



This document establishes the definitions followed by the University of Georgia's Human Research Protection Program.

1. **AAHRPP-accredited:** An institution that has earned accreditation from the Association for the Accreditation of Human Research Protection Programs, Inc.
2. **Administrative Reviewer:** refers to the person assigned to complete one of three alternate workflows: 1) determination of human subject research, 2) review of a project in development, or 3) review and processing of research that requires reliance upon an External IRB. This is usually the IRB Director or Assistant Director.
3. **Adult:** is a person who by virtue of attaining a certain age is regarded in the eyes of the law as being able to manage his or her own affairs. For the purposes of this policy, an adult is defined in the location where the research will take place. In Georgia, an adult is an individual who is 18 years of age or older.
4. **Adverse event:** any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research (modified from the definition of adverse events in the 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practice). Adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research, although on occasion, they can occur in the context of social and behavioral research.
5. **Affiliated Institution:** an institution where an existing Memorandum of Understanding or Agreement exists between UGA and the affiliated institution designating UGA IRB as the Reviewing IRB.
6. **Affiliated IRB Member:** a UGA employee or agent (or a member of this person's immediate family). They include, but are not limited to, individuals who are: part-time employees; current students; members of any governing panel or board of the institution; paid or unpaid consultants; healthcare providers holding credentials to practice at the institution; and volunteers working at the institution on business unrelated to the IRB.
7. **Affiliation:** an individual's relationship to a site through employment, enrollment, membership, or other similar means.
8. **Agenda:** a document that describes the topics of discussion for the IRB meeting.
9. **Agents:** are employees and individuals who: (1) act on behalf of an **institution**; (2) exercise institutional authority of responsibility; or (3) perform institutionally designated activities; can include faculty, staff, students, authorized affiliates, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation. An "authorized affiliate" is an individual granted research privileges at UGA by a department or college.
10. **Alternate Member:** a member who is designated to substitute for a regular IRB member for an entire meeting or at any time during a meeting. Alternate members have qualifications

comparable to the applicable regular member and may serve as alternate for more than one regular IRB member.

11. **Approval period:** is the interval between the day that the IRB grants approval of research and the day that the approval expires (see Expiration date.)
12. **Authorization:** under HIPAA, is an individual's signed permission that allows a covered entity to use or disclose the individual's PHI for the purposes and to the recipient(s) as stated in the Authorization. Also: **HIPAA Authorization.**
13. **Autonomy:** is defined as the personal capacity to consider alternatives, make choices, and act without undue influence or interference of others.
14. **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.
15. **Business Associate:** in general, is a person or organization, other than a member of a covered entity's workforce, who acts on behalf of, or provides certain services to, a covered entity that involves the use or disclosure of PHI.
16. **Certificate of Confidentiality (CoC):** allows the investigator and others who have access to research records to refuse to disclose identifying information in any civil, criminal, administrative, legislative, or other proceedings, whether at the federal, state, or local level. A CoC may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects, such as damage to their financial standing, employability, insurability, or reputation. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, a CoC helps to minimize risks to subjects by adding a layer of protection for maintaining confidentiality of private information. Certificates of Confidentiality are issued by the NIH and other HHS agencies to institutions or universities where the research is conducted; however, it is not limited to federally-funded studies.
17. **Child** (plural: **Children**): those unemancipated persons who have not attained the legal age for consent to treatments or procedures involved in the research (or clinical investigations) under the applicable law of the jurisdiction in which the research (or clinical investigation) will be conducted.
18. **Clinical Investigation (FDA):** the FDA has defined *clinical investigation* to be synonymous with *research, clinical research, clinical study, and study*. Any experiment that involves a test article (i.e., drug, medical device, food substance, biological product, or electronic product for human use), one or more human subjects, meets requirements for prior submission to FDA, or results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit [21 CFR 56.102].
19. **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. (45 CFR 46.102(b).)
20. **Coercion:** the practice of persuading someone to do something by using force or threats.

