1. PURPOSE
1.1. The purpose of this policy is to provide: (1) information to researchers about what human research activities are considered exempt; (2) a description of the responsibilities of the researchers in the ethical conduct of human participant research; (3) a description of the application and review process for exempt research, and (4) examples of modifications to exempt research studies that require and do not require IRB review.

2. DEFINITIONS
2.1. Exempt Research: studies that are exempt from meeting the requirements of the federal regulations for human subjects protections.
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 that those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
2.3. Federally Funded: projects with any funding or support from a US federal agency, including subawards or contracts, and projects where any Research Team Member is compensated or supported by a federal award or contract.
2.4. Individually Identifiable: the identity of the subject is or may readily be ascertained by the Investigator or associated with the information. Audio-recordings, video-recordings, or photographs of subjects would be considered identifiable information.
2.5. Existing: means information or a biological specimen that has been created or previously collected at the time of IRB submission.

3. POLICY
3.1. The University of Georgia Institutional Review Board (UGA IRB) requires that all activities involving the use of human subjects in research receive prior review, including human research activities that may qualify for exempt determination.
3.2. Research qualifies for exempt determination only if it involves no more than minimal risk or no risk to participants and falls within one or more of the exemption categories listed in the federal regulations (DHHS) or UGA’s flexibility criteria (FLEX). These categories, with certain conditions and examples, are listed in Appendix A of this policy.
3.3. Exempt research must meet the same ethical standards as non-exempt research and must protect human subjects as articulated in the Belmont Report and in disciplinary codes of professional conduct.
3.4. Researchers must submit an application for exempt determination through the UGA’s Click IRB Portal.
3.5. **Principal Investigator** and all individuals engaged in the conduct of the research should have successfully completed the appropriate IRB training at the time of initial application or submission of *modification* request to add new Research Team Members.

3.6. 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 [see footnote1, http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.101(b)(2)]:

3.6.1. Exempt determination does not apply to research involving **prisoners**.

3.6.2. All exemptions are applicable to research involving **children** except category 2. Exempt determination does not apply to federally-sponsored research with children involving survey, interview, or observation of public behavior (when the Investigator is participating in the activities being observed).

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

3.8. Research using **deception** or **incomplete disclosure** regarding the nature or purposes of the research is eligible for exempt determination if it meets the criteria for exempt determination as described in this policy and only if the subject authorizes the deception or incomplete disclosure. For the purpose of this policy, authorized deception or incomplete disclosure would be the prospective agreement by the subject to participate in research where the subject (or subject’s legally authorized representative) is informed that he or she will be unaware of or misled regarding the nature or purposes of the research. See *Policy and Procedure: Deception or Incomplete Disclosure*.

3.9. Research participants should be given sufficient information about the study through an **informed consent process**. This information includes:

3.9.1. That the activity involves research.
3.9.2. A description of the procedures.
3.9.3. That participation is voluntary.
3.9.4. Name and contact information for the Researcher(s).
3.9.5. There are adequate provisions to maintain the privacy interests of participants, if applicable.

See Appendix B of this policy for Exempt Consent Guidance.

3.10. All research activities involved must be eligible for at least one of the exempt categories in order to be determined exempt. If any of the research activities are not eligible for an exempt category, then the study will be reviewed by the IRB through an **expedited** or full board review.

3.11. 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.
3.11.1. The research may not commence or continue until the Investigator has received notification of IRB approval.

3.12. An exempt study is given an end date of five years.

3.13. Exempt Research must be compliant with other applicable federal, state laws and institutional policies. Applicable federal laws may include the Family Educational Rights and Privacy Act (FERPA) and Human Insurance Portability and Accountability Act (HIPAA). See Policy and Procedure: FERPA and Policy and Procedure: HIPAA.

3.14. Only significant modifications that may disqualify a study for exempt determination must be submitted to the IRB for prior approval. For examples of modifications that will require IRB review and approval, see Appendix C.1 of this policy.

3.15. Minor modifications to an approved exempt study may be implemented without IRB review and approval. For examples of modifications that will not require prior IRB Review and approval, see Appendix C.2 of this policy.

4. PROCEDURES: Researchers

4.1. In UGA’s Click IRB Portal, researcher should make a preliminary assessment that the submission is eligible for exempt review, and propose the applicable exempt category(ies).

4.2. All complaints and unanticipated events/problems involving risks to subjects or others must be reported to the IRB immediately.

4.3. The PI should submit a request for Study Closure when the study is complete.

5. PROCEDURES: Institutional Review Board

5.1. Assign to another IRB Staff Person if there is a conflicting interest (see Policy and Procedure: Conflicting Interest of IRB Members).

5.2. The IRB Staff applies the policy described in Section 3 to determine whether submission qualifies for exempt determination. If necessary, additional information or clarification is requested from the Investigator.

5.3. The IRB Staff determines that the research meets UGA’s ethical standards as listed in the Exempt Reviewer Checklist.

5.4. IRB Staff reviews the submission, makes the final determination if the submission is eligible for exemption, and records the applicable exemption category(ies).

