URTP Decision Form - 2023

Q26
Welcome to the Undergraduate Research Training Program (URTP) Decision Form! The purpose of this form is to help you decide whether the activities you will be undertaking need review by the Harvard University-Area Institutional Review Board (IRB).

The decision that this form provides is only applicable to the information you provide **NOW**. Should the intent, design, population, or purpose of your study change, the decision you receive now may no longer be applicable.

We ask that all Harvard College students completing independent projects like theses to fill out this form. This is not only so we can decide if you need oversight for a research project, but also so we can connect you with other offices or resources as needed, even if what you are doing is not research reviewed by the IRB.

Only complete this form after you have done the following:

--Identified a Research Supervisor
--Met with your Research Supervisor to discuss your project
--Read the URTP Student Guide
--Completed ethics training, either through a training facilitated by IRB staff or the online CITI training

Should you have any questions during this process, contact the IRB office at cuhs@harvard.edu.

Q41 When completing this form, the following information and documents will be needed:
Information about your Research Supervisor; Study documents, such as questionnaires that you have developed; and
CITI training certificate if you completed the online training.
Please be prepared before completing the form.

Q40
Harvard College Honor Code

Members of the Harvard College community commit themselves to producing academic work of integrity – that is, work that adheres to the scholarly and intellectual standards of accurate attribution of sources, appropriate collection and use of data, and transparent acknowledgement of the contribution of others to their ideas, discoveries, interpretations, and conclusions. Cheating on exams or problem sets, plagiarizing or misrepresenting the ideas or language of someone else as one's own, falsifying data, or any other instance of academic dishonesty violates the standards of our community, as well as the standards of the wider world of learning and affairs.

I affirm my awareness of the standards of the Harvard College Honor Code:

○ Yes, I affirm (1)

Q47 I affirm I have done the following:

Identified a Research Supervisor   Met with my Research Supervisor to discuss my project   Read the URTP Student Guide   Completed ethics training either through a training facilitated by IRB staff or the online CITI training

○ Yes, I affirm (1)

Q51

STOP!
Please read carefully. The following is essential information for helping you determine whether your project needs IRB review. There is a question at the end of this form that refers to this information.

Projects meeting the regulatory definition of research with human subjects require review and approval by an IRB, or a determination that the research is exempt from oversight. The Harvard University-Area IRB makes these determinations project-by-project.

Not all activities that involve people, their data, or specimens are covered by the regulations governing human subjects research, though! In determining if review is needed, the IRB considers 1) whether a project fits the regulatory definition of research and, if so, 2) whether it

also involves human subjects.

Federal regulations define research as "*a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.*" **Let's break this down a bit:**

• *Such projects have a well-defined research question/hypothesis/aim and a way to address that question. That is, something you are trying to find out and a way to find it out, like through collecting information from people. This is a systematic investigation.*

• *Such projects also aim to produce something (like a journal article, presentation, data for a repository, etc.) that is useful, usable, and accessible to others. That is, the outcome of the project has the potential to be impactful on your discipline or field. This is generalizable knowledge.*

• *In these projects, having an academic or personal growth experience is likely to be a secondary goal of the project, not the primary goal.*

Note that some activities look like research but may not need IRB review:

• *A* **quality assurance/quality improvement/organizational effectiveness study** *where intent is to assess, improve, or develop programs or services for an organization. Outcomes will remain specific to that organization and thus are not generalizable as above.*

• *An* **oral history or journalistic piece**, *since projects strive to document and report on events, situations, policies, institutions, or systems as they are, without the intent to form or answer research questions or draw general conclusions. These procedures are most typical within History programs.*

• *A project that is intended to be an* **educational experience for academic credit** *and/or an experience to explore a topic for personal growth. In such cases the project is not intended to produce something (e.g., journal article, presentation, data, etc.) that is useful, usable, and accessible to others. That may be a goal in the future, but it is not a goal at the outset.*

• *A* **literature review** *may involve obtaining, reading, and synthesizing lots of published information. This information is usually very accessible and/or not about individual people and thus falls outside IRB oversight.*

How do you think your project fits? This form will focus on whether what you are doing is considered research as we define it. There is a question about this at the end of the form.