21. **Collaborating Site:** refers to an institution or organization with which a non-UGA investigator or collaborating organization is affiliated.
22. **Collaborative Institutional Training Initiative (CITI):** is an on-line educational training course that provides relevant, up-to-date information on the protections of human research subjects in the format of instructional modules. The modules are divided into two groups, social/behavioral or biomedical.
23. **Commercial IRB:** Commercial or Independent IRBs are contracted agencies that are not affiliated with specific institutions and are paid to conduct reviews of research with human subjects. Fees for IRB review will be charged.
24. **Common Rule:**
25. **Compassionate Use:** is a provision that allows patients who do not meet the requirements for inclusion in the clinical investigation but for whom the treating physician believes the medical device may provide a benefit in treating and/or diagnosing their serious disease or condition. This provision is typically approved for individual patients but may be approved to treat a small group. Compassionate use is not the same as off label use of approved drugs, devices, or biologics. Note: The term compassionate use does not appear in the Food and Drug Administration (FDA) regulations, and its use is actively discouraged by the FDA Center for Drug Evaluation and Research (CDER). The term does appear in guidance issued by the FDA Center for Devices and Radiological Health (CDRH).
26. **Confidential:** refers to maintenance of the Researcher's agreement with the participant about how the participant's *identifiable private information* will be handled, managed, and disseminated.
27. **Confidentiality Agreement:** a written agreement that pertains to the treatment of information that was obtained during a review or consultation that is considered privileged or protected and will not be divulged to others without permission.
28. **Conflicting Interest:** a situation in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity. Also: **Conflict of Interest.**
29. **Consent Process:** is an active ongoing process that involves more than the documentation of consent. The process involves an information exchange and ongoing communication that takes place between the researcher(s) and the prospective subject. Also: **Consent.**
30. **Consultant:** a scientist or non-scientist from within or external to University of Georgia who has special expertise to assist in the review of a research project at the request of the IRB.
31. **Continuing non-compliance:** a pattern of repeated non-compliance actions or omissions that, if unaddressed, may compromise the integrity of the UGA human research protection program. The pattern may reflect a lack of knowledge on the part of the investigator or a lack of commitment by the investigator and/or research team to human subjects protection.
32. **Continuing Review:** the process of IRB review of approved research that will continue beyond the end of the approval period.
33. **Controverted Issue:** an issue discussed at an IRB meeting for which there is a disagreement between some IRB members or there are opposing viewpoints among the IRB members that are voiced during the IRB's deliberations.

34. **Cooperative Research:** is human subject research which involves more than one institution. Also: **Collaborative Research.**
35. **Covered Entity:** the organization that has to comply with HIPAA. A covered entity is a health plan, a health care clearinghouse, or a health care provider transmitting health information.
36. **Deception:** is the intentional misleading of research participants by providing false or misleading information about some aspects of the research. False or misleading information might relate to the purpose of the research, the role of the researcher or other participants, the true nature of the procedures to be followed, or other parts of the study.
37. **Designated Reviewer:** is the person assigned to complete the non-committee review of a submission.
38. **Disclosure (under HIPAA):** means the release of PHI (protected health information) outside of the covered entity holding the information.
39. **Documentation of Informed Consent:** means providing subjects with a written version of the required elements of consent and obtaining their signature (or other mark) on a written document as verification of their decision to participate in the research. Documentation of informed consent generally occurs during the consent process after the elements of informed consent have been presented to the prospective participant and the investigator has responded to any questions or concerns from the individual.
40. **Education Records:** those records that are directly related to a student and maintained by an educational agency or institution or by a party acting for the agency or institution. For a detailed description of education records including exceptions, see http://www.ecfr.gov/cgi-bin/text-idx?rgn=div5&node=34:1.1.1.1.33#se34.1.99_13.
41. **Effective date:** the date on which the IRB chairperson or assigned designee determines that any conditions for approval required at initial review have now been satisfied and research activities involving human subjects may be initiated.
42. **Electronic signature:** means an electronic or digital method executed or adopted by a party with the intent to be bound by or to authenticate a record. According to the Uniform Electronic Transactions Act, this means an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record. Also e-signature.
43. **Eligible Student:** as defined by FERPA, a student who has reached 18 years of age or is attending a postsecondary institution at any age.
44. **Emergency use:** the use of a test article with a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval.
45. **Engagement in human subjects research:** when an institution's employees or agents intervene or interact with living individuals for research purposes; or obtain individually identifiable private information for research purposes.

