



BROWN

# Human Subjects Research Self-Determination Tool


**Do not submit this tool to the HRPP (see “Exception” below)**

The federal regulations for the protection of human subjects ([45 CFR 46](#)) do not require a formal determination for projects that do not meet the definitions of [research](#) or [human subjects](#). This tool is intended to help you determine if your project meets these definitions.


**IMPORTANT:** Use this tool to self-determine if your project meets these definitions. If your project does not meet BOTH of these definitions, you are NOT required to submit anything to the IRB/HRPP. You may keep a copy of this tool for your records. Please DO NOT submit this form to the HRPP.

**EXCEPTION:** This Human Subjects Research Self-Determination Tool should be provided to the HRPP ONLY if documentation of the determination is required by your study sponsor/funding source. You may submit this completed tool and the sponsor/funding requirement for documentation to [IRB@brown.edu](mailto:IRB@brown.edu). The HRPP will provide you a memo indicating that the determination has been received and accepted by the HRPP.

## PART I. IS YOUR PROJECT [RESEARCH](#)? [45 CFR 46.102\(d\)](#)

1.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Does your proposed project involve a <a href="#">systematic investigation</a> ; that is a prospective plan that incorporates qualitative or quantitative data collection, and data analysis to answer a question?
2.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Is the intent of your proposed project to develop or contribute to <a href="#">generalizable knowledge</a> ; that is to create knowledge from which conclusions will be drawn that can be applied to populations beyond the specific population from which it was collected?
		<p>If you answered “no” to <u>either</u> of the above questions, your proposed project does NOT meet the definition of “research.”</p> <p>If you answered “yes” to <u>both</u> of the above questions, your proposed project does meet the definition of research. Continue to Part II to determine if your project involves “Human Subjects.”</p>

**PART II. DOES YOUR PROJECT INVOLVE HUMAN SUBJECTS? 45 CFR 46.102(e)**  
 (for further guidance see the **Human Subjects Research Self-Determination Decision Tree**)

1.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Does your proposed project involve an <i>intervention</i> ; that is a physical procedure or manipulation of a <i>living individual</i> (or their environment) to obtain information about them?
2.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Does your proposed project involve an <i>interaction</i> ; that is communication or contact with a <i>living individual</i> (in person, online, or by phone) to obtain information about them?
3.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Does your proposed project involve <i>identifiable private information</i> or <i>identifiable biospecimen</i> ; that is receipt or collection of private information or biospecimen about a <i>living individual</i> to obtain information about them?
4.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Does your proposed project involve <i>coded information / biospecimens</i> ; that is where a link exists that could allow information about a <i>living individual</i> to be re-identified <b>AND</b> you are able to access the link?
		<p><b>If you answered “no” to <u>all</u> of the above questions, your proposed project does NOT involve “Human Subjects.”</b></p> <p><b>If you answered “yes” to <u>any</u> of the above questions, your proposed project does involve “Human Subjects.” Continue to Part III to determine if your project is Quality Assessment, Quality Improvement, and/or Program Evaluation.</b></p>

**PART III. IS YOUR PROJECT QUALITY ASSESSMENT, QUALITY IMPROVEMENT, AND / OR PROGRAM EVALUATION?**

1.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Will the outcomes of your proposed project remain specific to the organization, programs, or services under study, even if other organizations may use the results for their own programs?
2.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Is the <u>primary</u> purpose of your proposed project <i>quality assessment and/or quality improvement</i> ; that is to assess, analyze, critique, and improve a current practice or process in an institutional setting or ensure it conforms to expected norms regardless of any professional benefit to you?
3.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Is the <u>primary</u> purpose of your proposed project <i>program evaluation</i> ; that is to evaluate a specific program in order to provide information for and about that program regardless of any professional benefit to you?
4.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Is your proposed project designed to study, evaluate, improve, or otherwise examine public benefit or service programs? <b><i>If “Yes” continue to 4a.</i></b>
		4a. And is your proposed project unfunded or funded by a Non-Federal department or agency?



If you answered “yes” to any of the above questions, your proposed project does **NOT** meet the definition of “human subjects research.” Skip to Part IV.

**Examples of Quality Assessment/Quality Improvement (QA/QI) Activities and Program Evaluation (PE) vs Research Activities**

<b>QA/QI</b>	<b>Program Evaluation</b>	<b>Research</b>
Purpose – Identify a problem, test a hypothesis, establish a standard, and/or to, assess/improve upon a specific program/service.	Purpose-To evaluate the effectiveness of a specific program in meeting the intended goals of the program.	Purpose – Generalizable knowledge to address a problem, improve upon/assess effectiveness of a treatment, procedure, or approach, applicable to a general population.
Benefit – Promptly improve a process, program, or system, and may not impact participants involved in a specific program/service.	Benefit – Findings of the evaluation are expected to demonstrate the success or the shortcomings of the program. Participants will not directly benefit from the evaluation of the program.	Benefit - Designed to contribute to generalizable knowledge and may or may not benefit participants enrolled in the study.
Risks – By design, does not add risk to participants with the exception of possible privacy or confidentiality concerns.	Risks – By design, does not add risk to participants with the exception of possible privacy or confidentiality concerns.	Risks – May increase risks to participants.
Knowledge is not generalized beyond scope of the activity.	Knowledge is not generalized beyond scope of the activity	Knowledge can be generalized to groups, populations beyond those involved in the research study.
No experimental activities.	No experimental activities.	Project activities may be experimental.

**PART IV. NOT HUMAN SUBJECTS RESEARCH**

The proposed project **DOES NOT** constitute human subjects research. IRB/HRPP review is **NOT** required.