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1. PURPOSE

1.1. This policy is an addendum to the University of Georgia Human Research Protections Program (UGA HRPP) Policies and Procedures and describes the variations in requirements and procedures that the UGA HRPP/IRB and investigators will adhere to for research subject to the revised Common Rule that is IRB approved, or determined exempt, on or after January 21, 2019. This policy also applies to any studies subject to the pre-2018 version of the Common Rule that UGA decides to transition to comply with the new rule. When the research invokes multiple regulatory frameworks (e.g., Common Rule, FDA, HIPAA), all will be applied following the procedures described in the UGA HRPP Policies and Procedures and this addendum. This policy addendum will remain in effect until such time as the UGA HRPP Policies and Procedures have been fully updated to incorporate the revised Common Rule.

2. DEFINITIONS

The following definitions will be applied when UGA IRB reviews research subject to the revised Common Rule, and for exempt determinations and evaluations regarding whether a proposed activity is human subjects research when the research (or activity) is conducted or supported by a Common Rule agency. Likewise, the definitions will be applied, as applicable, to the conduct of the research, investigator responsibilities, and organizational responsibilities. Some of these definitions are unchanged from the pre-2018 rule but are included here for context.

- 2.1. **Clinical trial:** a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.
 - 2.2. **Human subject:** a living individual about whom an investigator (whether professional or student) is conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
 - 2.3. **Intervention:** physical procedures by which information or biospecimens are gathered (e.g., venipuncture) or manipulations of the subject or the subject's environment that are performed for research purposes.
 - 2.4. **Interaction:** communication or interpersonal contact between investigator and subject.
 - 2.5. **Private information:** information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that
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has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

- 2.6. **Identifiable private information:** private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
- 2.7. **Identifiable biospecimen:** a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.
- 2.8. **Legally authorized representative:** an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.
- 2.9. **Minimal risk:** a level of risk wherein 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.
- 2.10. **Research:** a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this rule, the following activities are deemed not to be research:
 - 2.10.1. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected. The information in this resource is based upon information available at the time of publication: December 21, 2017
 - 2.10.2. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
 - 2.10.3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.



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2.10.4. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

2.11. **Written (or in writing):** writing on a tangible medium (e.g., paper) or in an electronic format.

3. POLICY

3.1. **IRB Composition** - The requirements for the composition of the IRB under the revised Common Rule vary slightly from the pre-2018 rule. The composition of the UGA IRB complies with both rules. The following excerpt describes the requirements for the composition of the IRB under the revised Common Rule:

3.1.1. Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

3.1.2. The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

3.1.3. The IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

3.1.4. No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

3.1.5. An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB. [§ __.107]



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- 3.2. **Expedited Review** will be conducted using the procedures described in the UGA HRPP Policies and Procedures with the following variations:
- 3.2.1. The IRB shall apply the most current list of categories of research published in the Federal Register that may be reviewed using expedited review procedures [§__.110(a)]
 - 3.2.2. Research that falls within the list of categories is presumed to be minimal risk unless the IRB determines and documents that the research involves more than minimal risk. [§__.110(b)(1)(i)] If the reviewer determines that the research involves more than minimal risk, it will be referred for review by the convened IRB
 - 3.2.3. The limited IRB review that is required for certain exempt research (See Policy and Procedure: Exempt Research) may be conducted using expedited review procedures [§__.110(b)(1)(iii)]
- 3.3. **Continuing Review** - The revised Common Rule modifies when continuing review is required. Unless UGA IRB determines otherwise, continuing review of research is not required for research subject to the revised Common Rule in the following circumstances:
- 3.3.1. Research eligible for expedited review in accordance with §__.110;
 - 3.3.2. Research reviewed by the IRB in accordance with limited IRB review as described in Section 4;
 - 3.3.3. Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study: 1) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or 2) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care
 - 3.3.4. UGA IRB may determine that continuing review is required for any research protocol that falls within the above criteria. When the UGA IRB determines that continuing review is required for such research, it will document the rationale in the IRB record and communicate the requirement to the investigator in the IRB determination letter. Factors that the IRB may consider when determining that continuing review is required include: when required by other applicable regulations (e.g., FDA), the research involves topics, procedures, or data that may be considered sensitive or controversial, the research involves particularly vulnerable subjects or circumstances that increase subjects' vulnerability, an investigator has minimal experience in research or the research type, topic, or procedures, and/or an investigator has a history of noncompliance
 - 3.3.5. UGA will require a Progress Report when continuing review is not required.
 - 3.3.5.1. The reporting period will be relayed to the investigator in the determination letter. Notifications will be sent to investigators 90, 60, and 30 days prior to the end of the reporting period.