46. **Equitable selection:** the process of defining the appropriate group of subjects for a research project using methods that will encourage a broad cross-section of subjects and will evenly distribute the burdens of research.
47. **Exculpatory Language:** as it applies to informed consent, is any written or verbal communication which has the general effect of freeing or appearing to free an individual or an entity from malpractice, negligence, blame, fault, or guilt.
48. **Exempt Research:** research that is exempt from the laws, regulations, codes, or institutional guidance that govern the research.
49. **Existing:** means information or a biological specimen that has been created or previously collected at the time of IRB submission.
50. **Expedited Review:** review of human research that may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. Also: Expedited Procedure.
51. **Experienced IRB Member:** an IRB member is considered experienced if the IRB Chairperson or designated IRB Staff considers the IRB member to have sufficient experience in and knowledge of conducting IRB reviews.
52. **Experimental subject:** An activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction [DoD Directive 3216.02.]
53. **Experimentation:** an activity that is designed to explore or develop new or unproven teaching methods or techniques and is a sub-set of human subject research where there is an interaction or intervention with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction.
54. **Expiration Date:** is the first date that the research is no longer approved.
55. **External Adverse Events:** those adverse events occurring in research at a site(s) other than UGA, over which an external (non- UGA) IRB has jurisdiction.
56. **External IRB:** is the local IRB at an **external site**.
57. **External Site:** a site or location, not owned by or under the direct authority of UGA, where the investigator would not normally have privileges to conduct any human research activity.
58. **Faculty Sponsor:** is a mentor who provides direct supervision to a post-graduate professional trainee and who shares in the responsibility for the ethical conduct of the research with the professional trainee. Used interchangeably with Faculty Advisor or Preceptor.
59. **Feasibility Study:** an assessment of the practicality of a proposed plan or method or use of an instrument for data collection, often involving colleagues or experts who can evaluate if the proposed method/design/instrument will result in sufficient information to answer the research questions.
60. **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**.
61. **Fetus:** the product of conception from implantation until delivery.

62. **Federal-wide Assurance (FWA)**: refers to an assurance of compliance filed with the U.S. Department of Health and Human Services (DHHS). An institution that is engaged in human subjects research that is conducted or supported by any agency of the DHHS must have an assurance of compliance. Through the FWA, an institution commits to DHHS that it will comply with its Policy for the Protection of Human Subjects at 45 CFR part 46.
63. **Financial Conflict of Interest (FCOI)**: is a significant financial interest (SFI) related to research that could directly and significantly affect decision making in the design, conduct, or reporting of externally funded instruction, research, or service activities performed on behalf of the University. See *Policy on Conflicts of Interest in Sponsored Programs*.
64. **Finder's Fee**: a payment made by an Investigator or Sponsor to an organization or individual (including non-research personnel or a research participant) for identifying and/or referring potential participants for research.
65. **Generalizable Knowledge**: Information will expand the knowledge base of a scientific discipline or other scholarly field of study and can be expressed in theories, principles, and statements of relationships; Results that can be generalized to a larger population beyond the site of data collection or participants studied; or Results that may be replicated or transferrable to other settings.
66. **Guardian**: an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.
67. **HRPP Policies and Procedures**: these are the policies and procedures that describe the requirements and practices related to the review, conduct, and oversight of human subjects research activities at UGA or under its auspices. These also describe the roles and responsibilities of those involved in these activities.
68. **Human Research**: any activity that either --
- Is Research as Defined by DHHS and involves Human Subjects as Defined by DHHS; or
 - Is Research as Defined by FDA and involves Human Subjects as Defined by FDA.
- Also: **Human Subject Research, Research Involving Human Subjects, Research Involving Human Participants, Clinical Research, Clinical Investigation, Clinical Study**, and other similar terms.
69. **Human Subject (DHHS)**: a living individual about whom an investigator (whether professional or student) 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. (45 CFR 46.102(e).)
70. **Human Subject (FDA)**: an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient [21 CFR 56.102(e)]. In addition, a human subject includes an individual on whose specimen an investigational device or control is used, even if the specimen is anonymous [21 CFR 812.3(p)].
71. **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.

