Exempt Research

Number:	Date:	Author:	Approved By:	Page(s):
UGAHRP-033-2	01/21/2019	HSO	IRB	Page **1** of **5**

1. PURPOSE

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

2. DEFINITIONS

2.1. ***Benign behavioral interventions:*** interventions that are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the participants, and the investigator has no reason to think the participants will find the interventions offensive or embarrassing.

2.2. ***Exempt Research:*** research that is exempt from the laws, regulations, codes, or institutional guidance that govern the research.

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. Also: **Supported or Funded by a Federal Department or Agency**.

2.4. ***Individually Identifiable:*** the identity of the participant is or may readily be ascertained by the investigator or associated with the information. Audio-recordings, video-recordings, or photographs of participants would be considered identifiable information.

2.5. ***Limited IRB Review:*** a process that is required only for certain exemptions, and does not require an IRB to consider all of the IRB approval criteria in §46.111. In limited IRB review, the IRB must determine that certain conditions, which are specified in the regulations, are met. Limited IRB review may be done via the expedited review mechanism, that is, by the Chair or an experienced IRB member designated by the Chair (although it can also be conducted by the full IRB). Continuing review is not required.

2.6. ***Prospective Agreement:***

2.6.1. the process of describing a benign behavioral intervention and data collection procedures prior to beginning the activities in order to obtain a potential participant's agreement to take part in the activities; or

2.6.2. the process of obtaining authorization from a potential participant to participate in research in circumstances in which they are informed that deception or incomplete disclosure regarding the nature or purposes of the research will be involved.

3. POLICY

3.1. The University of Georgia Human Research Protection Program (UGA HRPP) requires that all research activities involving human subjects receive prior review by someone other than the Investigator, including human research activities that may qualify for exempt determination.

3.2. Investigators must submit requests for exempt determination through the UGA's IRB Portal.

3.3. Research qualifies for exempt determination if the research holds out no more than minimal risk to participants **and** it 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.

3.4. There are certain restrictions on the involvement of vulnerable populations in federally funded exempt research which are as follows:

3.4.1. Federally defined exempt determination categories do not apply to research involving prisoners <u>except</u> for research aimed at involving a broader participant population that only incidentally includes prisoners.

3.4.2. Federally defined exemptions (1), (2), (4), (5), (6), (7), and (8) are applicable to research involving children. *Category 2 can only be applied when research activities are limited to educational tests or observation of public behavior (when the investigator is participating in the activities being observed). Category 3 does not apply if the project involves children.*

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

3.6. 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** the participant authorizes the deception through a prospective agreement. *See Policy and Procedure: Deception or Incomplete Disclosure*

3.7. 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 is not eligible for an exempt category, then the study will be reviewed by the IRB through an expedited or full board review.

3.8. Determinations regarding whether research subject to the revised Common Rule qualifies for exempt status will be made by IRB Staff.

3.9. Research that is exempt from federal (DHHS) regulation may not be exempt from other federal regulations, laws, codes, and guidance. 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.

3.10. Exempt research must meet the same institutional ethical standards as non-exempt research, including adequate provisions when warranted, to: protect vulnerable participants, maintain the confidentiality of the data and the privacy interests of the participants, and protect participants as articulated in disciplinary codes of professional conduct.

3.11. UGA IRB Staff are authorized to conduct the institutional ethical evaluation of exempt research.

3.12. When the research requires limited IRB review or a HIPAA determination (i.e., waivers or alterations of the requirement for HIPAA authorization), the review will be conducted by a designated member of the IRB and may be conducted using expedited review procedures. As with all other research subject to IRB review requirements, when conducting limited IRB review the IRB has the authority to approve, require modifications in (to secure approval), or disapprove all research activities. [§__.109(a)]

3.13. For exempt research subject to limited IRB review, the following criteria shall be applied:

3.13.1. For exempt categories 2(iii) and 3(iii) (See Section 3.2), the IRB may approve the research when it determines that there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

3.13.2. For exempt category 7, the IRB may approve the research when it determines that **all** of the following criteria are satisfied:

a.) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of §__.116(a)(1) - (4), (a)(6), and (d);

b.) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with §__.117; and

c.) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

3.13.3. For exempt category 8, the IRB may approve the research when it determines that the following criteria are satisfied: a.) There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data; and b.) The research to be conducted is within the scope of the broad consent obtained from participants.

3.14. Research initially determined to qualify for UGA FLEX-Exempt Category 3 or 7 and later becomes federally funded, supported, or regulated, must be reported by the investigator immediately to the IRB.

3.14.1. The research may not commence or continue until the investigator has received notification of IRB determination or approval of the funded research.