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3.3.5.2. The investigator will be required to provide: the enrollment totals; the status of research milestone (e.g., recruitment, data collection, analysis identifiable data; current conflict of interest status for all investigators, description of any changes to the study that have not been reviewed by the IRB, and a description of any adverse events, complaints, or other reportable events that have not been reviewed by the IRB.

3.3.5.2.1. IRB Staff may request corrective actions (e.g., submission of a Report of New Information).

3.3.5.2.2. The Progress Report will be acknowledged with a portal notification by email.

3.4. **Modifications to Previously approved Research** - Investigators must promptly report proposed changes to non-exempt research to the UGA IRB and must conduct the research activity in accordance with the terms of the IRB approval until any proposed changes have been reviewed and approved by the IRB, except when necessary to eliminate apparent immediate hazards to the subject.

3.4.1. This requirement applies to any aspect of exempt research subject to limited IRB review.

3.4.2. This requirement applies to non-exempt research for which continuing review is not required.

3.4.3. The UGA IRB will follow the procedures described in the UGA HRPP Policies and Procedures, and any applicable requirements and procedures in this SOP addendum, when reviewing modifications to IRB-approved research subject to the revised Common Rule.

3.5. **Approval Criteria** - The UGA IRB will apply the criteria for IRB approval described in the UGA HRPP Policies and Procedures to research subject to the revised Common Rule with the following variations:

3.5.1. Within criterion §__.111(a)(3), the text describing vulnerable subjects is replaced with the following: The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

3.5.2. Likewise, within criterion §__.111(b), the description of vulnerable subjects is updated and now reads: When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

3.5.3. While pregnant women are no longer described as vulnerable within the above criteria, the IRB shall continue to apply Subpart B "Additional Protections for Pregnant Women,



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Human Fetuses and Neonates” to federally-supported research and policies for equivalent protections to non-federally supported research as described in the UGA HRPP Policies and Procedures. The revised Common Rule does not eliminate or modify Subpart B.

- 3.6. **Review of Grant Proposals** - The revised Common Rule removes the requirement that the IRB review the Federal grant application or proposal for consistency with the protocol submitted to the IRB. Unless required by the Federal department or agency conducting or supporting the research, or by foreign, state, or local laws or regulations (including tribal law), the UGA IRB will no longer require submission of, or conduct review of, Federal grant applications or proposals when research is subject to the revised Common Rule.
- 3.7. **IRB Records** - The revised Common Rule includes additional requirements for IRB records. When the University of Georgia is engaged in human subjects research subject to the revised Common Rule the following records will be maintained in addition to those described in the UGA HRPP Policies and Procedures.
 - 3.7.1. For nonexempt research involving human subjects covered by the Common Rule (or exempt research for which Limited IRB review takes place) that takes place at an institution in which IRB oversight is conducted by an IRB that is not operated by the institution, the institution and the organization operating the IRB shall document the institution’s reliance on the IRB for oversight of the research and the responsibilities that each entity will undertake to ensure compliance with the requirements of this policy (e.g., in a written agreement between the institution and the IRB, by implementation of an institution-wide policy directive providing the allocation of responsibilities between the institution and an IRB that is not affiliated with the institution, or as set forth in a research protocol)
 - 3.7.2. The rationale for conducting continuing review of research that otherwise would not require continuing review will be maintained in the IRB records
 - 3.7.3. The rationale for a determination that research appearing on the expedited review list published in the Federal Register is more than minimal risk will be maintained in the IRB records
- 3.8. **Informed Consent** - When reviewing research subject to the revised Common Rule, the UGA IRB will evaluate the provisions for informed consent as described in the UGA HRPP Policies and Procedures with the below variations.
 - 3.8.1. Investigators conducting research subject to the revised Common Rule must adhere to these requirements.
 - 3.8.2. Investigators conducting research that is not subject to the revised Common Rule (i.e., not federally-supported) should adhere to these requirements. If the IRB does not require an



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element of consent or allows an alternate approach, the IRB record will document this and the justification for the determination.

3.8.3. The revised Common Rule includes a requirement for the posting of one IRB-approved consent form to a publicly available Federal website for each clinical trial conducted or supported by a Common Rule department or agency after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject. This requirement may be satisfied by either the awardee or the Federal department or agency. If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal website (e.g., confidential commercial information), the department or agency may permit or require redactions to the information posted.

3.8.3.1. Federal guidance or instructions regarding the implementation of this requirement was not available at the time this SOP went into effect. Until federal guidance or instructions are available, when UGA is the prime awardee, investigators should consult with the grant officer regarding how to satisfy this requirement.

4. **MATERIALS** - None

5. **REFERENCES**

- 5.1. 45 CFR 46 Department of Health and Human Services Protection of Human Subjects
 - 5.2. 21 CFR 50 Food and Drug Administration Protection of Human Subjects
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