Q55 Please answer the following questions. This information is required for you to receive your decision.

○ Name (1) _____

○ Email Address (4) _____

○ Current Year (e.g. sophomore) (2)
_____

○ Class Year (e.g. 2027) (3)
_____

○ Research Supervisor name (5)
_____

○ Research Supervisor Email Address (7)
_____

○ Other Research Supervisor name (i.e., DUS) Leave blank, if not applicable (8)
_____

○ Other Research Supervisor Email Address (leave blank, if not applicable) (9)
_____

Q28 What academic department are you part of?

▼ African and African American Studies (1) ... Women, Gender and Sexuality Studies (57)

Q38 Have you completed human subjects training?

○ Yes, session led by IRB staff (1)

○ Yes, online CITI training (2)

○ No, not yet (3)

Q39 Please upload your human subjects training certificate from CITI saved as "YOUR LAST NAME_YOUR FIRST NAME_CITI_Certificate":

Q43
Before completing the URTP Decision Form, it is a requirement that human subjects training be completed either by attending a session facilitated by IRB staff or completing the online CITI training. Options for meeting this requirement may be found here: https://cuhs.harvard.edu/required-ethics-training

Once you have completed this training, you may complete the URTP Decision Form.

Q45 Is your project 1) part of an existing study led by another investigator and/or 2) will your project involve adding you as a study team member to an existing IRB-approved study at Harvard or elsewhere?

○ Yes (1)

○ No (2)

Q46 If your research is part of an existing study or you will be added as a study team member to an existing IRB-approved study, do not complete this form. Instead, please immediately contact the IRB office at cuhs@harvard.edu for further instructions.

Q49 Why are you conducting this activity?

○ Course Requirement / Senior Thesis / Junior Paper (1)

○ Funding received from Harvard (2)

○ Other (please specify) (3)
_____

Q2 Please briefly provide information about the purpose of your project. What are you trying to investigate or discover?

_____

_____

_____

_____

_____

Q4 Please describe your study procedures. What will you be doing in your project?

_____

_____

_____

_____

_____

Q35 Please submit any documents that may be valuable in evaluating your project saved as "YOUR LAST NAME_YOUR FIRST NAME_FILE NAME" (where file name gives a description of

the content). These documents may include information sheets, interview questions, or other documentation like research proposals for your department or funding application. A URTP-specific study template and information sheet template may be found on the URTP website: https://cuhs.harvard.edu/urtp-portal

This question will only allow you to upload one document. Please upload an additional document on the next question. Skip question if not applicable:

Q36 Please submit any documents that may be valuable in evaluating your project saved as "YOUR LAST NAME_YOUR FIRST NAME_FILE NAME" (where file name gives a description of the content). This question will only allow you to upload one document. Skip question if not applicable:

Q5 Will your study involve any "sensitive" populations?

A sensitive population may have less perceived power than the majority of their peers and may be relatively (or absolutely) incapable of protecting their own interests and may be exposed to harm. Examples vary according to the context of the research but may include children, the elderly, prisoners, students, historically marginalized populations (e.g., LGBTQ+), those that are drug addicted, those that are economically disadvantaged, or those that are undocumented and in the United States.

○ Yes (1)

○ No (2)

Skip To: Q52 If Will your study involve any "sensitive" populations?   A sensitive population may have less perce... = No

Q34 Please describe the sensitive populations that you will include in your project:

_____

Q52 Will you project uncover any illegal activity (e.g., drug use, alcohol use by minors, theft, etc.)?

○ Yes (5)

○ No (6)

Q6 Will you undertake activities outside of the United States (i.e., travel outside the United States for this project) or enroll participants who are located outside the United States (e.g., using Zoom to conduct video interviews or launching an online survey for people outside the United States)?

○ Yes (1)

○ No (2)

Skip To: Q10 If Will you undertake activities outside of the United States (i.e., travel outside the United State... = No

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Q7 Please specify below where your project will take place:

Be aware that all students who are traveling to an international location are required to register with Harvard Global Support Services (GSS) prior to their departure. More information may be found on the GSS website at https://www.globalsupport.harvard.edu/
  If you will be collecting data from individuals that reside in the UK or EEA which includes the 28 states of the European Union and four additional countries (Iceland, Liechtenstein, Norway, and Switzerland), your activity may be subject to the E.U. General Data Protection Regulation (GDPR). More information may be found at https://cuhs.harvard.edu/news/gdpr/

_____

Q10
Earlier you were provided a summary of projects that meet the definition of research with human subjects and need IRB review.