3.15. Proposed modifications to federally funded exempt research, must be submitted to and approved by the IRB prior to implementation, except when necessary to eliminate apparent

immediate hazards to the participants, in which case the change must be promptly reported to the IRB. [§__.108(a)(3)(iii)]

3.16. Proposed modifications to exempt research that is not federally funded but that may disqualify a study for exempt determination or that may affect the applicable exemption category must be submitted to the IRB prior to implementation. For examples of modifications that will require IRB review and approval, see Appendix C.1 of this policy.

3.17. Minor modifications to exempt research that is not federally funded may be implemented without IRB review and approval. The process to notify the IRB Office of these changes is described in the Procedures below (4.5.) For examples of modifications that will not require prior IRB Review and approval, see Appendix C.2 of this policy.

3.18. Continuing review is generally not required for research determined to be exempt, even when that research is subject to limited IRB review. No expiration date will be assigned for most exempt research. However, the IRB may determine that continuing review is required for a particular study subject to limited IRB review, in which case it shall document the reasons for its determination in the IRB record and communicate the requirement to the investigator in the IRB determination letter. [§__.109(f)(ii), §__.115(a)(3)]

3.19. Principal Investigators are responsible for closing studies when all research activities are complete. A Progress Report will be requested five years after the Exempt determination is made to prompt for closure or otherwise report the status of the research project.

3.20. All complaints and unanticipated events/problems involving risks to participants related to the research must be reported promptly to the IRB.

4. PROCEDURES: Investigators

4.1. Create a new study in the IRB Portal. Respond to all submission questions and upload attachments where prompted.

4.2. Where prompted in the submission, make a preliminary assessment that the submission is eligible for exempt review, and propose the applicable exempt category(ies).

4.3. If a consent process is proposed or the exempt category requires prospective agreement, refer to Appendix B for guidance.

4.4. If there are requests for revisions or additional information during the review, submit revisions/responses in the portal.

4.5. After initial determination is documented, minor modifications may be recorded in the portal by using the “Add Comment” activity to enter a description of the modification and to upload new or revised materials. See Appendix C2 for examples of minor modifications.

4.6. Create Modifications for changes to the research that require new review or determination. See Appendix C1 for examples of modifications that will require new review or determination.

4.7. Submit a request for closure the study when it is complete.

5. PROCEDURES: IRB Staff

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 apply the policy described in Section 3 to determine whether submission qualifies for exempt determination. The IRB Staff determine that the research meets UGA's ethical and institutional standards as listed in the Exempt Reviewer Checklist.

5.3. If the selected Exempt category requires Limited IRB Review, a qualified IRB member is consulted.

5.4. When necessary, additional information or clarification is requested from the investigator.

5.5. IRB Staff review the submission, makes the final determination if the submission is eligible for exemption, and records the applicable exemption category(ies) and Limited IRB review findings.

5.6. The Exempt determination is communicated through portal notifications linked to the submission and official determination letter.

6. **MATERIALS**

6.1. CHECKLIST: Exempt Review

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. 45 CFR 46 Department of Health and Human Services Protection of Human Subjects

7.2. 21 CFR 50 Food and Drug Administration 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

Revision History:
09/19/2014: REV0 New Document
08/19/2016: REV1
01/21/2019: REV2

Appendix A: Exempt Categories, Conditions and Examples

EDUCATIONAL RESEARCH (DHHS Exempt 1) - 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.	**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. **Schools where activities take place should provide assurance in their site authorization documentation that the planned activities are not likely to adversely impact students' opportunity to learn. **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.
SURVEYS, INTERVIEWS, OBSERVATION OF ADULTS (DHHS Exempt 2) - Research that only includes interactions 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	--(2i) and (ii) for research involving survey or interview procedures or observations of public behavior does NOT apply to research in children, except for research involving observations of public behavior when the investigator does not participate in the activities being observed. --(2)(iii) of this section may not be applied to research involving children.

Appendix A: Exempt Categories, Conditions and Examples

(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 determine that, when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.	
BENIGN BEHAVIORAL INTERVENTIONS WITH ADULTS (DHHS Exempt 3(i)) 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: (A) 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; (B) 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 (C) 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 determine that, when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.	--This category does not apply to research involving children. ** Examples of benign behavioral interventions include having the subjects play an online game; role-playing; having them solve puzzles under various noise conditions; reading scenarios; writing/journaling; card-sorting tasks; playing computer and video games; conducting internet searches; photo/video elicitations; watching videos, looking at pictures, or listening to music; or having subjects decide how to allocate a nominal amount of received cash between themselves and someone else.
SECONDARY DATA ANALYSIS (DHHS Exempt 4) - 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:	**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

Appendix A: Exempt Categories, Conditions and Examples

(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; (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of ``health care operations'' or "research'' as those terms are defined at 45 CFR 164.501 or for ``public health activities and purposes'' as described under 45 CFR 164.512(b); or (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.	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 investigators should determine if they need a Materials Transfer Agreement (MTA) or Data Use Agreement.
FEDERAL AGENCY RESEARCH (DHHS Exempt 5) - Research and demonstration projects that are	**The program under study must deliver a public benefit

Appendix A: Exempt Categories, Conditions and Examples

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. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended. (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.	(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.
FOOD TASTING (DHHS Exempt 6) - Taste and food quality evaluation and consumer acceptance studies if: (i) wholesome foods without additives are consumed; or	** 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.