72. **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.
73. **Identifiable sensitive information:** information about an individual and this is gathered or used during the course of research and: 1) through which an individual is identified or 2) for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual (Title 42 U.S.C. 241(d)(4)).
74. **Immediate Family:** spouse, domestic partner and dependent children.
75. **Incentive:** a form of payment offered to an individual in exchange for time and effort or to offset costs of participation (e.g., travel to study site). Payment can be in any form, including but not limited to, gift cards, check, cash, and course credit/extra credit. Also: **Compensation.**
76. **Incomplete Disclosure:** occurs when investigators withhold information to participants about some aspects of the research (typically, about the real purpose or nature of the study).
77. **Individual Investigator Agreement (IIA):** a written agreement between UGA and a collaborating external investigator who is engaged in non-exempt research but not acting as an employee or agent of any institution, or as an employee or agent of a non-assured institution that does not routinely conduct human subjects research.
78. **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.
79. **Informed Consent:** is the agreement to participate in research expressed by an adult person (or by the legally authorized representative (LAR) for a child or for an adult with cognitive impairment, based on sufficient information and adequate opportunity to consider voluntary participation. Also referred to as legally effective informed consent.
80. **Institution:** any public or private entity or agency, which includes but is not limited to federal, state, and other agencies.
81. **Institutional Official:** is the individual authorized by the terms of the federal-wide assurance to act for the institution and to assume on behalf of the institution the obligations imposed by the federal regulations for protections of human research subjects.
82. **Interaction:** includes communication or interpersonal contact between investigator and subject.
83. **Internal Adverse Events:** those adverse events occurring in a UGA research at a site(s) under its IRB's jurisdiction.
84. **International Research:** any human subject research activity that is conducted outside of the United States of America (USA) and its territories.
85. **Internet Protocol (or IP) Address:** is a unique identifier associated with every computer connected to the Internet. On many networks, the IP address of a computer is always the same, i.e., fixed or static. On other networks, the IP address is assigned each time a computer connects to the network, i.e., dynamic. Knowing a fixed IP address is equivalent to knowing the identity of its users.

