IRB – What Does My Review Type Mean?

When your human subjects research protocol is reviewed by the SCSU Institutional Review Board (IRB), it will be assigned <u>a review type</u>. Remember that *human subjects research* is an activity that meets both of the criteria listed below, as determined by the United States Code of Federal Regulations under <u>45 CFR 46.102</u>:

- **Research** is means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge
- A human subject is a living individual about whom an investigator conducting research 1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, OR; 2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable specimens

Regardless of the review type assigned, you are asked to notify the IRB if, during your study, anything changes about your design, data collection methods, or the potential risks to study participants.

Review Type	Definition
Not Human Subjects Research (NHSR)	Based on a review by the IRB, it has been determined that the work you are doing is not human subjects research. This may be because you are not collecting information about the individuals involved, because the information you collect is not meant to contribute to generalizable knowledge, because it involves activities such as literary criticism, journalism, historical scholarship, or another criterion. This work is not under the IRB's purview and therefore any reference to the IRB in your materials can be removed.
Exempt	Your human subjects research has been reviewed by the IRB and it has been determined that it falls under one of the categories defined in <u>45 CFR 104</u> . Your protocol is therefore exempt from ongoing review by the IRB. However, research considered 'Exempt' is still classified as human subjects research and thus is conducted under the IRB's purview.
Expedited	This assigned review type, when finalized, means that your human subjects research does not fall under a category that would classify it as 'Exempt' and will require an annual report , also submitted to the IRB, but it poses no more than minimal risks to the human subjects and therefore did not merit a review by the full board. Your protocol instead underwent an abbreviated review by one or several senior IRB members, <i>and therefore 'Expedited' should not be understood as having its more commonplace definition of 'as soon as possible.'</i>
Full Board	One or more features of your proposed human subjects research, such as the populations involved or the types of data being collected, merited review by the full institutional review board , which is composed of individuals both internal and external to the university and is meant to represent the interests of the campus as well as the wider community. It was assigned to and discussed at a convened meeting because it could not be assigned an 'Exempt' or 'Expedited' review type.