Appendix A: Exempt Categories, Conditions and Examples

(ii) 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.	**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.
(REPOSITORY WITH BROAD CONSENT DHHS Exempt 7) - 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 a limited IRB review and makes the determinations required by §46.111(a)(8).	**Setting up a repository
(USE OF A REPOSITORY WITH BROAD CONSENT DHHS Exempt 8) - Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met: (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d); (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117; (iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.	**Using the data/specimens from a repository
FLEX Exempt 3 - Minimal risk research that is not federally funded: (i) involving benign behavioral	**This category may be applied to studies involving children.

Appendix A: Exempt Categories, Conditions and Examples

interventions and/or gentle physical movement in conjunction with the collection of information from a subject through verbal or written responses (including data entry), audiovisual recording, or use of commercially available measurement technology or tools. The subject/subject's parent or legally authorized representative prospectively must agree to the intervention and information collection and at least one of the following criteria must be met: (A) 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; (B) 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 (C) 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, when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.	**Examples of benign behavioral interventions include having the subjects play an online game; role-playing; having them solve puzzles under various noise conditions; reading scenarios; writing/journaling; card-sorting tasks; playing computer and video games; conducting internet searches; photo/video elicitations; watching videos, looking at pictures, or listening to music; or having subjects decide how to allocate a nominal amount of received cash between themselves and someone else. **Data collection may include: Focus groups; interviews with children; **Physical activities may include: simple physical actions like sitting and standing up, walking from room to room, or gentle head or arm movement; non-invasive tasks that do not increase risk to the participant. **Data may be collected by non-invasive technology and tools: using eye-tracking technology as the subject reads from a computer screen; measuring waist circumference with a standard tape measure; weighing the subject using a standard scale; measuring the subject's height; using a FitBit to record steps taken during the course of a subject's normal day during a study on social interactions;
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 interactions and data collection procedures	** Established qualitative methods include ethnography, action research teams, phenomenonology.

Appendix B: Exempt Consent Guidelines

The proposed consent process and/or materials for exempt research will be assessed during the determination review. The consent process should provide sufficient opportunity for participants to consider whether to participate. Any information that will be disclosed to participants to make a decision must be 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 indicates that participation is voluntary.
4. A brief description of the study procedures.
5. Anticipated duration of participation.
6. Name and contact information of individual to contact for answers to questions about the research. [This is usually the PI and/or the Student Co-PI (if this is a student's project).]
7. Contact information for IRB, to respond to questions or concerns about participant rights.
8. The following additional information, only if applicable:
    a. A description of how individually identifiable results will be disclosed outside the research team (e.g., use of direct quotes that will be attributed to an individual in presentations/publications; data that will be shared with the classroom teacher or the school administrators; focus group limitations; internet data collection security issues).
    b. A description of the provisions to maintain the privacy interests of participants.
    c. A statement that refusal to participate or withdrawal from the study at any time will not affect participants' grades or class standing (if participants are students in a class), or their employment or employment evaluations (if participants are employees at a workplace).
    d. A description of any incentives, compensation, or reimbursement for research participation.
    e. For funded studies, name of the sponsor funding the research.

Human Research Protection Program
UNIVERSITY OF GEORGIA

Appendix C: Modifications to Exempt Research

C.1. Modifications that will require prior IRB review and approval – Create a modification in the Portal.

- Receipt of new or additional federal funding or support for the human research activities.
- New knowledge or 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*.
- Addition of 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; adding prisoners)
- Changes to procedures (intervention or data collection) that would change the applicable review level (Exempt, Expedited) or category (Exempt 1, Exempt 3).
- Changes to data security measures or privacy protections for studies that required Limited IRB review.
- Changes that would make the research now subject to FDA regulations (except if exempt category 6 applies).
- Change of Principal Investigator and/or of other Members of the Study Team.
- Any changes to federally supported research.
- Any changes to research that received Limited IRB Review.
- Changes to research involving privacy or confidentiality issues.

C.2. Modifications that will not require prior IRB review and approval – Describe the changes and upload any new or revised materials using the "Add Public Comment" activity in the Portal.

- Editorial or administrative revisions to consent documents, recruitment materials, data collection materials, or other study documents (e.g., fixing typos/grammatical errors, restating the same questions for clarity, reordering or reformatting the questions, splitting one question into multiple questions).
- 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 and do not change the previous assessment pertaining to the sensitivity of the data.
- 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) or the identifiability of the data.
- 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).