86. **Intervention:** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
87. **Investigational:** this means that an item has not been approved by the FDA for marketing in the United States, or that it is being evaluated for a new and not-yet-approved indication, dosage, or formulation.
88. **Investigational Device Exemption (IDE):** an IDE application is the document submitted to the FDA for permission to conduct a clinical study using a significant risk device that is new or not approved for a given use. When the FDA approves an IDE application, it assigns an IDE number to the specific use of the device.
89. **IRB Actions:** are decisions the IRB can make when reviewing proposed research, and include:
- **Approve:** an IRB action taken when no modifications to the submission are required; all criteria for approval of *research* and required determinations have been met.
 - **Approve with Modifications Required to Secure Final Approval:** means that at the time when the IRB reviews and approves a research study (or proposed changes to a previously approved research study), the IRB requires as a condition of approval that the Investigator (a) makes specified changes to the research protocol or informed consent document(s), (b) confirms specific assumptions or understandings on the part of the IRB regarding how the research will be conducted, or (c) submits additional documents, such that, based on the assumption that the conditions are satisfied, the IRB is able to make all of the determinations required for approval.
 - **Defer:** an IRB action taken when the IRB cannot fully evaluate the research under review and make the determinations required for approval without significant modifications to the protocol and/or informed consent document, or submission of clarifications or additional information/materials. The IRB will include in its written notification a statement of the reasons for this decision and give the Investigator an opportunity to respond in person or in writing. Investigator deferral responses require review by the convened IRB.
 - **Disapprove:** an action made when the IRB determines that it is unable to approve research and the IRB cannot describe modifications that might make the research approvable. The IRB will include in its written notification the reasons for this decision and give the Investigator an opportunity to respond to the IRB in person or in writing.
 - **Table:** is not an action of the IRB, but is a determination based on the inability of the IRB to initiate or complete a review (usually due to reasons of quorum).
90. **IRB Authorization Agreement (IAA):** a written agreement between two *institutions* collaborating in non-Exempt research that describes each institution's authority, roles, and responsibilities for review and oversight of the research and communication between the reviewing and the relying IRBs.. An IAA is usually for a single project. Also: **Reliance Agreement.**
91. **IRB Portal:** the electronic submission and record-handling system for UGA's HRPP.
92. **IRB-of-Record:** refers to the IRB that conducts the review of and provides oversight for multi-site or collaborative research projects. Also: **Central IRB; Reviewing IRB.**
93. **IRB Member:** is either of the following:

- **Regular Member**
- **Alternate Member**

94. **IRB Roster:** a list of all active IRB Members and their degrees, affiliation, status, and expertise.
95. **Justice:** one of the basic ethical principles in the Belmont Report requiring fairness in distribution of burdens and benefits; that is, one group in society should not bear the costs of research while another group reaps its benefits.
96. **Lapse of Approval:** refers to the time including the **expiration date** to the day before the IRB grants a new **approval period**.
97. **Lead Institution:** is one that initiates or manages a research study involving multiple sites that conduct research procedures for the study.
98. **Lead PI:** Principle Investigator at the Lead Institution.
99. **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.
100. **Letter of Authorization (LOA):** any written record from an External Site providing authorization, approval, or permission for the researcher to engage in research activities at that site: this can be an e-mail, letter, or site-specific standard form. (sometimes known as Letter of Support).
101. **Life-threatening Situation:** for an emergency use of a test article, FDA regulations define this situation to include the scope of both life-threatening and severely debilitating, as defined below.
 - **Life-threatening:** means diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival. The criteria for life-threatening do not require the condition to be immediately life-threatening or to immediately result in death. Rather, the subjects must be in a life-threatening situation requiring intervention before review at a convened meeting of the IRB is feasible.
 - **Severely debilitating:** means diseases or conditions that cause major irreversible morbidity. Examples of severely debilitating conditions include blindness, loss of arm, leg, hand or foot, loss of hearing, paralysis or stroke.
102. **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.
103. **Local context:** Refers to the acceptability of proposed research in terms of institutional commitments and policy, applicable law, and standards of professional conduct and practice in the locale where research will be conducted.

104. **Lottery and Raffles:**

- Georgia law defines a lottery or raffle as any scheme or procedure whereby one or more prizes are distributed by chance among persons who have either paid or promised consideration (agreed to do something in exchange) for a chance to win such prize. Such terms shall also include door prizes which are awarded to persons attending meetings or activities provided that the cost of admission to such meetings or activities does not exceed the usual cost of similar activities where such prizes are not awarded.
- For IRB purposes, a proposed incentive plan wherein prospective research participants are offered the chance to enter a drawing to win one or more prizes is considered to be a lottery or raffle.

88. **Meeting Minutes:** a written record of the decisions and discussed topics of a convened meeting.

89. **Memorandum of Understanding (MOU):** is a written agreement between two institutions describing terms for determining the **IRB of record** for research projects in which the two institutions are both engaged. It also may describe each institution's authority, roles, and responsibilities for review and oversight of the research and communication between the reviewing and the relying IRBs. An MOU generally covers multiple studies.

