Determination of Human Subject Research

All university projects involving both “RESEARCH” and “HUMAN SUBJECTS” must be submitted to the Brown University IRB for review and approval or exemption determination before starting any human subjects-related study procedures, including recruitment, consenting, data collection, and analysis. For guidance in determining whether your study meets both of these definitions, please follow the charts below.

Step 1: Is your project RESEARCH?

Start Here

Is the study a *systematic investigation*?

Looking more closely at the term “systematic investigation,” research should:

- Be an activity that is methodologically driven
- Involve a prospective plan
- Have a hypothesis
- Collect data or information in an organized and consistent way
- Involve some kind of analysis of the data or information
- Draw conclusions from the results of the investigation

- No

- Yes

Is the study *designed* to develop or contribute to *generalizable knowledge*?

Generalizable knowledge refers to findings/knowledge gained from the study that apply to populations outside of the study population or sites outside of Brown University. For conclusions to be generalizable, they must be shared for research purposes beyond the local setting or be part of a program of investigation that will be disseminated.

Bear in mind: OHRP does not consider intent to publish to be a reliable indicator of whether an activity is research. Publication alone does not make it research—it must also meet the criteria above.

- No

- Yes

STOP

The study does **not** meet the regulatory definition of research.

This study meets the regulatory definition of research.

Go to Step 2.
Step 2: Does your research involve HUMAN SUBJECTS?

Is the information being obtained ABOUT living individuals?

Yes

Will you collect information through some type of intervention or interaction?

• An intervention includes all physical procedures (i.e. blood draw, surveys) to gather data and all physical, psychological, or environmental manipulations that are performed for research purposes.

• Interactions with subjects include face-to-face interactions as well as remote interactions such as surveys administered via Internet or e-mail

No

This project meets the regulatory definition of Research with Human Subjects.

Please send your submission to Brown University’s IRB for review prior to starting any study procedures.

Will you have access to individually identifiable information?

Individually identifiable means that the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Examples of individually identifiable data:

• a dataset that includes identifying information such as name, DOB, address, phone number, etc., or

• a combination of variables that would allow and investigator to readily identify individuals

No

Will you have access to private information?

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, or

• information that has been provided for specific purposes by an individual and which the individual can reasonably expect the information will not be made public.

Examples of private information:

• medical records

• school records

• observation of private behavior

Yes

No

STOP
The research does not involve human subjects.
IRB review is not required.

Yes

No