

**Brown University**

**Human Subjects Research Determination Form**

**Protocol Title:**

**Principal Investigator:**

**Department:**

**Phone number:**

**Email address:**

**Is this a graduate student project?\*  Yes  No**

**If student PI, please provide the following:**

**Advisor:**

**Department:**

**Phone number:**

**Email address:**

**Is this an undergraduate student project?\*  Yes  No**

**If yes, name of undergraduate student:**

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| **PART I. PURPOSE** |
| **The federal regulations for the protection of human subjects (**[**45 CFR 46**](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML)**) do not require a formal determination for projects that do not meet the definitions of** [**research**](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#R) **or** [**human subjects**](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#H)**.**  **Your proposed project must meet BOTH definitions of “research” and “human subjects” for HRPP review. Use this form to self-determine if your project meets these definitions.**  **This form is to be used when an external sponsor, journal, or other entity requires documentation that a study does not meet the federal definition of human subjects research and IRB review is not required. You MUST submit with this form evidence of the requirement from the sponsor, journal, etc. in writing.** |
| **Briefly describe the primary purpose of the project**:  Click or tap here to enter text. |

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| **PART II. IS YOUR PROJECT** [**RESEARCH**](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#research)**?**  [**45 CFR 46.102(l)**](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1102) | | |
| 1. | Yes  No | Does your proposed project involve a [*systematic* *investigation*](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#systematicinvestigation); that is a prospective plan that incorporates qualitative or quantitative data collection, and data analysis to answer a question? |
| 2. | Yes  No | Is the intent of your proposed project to develop or contribute to [*generalizable knowledge*](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#generalizableknowledge); 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? |
| **If you answered “no” to either of the above questions, your proposed project does NOT meet the definition of “research.” Skip to Part VIII.** | | |

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| **PART III. DOES YOUR PROJECT INVOLVE** [**HUMAN SUBJECTS**](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#humansubject)**?**  [**45 CFR 46.102(e)**](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1102) | | |
| 1. | Yes  No | Does your proposed project involve an [*intervention*](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#intervention); that is a physical procedure or manipulation of a *living individual* (or their environment) to obtain information about them? |
| 2. | Yes  No | Does your proposed project involve an [*interaction*](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#interaction); that is communication or contact with a *living individual* (in person, online, or by phone) to obtain information about them? |
| 3. | Yes  No | Does your proposed project involve [*identifiable* *private information*](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#identifiableprivateinformation) or [*identifiable biospecimen*](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#identifiablebiospcimen); that isreceipt or collection of private information or biospecimen about a *living* *individual* to obtain information about them? |
| 4. | Yes  No | Does your proposed project involve [*coded information / biospecimens*](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#codedinformation); that is where a link exists that could allow information about a *living individual* to be re-identified AND you are able to access the link? |
| **If you answered “no” to all of the above questions, your proposed project does NOT involve “Human Subjects.” Skip to Part VIII.** | | |

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| **PART IV. IS YOUR PROJECT QUALITY ASSESSMENT, QUALITY IMPROVEMENT, AND / OR PROGRAM EVALUATION?** | | |
| 1. | Yes  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. | Yes  No | Is the primary purpose of your proposed project [*quality assessment and/or quality improvement*](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#QAQI); 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. | Yes  No | Is the primary purpose of your proposed project [*program evaluation*](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#programevaluation); 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. | Yes  No | Is your proposed project designed to study, evaluate, improve, or otherwise examine public benefit or service programs? ***If “Yes” continue to 4a.*** |
|  |  | 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 VIII.** | | |

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| **PART V. DOES YOUR PROJECT INVOLVE THE FDA?** | | | |
| 1. | Yes  No | Is your proposed project subject to FDA [IND](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#IND) regulations; that is it involves one or more human subjects and any use of a drug other than the use of a marketed drug in the course of medical practice? |
| 2. | Yes  No | Is your proposed project subject to FDA [IDE](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#IDE) regulations; that is it involves one or more human subjects and any evaluation of the safety or efficacy of a medical device? |
| 3. | Yes  No | Will the results of your proposed project be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit? |
| **If you answered “no” to all of the above questions, your proposed project does NOT involve the FDA. Continue to Part VI.** | | |

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| **PART VI. HUMAN SUBJECTS RESEARCH DETERMINATION** |
| **If your proposed project meets BOTH the definition of “research” AND “human subjects,” skip to Part VII.**  **If your proposed project DOES NOT meet BOTH the definition of “research” AND “human subjects,” skip to Part VIII.** |

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| **PART VII. NEXT STEPS FOR HUMAN SUBJECTS RESEARCH** | |
| **If your proposed project meets the definition of “human subjects research,” use the following steps to submit an Application to the HRPP for review.** | |
| 1. | Complete Brown’s [education requirements](https://www.brown.edu/research/conducting-research-brown/preparing-proposal/research-integrity/hrppirb-home-page/hrpp-training/citi-instructions) (CITI) |
| 2. | Complete a [Conflict of Interest disclosure](https://www.brown.edu/research/electronic%20reporting) |
| 3. | Determine if your research needs [Exempt, Expedited, or Full Board review](https://www.brown.edu/research/conducting-research-brown/preparing-proposal/research-integrity/hrppirb-home-page/brown-univ-pol-proc#2) |
| 4. | Complete the appropriate Application available on the HRPP [Forms and Templates](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/forms-and-templates) page |
| 5. | Review the HRPP [submission instructions](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/forms-and-templates#submission) |

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| **PART VIII. NOT HUMAN SUBJECTS RESEARCH** |
| The proposed project ***DOES NOT*** constitute human subjects research. HRPP/IRB review is ***NOT*** required. This self-determination only applies to the activities associated with this project title.  E**vidence of the documentation requirement from the sponsor, journal, or other entity is attached.** |

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**Principal Investigator/Undergraduate Investigator certifies the following:**

By my signature below, I certify that the project does not meet the definition of human subjects research, and I will contact the Human Research Protection Program if there are any changes that may alter this determination.

**Principal Investigator signature:**  **Date:** Click here to enter a date.



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**An Advisor’s signature is required for all student projects**

**Advisor certifies the following:**

I have read the complete proposed project, agree with the determination that the project does not meet the definition of human subjects research, and will remain available to advise the student to contact the Human Research Protection Program if there are any changes that may alter this determination.

**Advisor's signature:** **Date:**  Click here to enter a date.

***For HRPP Use Only*:**

Based on the information included in the Human Subjects Determination Form, the Human Research Protection Program agrees with the investigator’s self-determination that the project does not meet the definition of human subjects research. ***The complete project has not been reviewed by the Brown University HRPP.***

**Signature of the HRPP:  Date:** Click here to enter a date.