Information Regarding Human Subjects Research Projects for the GCRSEF

Please be sure your student is actually doing the research and not just performing literature reviews or only attending meetings about the research.

Anonymous survey projects where there is no identifying information to link the surveys to the participants is not human subjects research. Consent documents are not needed for this type of research. If you have a consent document, then that document will link the research survey to the participant and other measures related to confidentiality must be in place.

Personal Health Information requires a HIPAA authorization and informed consent. A HIPAA waiver can also be reviewed by the IRB, but it must meet the HIPAA criteria for a Waiver. Please see the following link https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/research/index.html

Consent Documents must have withdrawal information including the PI's information to contact when wishing to withdrawal. All risks should be provided including, social, psychological, legal, economic, and loss of confidentiality. Benefits should be clearly outlined even if there is no direct benefit to the participants. If that is the case, then it must be stated in the consent document and information how the research will benefit the general public must be stated. Please see the following: The basic required elements of informed consent can be found in the HHS regulations at 45 CFR 46.116(a). Also see OHRP Informed Consent Tips.

If you are using a specific site for recruitment of participants – there should be an institutional approval letter included with submission. Also, if you are getting data/specimens from an institution to use in your research there should be an authorization letter.

Remember, just because you have access to data and/or specimens does not mean it can be used for research without authorization from the owner of the data and/or specimens.

Make sure your student is providing a detailed research plan if they are doing human subjects research.

Research Plans involving human subjects should include purpose of research, research questions (hypotheses), both risk and benefits of the research, consenting procedures, research procedures/methods safety measures for human subjects' research, privacy and confidentiality, recruitment information and if permissions have been obtained. There should also be a detailed description of data being collected and analyzed.

Any research involving genetics or genome testing or analyzing of specimens must follow the NYS Civil Rights Law 79I. The consent is required to include specific information for any testing related to genetics or genomes. (There was a study that

included genetic testing for 2022 that the informed consent did include the criteria outlined by the NYS Civil Rights Law 79I). The research should not have been approved by the IRB without this information.

Studies that don't require IRB Review:

- Projects that involve students receiving pre-existing retrospective data that is deidentified and anonymous with no linkage to participants that the researcher has access.
- Student designed inventions, prototypes, computer applications and testing if only the student is testing the project.
- Data record reviews if the data is preexisting data sets.
- Behavioral observations from unrestricted public settings (malls, parks) and there is no interaction with the individuals, the environment is not manipulated in any way and there is no personal identifiable information that is recorded.