90. **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.

91. **Minor Changes:** are changes that do not affect the overall conduct and design of a study or the potential risk assessment. These may include: editorial or administrative revisions to consent documents, data collection materials, or other study documents; adding or revising questions to a survey, interview or focus group, if the questions are similar in nature or follow the same theme/topic; adding or revising recruitment procedures and/or materials, if consistent with UGA's policy for recruitment and advertisements; adding a new group of participants that have the identical inclusion/exclusion criteria as the previously approved group; onboarding of relying sites when UGA IRB serves as the IRB of record; adding or revising research incentive that does not influence a participant's voluntary participation; change in study title; changes to study team, excluding change in Principal Investigator.

92. **Modification:** any change to a previously approved protocol. Also: **Amendment.**

93. **Multi-Site study:** means that the same research procedures (i.e., protocol) are being conducted at one or more domestic sites and that each site is under the control of a local participating investigator. This typically involves a lead site that receives the grant or contract directly and that then establishes a sub-award or subcontract to each participating site. The research could be a clinical trial, an observational study, or a basic clinical research study.

94. **Neonate:** a newborn from birth to 30 days.

95. **Non-Committee Review:** any of the following:

95.1. **Exempt Determination:** determination of whether Human Research is exempt from regulation

95.2. **Expedited Review:** review of non-exempt research using the expedited procedure

96. **Non-Compliance:** failure (intentional or unintentional) of the Principal Investigator or member(s) of the research team to adhere to the terms of IRB approval or other requirements or determinations by the IRB; or failure to abide by applicable laws or regulations or UGA policies, including failure to submit research for IRB review and approval before initiating research.
97. **Non-exempt human research:** any of the following:
- **Expedited Review**
 - **Full Board Review:** reviewed at a convened IRB meeting
98. **Non-Scientist:** members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline.
99. **Non-serious or Minor Non-compliance:** non-compliance that does not place, or have the potential to place, participants and others at greater risk than previously anticipated, compromise participants' rights or welfare, or affect the integrity of a facility's human research protection program; and result from willful or knowing misconduct on the part of the investigator(s) or study team members.
100. **Off-label Use:** the clinical use of an FDA-approved drug, device or biologic for a purpose or population that has not been approved by the FDA, or in a route or dose that has not been approved by the FDA.
101. **PHS Agencies:** agencies funded by the Public Health Service (PHS) include National Institutes of Health (NIH), Food and Drug Administration (FDA), Substance Abuse and Mental Health Services Administration (SAMHSA), Agency for Healthcare Research & Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), Health Resources and Services Administration (HRSA), and Indian Health Service (IHS).
102. **Pilot Study:** a preliminary investigation usually conducted on a small scale (e.g., 10 or fewer subjects) that may be exploratory in nature or designed to test **procedures** that are intended for a larger study.
103. **Policy:** a formal statement of principles on which action(s) for a specific issue are based.
104. **Pregnant Woman:** a woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery. Pregnancy encompasses the period of time from implantation until delivery.
105. **Pre-Review:** the process performed by IRB staff to determine that a submission for IRB review is complete, including the required responses and materials, and that the institutional requirements, such as completion of human subjects protection training, principal investigator (PI) eligibility, and conflict of interest disclosure, have been met.
106. **Primary Reviewer:** the member with the most relevant expertise or experience pertaining to the study procedures, design, and/or targeted human participants.
107. **Principal Investigator (PI):** is the individual primarily responsible for overseeing the preparation, conduct, and administration of human subjects research. Also: **Investigator: Principal Researcher; Researcher.**
108. **Prisoner:** any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil

statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

109. **Prisoner of War (DoD)**: any person captured, detained, held, or otherwise under the control of DOD personnel (military, civilian, or contractor employee). Such persons include: Enemy Combatant, Lawful Enemy Combatant, Unlawful Enemy Combatant, Enemy Prisoner of War, Retained Person., and Civilian Internee. Such persons do not include personnel of the DOD being held for law enforcement purposes.
110. **Privacy**: is the control over the extent, timing, and circumstances of sharing one's personal data with others, including but not limited to thoughts, feelings, images, and biological materials.
111. **Privacy Board**: is a committee established to review requests for a waiver or alteration of the Authorization requirement for uses and disclosures of PHI (protected health information) in a particular research study.
112. **Private information**: includes 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 which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.
113. **Procedure**: a series of actions conducted in a certain order or manner; operational method by which policy is put into practice.
114. **Progress Report**: a report to the IRB providing the status of human research activities for approved, ongoing research including information that may impact the risk assessment or other approval criteria for the research.
115. **Prospective Agreement**:
- 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
 - 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.
116. **Protected Health Information (PHI)**: is health information that has one or more of the 18 identifiers associated with the individual, and is held or transmitted by a Covered Entity (or its Business Associate), in any form or media (electronic, paper, or oral). PHI is information, including demographic information, that identifies, or could be used to identify, an individual and relates to:
- the individual's past, present or future physical or mental health or condition,
 - the provision of health care to the individual, or
 - the past, present, or future payment for the provision of health care to the individual.
- [For a list of these 18 identifiers, see HIPAA FAQs, Q1.](#)
117. **Protocol**: the precise and detailed design for conducting a research study; specifically, it is the study plan submitted to an IRB for review.

118. **Public Benefit or Service Program:** a program that delivers a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act).
119. **Quality Improvement Program (QIP):** the systematic and continuous actions that lead to measurable improvement in the Human Research Protections Program.
120. **Quorum:** to achieve quorum at meetings, at least one more than half the number of regular IRB Roster members, including a nonscientist and one member who represents the general perspective of participants, must be present. When the membership roster consists of an even number (N), a quorum is defined as $(N/2)+1$.
121. **Recruitment Bonus:** a payment, merchandise, or other gift or service offered by an Investigator or Sponsor as an incentive or reward to an organization, investigator, or key research personnel designed to accelerate the rate, timing, and/or number of participant recruitment.
122. **Recruitment Materials:** any information that prospective subjects will hear or see during the process of recruitment to announce the research or invite individuals to participate in the research.
123. **Recusal:** an IRB member's absence from the IRB meeting due to a conflicting interest in the item under consideration. This member will not count towards the quorum.
124. **Regular member:** a primary member of the IRB.
125. **Regulatory Reviewer:** is the person assigned to complete the non-committee review for a submission where there is also a Subject Matter Reviewer assigned.
126. **Relying PI:** Principle Investigator at a Relying Site.
127. **Relying Site:** Institution that relies on the **reviewing IRB** for regulatory oversight.
128. **Report of New Information (RNI):**
129. **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.
130. **Research (DHHS and HIPAA):** A systematic investigation including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102(l) and 45 CFR 164.501.)
131. **Researcher:** a principal investigator or an individual authorized by the principal investigator and approved by the IRB as a member of the study team, such as a co-investigator, research assistant, or coordinator.
132. **Reviewing IRB:** The selected **IRB of record** that conducts the regulatory review for participating sites of the **multi-site study**, including initial reviews, modifications, continuing reviews, and reportable events.
133. **Scientist:** members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline.
134. **Secondary research:** research use of information or biospecimens originally collected for non-research purposes or for research studies other than the currently proposed one.

