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

**Human Subjects Self-Determination Decision Tree**

Use this decision tree to help you determine if your study involves the federal definition of [human subjects](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#human). This decision tree may assist you when completing the **Human Subjects Research Self-Determination Tool**.

Yes

No

[**Secondary data collection**](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#secondary) **involving obtaining, using, or analyzing** [anonymous data](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#anonymous) **not collected by you, your** [**research personnel**](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#researchpersonnel)**, or on your behalf.**

[**Secondary data collection**](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#secondary) **involving obtaining, using, analyzing, or generating** [identifiable private information](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#identifiableprivate) **or** [**identifiable biospecimens**](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#identifiable)**.**

**Primary data collection involving** [interactions](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#interaction) **or** [interventions](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#intervention) **with participants.**

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 does not include, and when in your possession, has never included, any [personally identifiable information](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#personally) (PII) or [protected health information](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#phi) (PHI).

Data includes [coded information/biospecimens](file:///%5C%5Cfiles.brown.edu%5Cdfs%5CResearchProtection_Shared%5CORI%5CHRPP%5C3.%20Applications%2C%20Forms%2C%20and%20Templates%5C4.%20PI%20Eligibility%20Form%20and%20Self%20Checklists%5CDrafts%5Cv) 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.

**Examples:**

Data includes [personally identifiable information](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#personally) (PII) or [protected health information](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#phi) (PHI).

Data includes [coded information/biospecimens](file:///%5C%5Cfiles.brown.edu%5Cdfs%5CResearchProtection_Shared%5CORI%5CHRPP%5C3.%20Applications%2C%20Forms%2C%20and%20Templates%5C4.%20PI%20Eligibility%20Form%20and%20Self%20Checklists%5CDrafts%5Cv) and you have access to the key to decipher the code and re-identify the information.

No

Yes

Yes

Yes

**Your study involves Human Subjects:**

Your study requires IRB/HRPP review to conduct human subjects research. Please visit the [HRPP Forms & Templates](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/forms-and-templates) page for submission instructions, applications, and supporting document templates and the [IRB Guidance & Policies](https://www.brown.edu/research/conducting-research-brown/preparing-proposal/research-integrity/hrppirb-home-page/brown-univ-pol-proc) 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.