

Human Subjects Self-Determination Decision Tree

Use this decision tree to help you determine if your study involves the federal definition of [human subjects](#). This decision tree may assist you when completing the **Human Subjects Research Self-Determination Tool**.

The study includes information or biospecimens *about living individuals*.

No

Yes

Primary data collection involving [interactions](#) or [interventions](#) with participants.

[Secondary data collection](#) involving obtaining, using, analyzing, or generating [identifiable private information](#) or [identifiable biospecimens](#).

[Secondary data collection](#) involving obtaining, using, or analyzing [anonymous data](#) not collected by you, your [research personnel](#), or on your behalf.

Yes

Yes

Yes

Interaction examples (in person, online, or by phone): interviews, surveys, assessments, observation, or physical measurements.

Intervention examples: any physical procedure, blood draws, manipulation of a participant's environment, asking a participant to change their behavior for the research study.

Examples:

Data includes [personally identifiable information](#) (PII) or [protected health information](#) (PHI).

Data includes [coded information/biospecimens](#) and you have access to the key to decipher the code and re-identify the information.

Examples:

Data does not include, and when in your possession, has never included, any [personally identifiable information](#) (PII) or [protected health information](#) (PHI).

Data includes [coded information/biospecimens](#) and you do not have, have never had, and will never have access to the key to decipher the code to re-identify the information.

Yes

Yes

No

Yes

Your study involves Human Subjects:

Your study requires IRB/HRPP review to conduct human subjects research. Please visit the [HRPP Forms & Templates](#) page for submission instructions, applications, and supporting document templates and the [IRB Guidance & Policies](#) page to assist you with this process.

Your study does not involve Human Subjects:

Your study is not subject to IRB regulations or HRPP oversight.