135. **Secondary Reviewer:** is the member with similar relevant expertise or experience pertaining to the study procedures, design, or human participants. The secondary reviewer also conducts a full review of the submission and confirms the recommended determination or provides supplemental information for consideration.
136. **Sensitive Information:** is private information which if released could reasonably place subjects at risk of criminal or civil liability or could damage their financial standing, employability, insurability, reputation or could be stigmatizing. This includes, but is not limited, to sexual attitudes, preferences or practices, use or treatment for alcohol, drugs or other addictive products, illegal behaviors, certain health information, including psychological or mental health.
137. **Serious Adverse Event:** is any event associated with the subject's participation in research that:
- results in death;
 - is life threatening (places the subject at immediate risk of death from the event as it occurred);
 - requires in-patient hospitalization or prolongation of existing hospitalization;
 - results in a persistent, significant or permanent disability/incapacity;
 - results in a congenital anomaly/birth defect; or
 - any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed above. Examples of such events include allergic bronchospasm (a serious problem with breathing) requiring intensive treatment in the emergency room or at home, blood dyscrasias (disorders) or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.
138. **Serious Non-compliance:** non-compliance that may reasonably be regarded as: involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research staff, or others, or substantively compromising the integrity of a facility's human research protection program.
139. **Signature:** is a subject's name written by him or her in a characteristic way as a form of identification or authentication.
140. **Single IRB (sIRB):** One **IRB of record** selected on a study-by-study basis, providing the regulatory review for all sites participating in a specific multisite study.
141. **SMART IRB:** A platform that offers a master IRB **reliance agreement** (the SMART IRB Agreement) and a web-based system (SMART IRB's Online Reliance System) that provides a central process for participating institutions and their investigators to request, track, and document study-specific reliance arrangements.
142. **Sponsored research**
143. **Student:** as defined by FERPA, any individual who is or has been in attendance at an educational agency or institution and regarding whom the agency or institution maintains education records. Any individual who is enrolled in a graduate or undergraduate program at UGA.
144. **Student Pool:** a recruitment tool used by some departments in academic settings as a registry of students who may be interested in volunteering to participate in research studies. Student

pools provide researchers with a group from which to recruit student participants. These pools may offer course credit for participation in research studies.

145. **Subject Matter Reviewer:** is the person who may provide scientific or scholarly review and expert assessment of risk when the submission requires expertise outside of the IRB staff.
146. **Suspension of IRB Approval:** an action to temporarily withdraw IRB approval of some or all research activities.
147. **Systematic Investigation:** a predetermined and organized method of data collection, intervention and interaction, and analysis to study a specific topic, answer a specific question, test a hypothesis, or develop a theory. It is usually described in a formal protocol that sets forth an objective and a set of procedures to reach that objective.
148. **Termination of IRB Approval:** an action to permanently withdraw IRB approval of some or all research activities.
149. **Test Article:** any [investigational] drug, biological product, or medical device for human use.
150. **Transnational Research:** any human subject research activity that is conducted outside of the United States of America (USA) and its territories.
151. **Unaffiliated IRB Member:** an individual who has no affiliation with UGA, other than as an IRB member. They may include people whose only association with the institution is that of a patient, subject, or alumni/former student at UGA. Paying unaffiliated members for their services would not make the member “otherwise affiliated” as stated in the regulations, or cause the member to have a conflicting interest.
152. **Unanticipated Problem Involving Risks to Subjects or Others (UPIRSO):** any incident, experience, or outcome that meets all of the following three criteria:
 - unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
 - related or possibly related to a subject’s participation in the research (**possibly related** means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
 - suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.
153. **Undue Influence:** influence by which a person is induced to act otherwise than by their own free will or without adequate attention to the consequences.
154. **Unexpected Adverse Event:** any adverse event occurring in one or more subjects in a research protocol, the nature, severity, or frequency of which is not consistent with either:
 - the known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the protocol–related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and (b) other relevant sources of information, such as product labeling and package inserts; or

- the expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.
155. **Voting Member**: when both a regular member and his/her designated alternate attend a meeting, only one may count toward the quorum and may vote on any specific protocol; this member is called the **voting member**.
156. **Vulnerable Population**: a population whose members may have limited autonomy and/or who are at risk for coercion or undue influence.
157. **Written (or in writing)**: writing on a tangible medium (e.g., paper) or in an electronic format.