Terminology and Acronym Definitions (Adapted from the Emory IRB, FDA, HHS, OHARP)

Term	Definition
Common Rule Changes	Video Explanation of Common Rule changes.
Common Rule (2018)	Federal policy with intent to protect human subjects involved in research, while better facilitating research conduct by reducing ambiguity, burden and delay for investigators (Original rule 1991). The revision modernized, strengthened and increased effectiveness of the Federal Policy (2018). The 2018 Common Rule is also known as 'The Revised Common Rule' or 'New Common Rule". For policy link, click here.
Data Analysis Studies	Studies analyzing existing data, previously collected for another purpose, without acquisition of new or ongoing data gathering. The assigned IRB will decide if the data analysis study qualifies for an exemption, an expedited review or full IRB review.
Electronic Code of Federal Regulations	TITLE 45 (Public Welfare) and PART 46(PROTECTION OF HUMAN SUBJECTs) This link itemizes eCFR discussion of the Protection of Human Subjects.
Exempt Human Subjects	Human subject's meeting one of 8 criteria for exemption and thus are released or immune from 45 CFR 46 Requirements. Final determination of exemptions should be made by IRB in accordance with 45 CFR 46. For exemption guidance, click here.
FDA	The US Food and Drug Administration
FDA Regulated Research	The FDA regulates clinical studies using a drug, device or biologic, approved for marketing or not, outlined under 21 CFR 312 (drugs), 21 CFR 812 (devices), and 21 CFR 600 (biologics). FDA regulations for informed consent (21 CFR 50) and Institutional Review Boards (21 CFR 56) also apply.
Federalwide Assurances (FWAs)	Through Federalwide Assurance (FWA), an institution commits to Health and Human Services (HHS) that it will comply with the requirements in the Protection of Human Subjects regulations at 45 CFR part 46. To search for an institution in the Office for Human Research Protections (OHRP) database for approved FWAs, click here.

Georgia CTSA	The Georgia Clinical & Translational Science Alliance (Georgia CTSA) is part of a national network of medical research institutions who work together to improve the translational research process to get more treatments to more patients. Emory University partnered with Morehouse School of Medicine, Georgia Institute of Technology, and the University of Georgia to form Georgia CTSA and offer research resources. To learn more about Georgia CTSA, click here.
Health & Human Services (HHS)	The US Department of Health and Human Services has the mission to enhance and protect the health and well-being of all Americans.
Human Subject	The FDA regulations define a human subject as an individual who is or becomes a participant in research, as a recipient of either a 'Test Article or a Control'. A subject may be either a healthy human or a patient. [21 CFR Section 50.3(g)]. In the case of an investigational medical device (e.g. an assay, genetic test, in-vitro diagnostic device), a human subject/participant also means a human on whose specimen an investigational medical device is used (whether identifiable or not). For Human Subject Regulations Decision Charts, click here.
IRB	Institutional Review Board
IRB Reliance Agreements	Reliance agreements are signed documents between institutions that allow the IRB of one institution to 'rely' on the IRB of another institution, to review human subjects' research. Effective January 25, 2018, the National Institutes of Health (NIH) mandated use of single IRBs as a contingency for funding of domestic, non-exempt human, multi-site studies. Commonly-Used Terms/acronyms of Reliance: Institutional Authorization Agreements (IAA), Memorandum of Understanding (MOU), Master Reliance Agreement (MRA). For more information on IRB Reliance Agreenments, click here.
OHRP	The Office for Human Research Protections (OHRP) provides leadership in the protection of the rights, welfare, and wellbeing of human subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). For more information on OHRP, click here.
Minimal Risk Studies	Studies that are determined by the IRB to present no more than minimal risk to human subjects. They may receive expedited review if the procedures fall into one or more of the expedited categories. For OHRP Expedited Review Categories, click here.
Multi-Site Study	A multi-site study uses the same protocol to conduct non-exempt human research at more than one site. Under the new regulation will use a single IRB.

Participating Site	In a multi-site study, a 'participating site' is a domestic entity that will rely on the designated sIRB to carry out the IRB review of human research for the study.
NIH	National Institutes of Health
Reliance Training	A reliance agreement is a contract which requires a back-and-forth negotiation between the institutions. The IRB review is what is ceded to the other institution.
RKS	The Regulatory Knowledge & Support program of the Georgia CTSA.
SOP	Standard Operating Procedure
sIRB	Single Institutional Review Board
Studio Consultation	A meeting between clinical investigator (and/or team) and representatives of the appropriate Georgia CTSA programs to brainstorm or problem-solve on behalf of Investigator.