Does my study need approval from the NSU Institutional Review Board?

Does my activity involve human subjects? (check all the boxes below that apply)
If you checked yes to any of the below options, your study involves human subjects for IRB purposes.

☐ The activity involves obtaining information about living individuals and/or collection of fetal tissue.

☐ The activity involves intervention which includes physical procedure by which data are gathered or manipulations of the subject or the subject's environment that are performed for research purposes.

☐ The activity involves interaction which includes communication or interpersonal contact with the individuals (including electronic interaction).

☐ The activity involves collection of Individually identifiable **AND** private information

- Individually identifiable: information contains one or more elements that identify the individual or can be combined with other available information to ascertain the identity of the individual
- Private information: information provided for specific purposes by an individual and which the individual can reasonably expect will not be made public or information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place

☐ Human Subject (FDA Drugs): The activity is conducted in the United States and involves use of a drug in one or more human subjects (as recipients of a test article or as controls, patient or healthy), but is not the use of an approved drug in the course of medical practice.

☐ Human Subject (FDA Device): The activity is conducted in the United States and evaluates the safety or effectiveness of a device in one or more human participants.

☐ Data regarding participants (including controls) will be submitted to or held for inspection by FDA as part of an application for a research or marketing permit.

☐ Data regarding the use of a device (IVD) on human specimens (including de-identified/anonymous specimens) will be submitted to or held for inspection by FDA as part of an application for a research or marketing permit.

Is my activity considered research for IRB purposes? (check all the boxes below that apply)
If you checked yes to any of the below, your activity is research for IRB purposes.

☐ The activity is a systematic investigation involving recruitment of more than three individuals, designed to develop or contribute to generalizable knowledge.

- Systematic: involves data collection, either quantitative or qualitative, and data analysis to answer a question, involving the recruitment of more than three individuals.
- Generalizable knowledge: knowledge gained from the activity draws general conclusions which may be applied to populations beyond the specific study population.

☐ The activity is a clinical investigation that involves the development, testing, evaluation, and/or search for information.

- If your activity involves human subjects **AND** is research for IRB purposes, your activity will require NSU IRB approval via the *New Protocol Submission Form* in IRBManager.
- If your activity **DOES NOT** involve human subjects **AND/OR** is **NOT** research for IRB purposes, your activity does not require NSU IRB approval. Complete the *Human Subjects Research Determination xForm* in IRBManager.