research with the intent to apply to the FDA for marketing of the additive(s).</strong> Taste and food quality evaluation studies conducted under this exemption may not involve the consumption of any type or volume of food that would present any risk to the subjects and should fall into what would be considered reasonable eating behaviors by the subject. <strong>The food must be “wholesome” (no additives), or if it involves plants or animals raised for food products, the level of chemical additives or environmental contaminants must be at or below the levels approved by the FDA, EPA, or USDA.</strong> <strong>Studies involving the consumption of alcohol, vitamins, and other dietary supplements do not qualify for exempt status.</strong></th>
</tr>
</thead>
</table>

Example 1: A taste test on different varieties of a fruit to determine consumer preference, when the fruits do not have any additives and subjects are asked to indicate which fruit they prefer.

Example 2: A study involves taste testing of various beef products from cattle that have been given feed with a chemical additive, if the investigator can document that the amount of the additive was at or below the level found to be safe by the FDA or approved by the EPA/USDA’s FSIS.

<table>
<thead>
<tr>
<th>FLEX-Exempt 7</th>
<th>Non-federally funded, when the research activities do not conform to one of the six DHHS exempt categories, and involves research of individual or group characteristics or behavior using established qualitative data collection procedures which includes performance of non-physically invasive tasks and physical actions by a subject, presentation of stimuli, or manipulations. <strong>Established qualitative data collection procedures include ethnography, action research teams and focus groups.</strong> <strong>Activities may include reading, writing, and card-sorting tasks; eye-tracking technology; computer and video games, internet searches, and photo/video elicitations; game or role playing, simple physical or mental actions; and, non-invasive visual/audio stimuli or tasks where the primary intention is not to affect emotional or physiological responses.</strong> <strong>Activities or tasks must not involve input of significant amounts of time and effort from the participants.</strong></th>
</tr>
</thead>
</table>

Example 1: A graduate student researcher in the Linguistics Department will ask participants to read on a computer screen twenty (20) words in English and in Latin while eye movements are being recorded.

Example 2: A researcher is studying the Kashmiri cuisine among members of a tribe in the Himalayas. In the process, the investigator will immerse herself in the ongoing everyday activities of the community for
the purpose of describing the social context, relationships and processes relevant to the cuisine. She will also conduct unobtrusive direct observations, participant observations, structured and unstructured interviews, and focused discussions with tribal members.

| FLEX-Exempt 8 | Non-federally funded, when the research activities do not conform to one of the six DHHS exempt categories research and is limited to analysis of existing or prospective materials (data, documents, records, or specimens) and information may be recorded by the investigator in such a manner that subjects can be identified, directly or through identifiers linked to the subjects. | ** Research which is FDA regulated are excluded from this category. ** Research with a Certificate of Confidentiality are excluded from this category. **Studies that typically fall under expedited category 5 may now fall under exempt category 8. |

**Example 1:** A study that is limited to the analysis of non-sensitive coded data that will be collected from participants who have signed up to join a non-research exercise program. It is important for the researchers to retain the codes (indirect identifiers) for the proposed analysis.

**Example 2:** A study will investigate the progression of cancer in individuals exposed to asbestos using existing biological tissues that were obtained from a previous research study. The researchers will retain the identifiers. The proposed analysis is specified in the consent form for initial sample collection.