Remember, research that needs IRB review meets **ALL** of the following criteria:

--The intent of your study is NOT just an educational exercise intended to prepare you for future

research that you may conduct.

--Your study is focused on a well-defined research problem or question.

--Your research is informed by the empirical findings of other studies.

--The results of your study are intended to expand the knowledge base of a scientific discipline.

--The results from your study will be applicable to a larger population beyond the individuals that you are studying.

Answering **Yes** means you have designed your project intending to produce something (e.g., journal article, presentation, data, etc.) that is useful, usable, and accessible to others. Your sole intent is not to have an academic or personal growth experience, though that may be a secondary goal. **Your project meets all of the criteria above.**

Answering **No** below means your activities are intended to be an experience for academic credit and/or an experience to explore a topic for personal growth. You have not designed your project intending to produce something (e.g., journal article, presentation, data, etc.) that is useful, usable, and accessible to others. That may be a goal in the future, but it is not a goal currently. **Your project does not meet all of the criteria above.**

If you are uncertain how to answer, please mark **Yes** so that you receive instructions for working with IRB staff on a final outcome.

Does your project meet the criteria of research needing IRB review as summarized above?

○ Yes (1)

○ No (2)

Q18

It appears that your project does not meet the regulatory definition of research, as it is not a systematic investigation that will contribute to generalizable knowledge.

 Your responses will be double-checked by an IRB staff member. **If you do not hear from the HUA IRB office within five business days, IRB review is not needed and you may begin your work.** However, it is still your responsibility to be an ethical researcher. If the IRB identifies concerns about the sensitivity or risk of your project, staff will contact you for additional information.

Please be certain to click the arrow button below to receive a URTP determination. A copy will be sent to the email address included earlier in this form for your records. For questions, please

contact the IRB office at cuhs@harvard.edu.

NOTE: *Data Security*
Whether your project needs IRB review or not, breach of confidentiality is a serious risk posed to participants. Rigorous data security is a key element of protecting subject data from an accidental or malicious breach. Data security includes:

· A plan to manage the physical and electronic documentation associated with the project, such as paper surveys, signed consent forms, or documents that contain contact information for subjects and
· Steps to ensure that those materials are not lost or accessed inadvertently by an unauthorized person.

The management of electronic data (on desktops or servers as well as on mobile devices such as laptops and flash drives) is increasingly important. See the Harvard University Research Data Security policy for information on how to protect your data, links to University resources, and more on your responsibilities as a researcher: http://vpr.harvard.edu/pages/harvard-research-data-security-policy

Skip To: End of Survey If It appears that your project does not meet the regulatory definition of research, as it is not a... Is Displayed

Display This Question:
    If Earlier you were provided a summary of projects that meet the definition of research with human s... = Yes

Q20
It appears that IRB review may be needed, as your project might meet the regulatory definition of research, or more information is needed to make this determination.

--Please create a submission through our online IRB submission system, ESTR, which may be accessed using your Harvard Key at https://irb.harvard.edu
--Instead of using the standard IRB protocol template, complete an abbreviated URTP form where you will be asked more about the overall goals of your project. You may access further instructions, including that form, here: https://cuhs.harvard.edu/URTP-IRB-Needed
--For general instructions on how to create an entry in ESTR, please visit the ESTR help site here: https://estrsupport.fss.harvard.edu/study-submission-guide. This resource references the standard IRB protocol template; use the abbreviated URTP form instead, as outlined above.

If you believe you received this decision in error, follow the instructions above and explain this in the abbreviated form. **Do not submit duplicate Decision Forms to correct your initial decision.**

Please be certain to click the arrow button below to receive a URTP determination. A copy

will be sent to the email address you included earlier in this form for your records. For questions, please contact the IRB office at cuhs@harvard.edu.

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Skip To: End of Survey If It appears that IRB review may be needed, as your project might meet the regulatory definition of... Is Displayed

End of Block: Default Question Block