6. MATERIALS

6.1. Exempt Reviewer Checklist
6.2. Appendix A: Exemption Categories, Conditions and Examples
6.3. Appendix B. Exempt Consent Guidance
6.4. Appendix C: Modifications to Exempt Research
7. REFERENCES

7.1. Belmont Report
7.2. 45 CFR 46 Department of Health and Human Services Protection of Human Subjects
7.3. Policy and Procedure: Deception or Incomplete Disclosure
7.4. Policy and Procedure: Conflicting Interest of IRB Members
7.5. Policy and Procedure: FERPA
7.6. Policy and Procedure: HIPAA
### Appendix A. Exemption Categories, Conditions and Examples

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<tr>
<th>Category</th>
<th>Definition</th>
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<tr>
<td><strong>DHHS-Exempt 1</strong></td>
<td>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.</td>
<td><strong>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.</strong>&lt;br&gt;<strong>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.</strong>&lt;br&gt;<strong>Surveys, interviews, and participant observations are acceptable if they are about the curriculum or educational activity that is being studied. 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.</strong></td>
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**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.<br>**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 | Research involving children does not qualify for Category 2 exempt determination when it involves:<br>**Surveys or interview of children which do not fall into Category 1.**<br>**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.**<br>The following activities are excluded from Category 2: |

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**Note**: The table and text content is formatted for clarity and readability. The content includes definitions and examples of exempt research categories under DHHS-Exempt 1 and 2, with conditions and examples provided for each. The text also references example studies to illustrate the application of these categories.
**Tasks or interventions directly intended to manipulate the environment and/or affect the subjects’ perceptions or responses.**

**The risk of disclosure criterion means that there would be significant detrimental consequences to the subject if identifiable information were disclosed outside of the research. 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.

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**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.*

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**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

**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.

**(b)** 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.
| 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. **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/data does not meet the criteria for Category 4, even if they were destined to be discarded. **Research can qualify for this category of exemption if the Investigators initially have access to identifiable private information/data, but abstract the data 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). **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. |

**Example 1:** A researcher conducts a retrospective chart review -- that is, the researcher will only review data that was already in the medical record when the submission entered the UGA’s Click IRB Portal. When extracting the data, the Investigator does not record any identifiers or any other information that could link data to individual subjects. |
### Exempt Review

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**Exempt Review**

- 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.

- 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.

### DHHS-Exempt

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| 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.

**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.**

**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.**

**Studies involving the consumption of alcohol, vitamins, and other dietary supplements do not qualify for exempt status.**

**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.
**Exempt Review**

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**Example 2:** A study that 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.

**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 or quantitative data collection procedures that may include benign interventions or performance of non-physically invasive tasks and physical actions by a subject, presentation of stimuli, or manipulations.

**Established qualitative data collection procedures include ethnography, action research teams and focus groups.**

**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.**

**Benign interventions would be brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and where the Investigator has no reason to think the subjects will find the interventions offensive or embarrassing.**

**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 information or biological specimens, and information may be recorded by the Investigator in such a way that the information is not acted upon.

**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.**

**This category may include information or specimens from children.**
manner that subjects can be identified, directly or through identifiers linked to the subjects.

Example 1: A study that is limited to the analysis of 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.

Appendix B. 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 brief statement of the purpose of the study.
4. A brief but complete description of the study procedures.
5. A statement that describes that participation is voluntary.
6. A statement that subjects can refuse to participate or withdraw their participation at any time.
7. Anticipated duration of participation.
8. A description of any risks or discomforts to study participants. If none, the Investigators should indicate so.
9. A description of any benefits to participants or society.
10. 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).]
11. Contact information for IRB, to respond to questions or concerns about subject rights.
12. 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. Adequate provisions to maintain the privacy interests of participants.
iii. 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).

iv. A description of any incentives, compensation, or reimbursement for research participation.

v. For funded studies, name of the sponsor funding the research.

Appendix C. Modifications to Exempt Research

Note: This is not intended to be an all-inclusive list and should serve as general guidance only. If there is any question if a modification requires review and approval, the researchers should consult the IRB Office.

C.1. Modifications that will require prior IRB review and approval

- Receipt of new or additional federal funding or support for the human research activities.
- New knowledge, information or research question that increases the risk level and/or significantly changes the overall research design.
- Changes to, or additions of, conflicts of interest disclosures for Study Team Members. See Policy and Procedure: Conflicting Interest.
- 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)
- 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).
- Surveys, interview procedures, or observation of children that involves participation by the researcher not eligible under exempt category 1.
- Research subject to FDA regulations (except if exempt category 6 applies).
- Change in PI and/or to other Members of the Study Team.

C.2. Modifications that will not require prior IRB review and approval

- Editorial or administrative revisions to consent documents, recruitment materials, 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
Revision and/or addition of questions to a survey, interview, or focus group, including follow-up questions or clarifications, if the questions are similar in nature, topic or theme to the approved data collection instruments.

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

Addition and/or decrease in the number of the study participants, if identical in inclusion/exclusion criteria as the previously approved group.

Addition/revision of participant incentive that does not unduly influence an individual’s decision to participate.

Revision of data collection procedures that does not alter the research design (e.g., switch from a paper-and-pencil to an online survey or vice-versa).

Study title change.

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).