This guide walks researchers step-by-step through the **Not Human Subjects Research (NHSR)** submission process at Teachers College using Mentor IRB.

- 1. Start a New NHSR Application
 - From the IRB dropdown in the left-hand navigation menu, select "NHSR."

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• Click "Create New NHSR Application."

TC IRB Walkthrough for Submitting a Research Determination Form in Mentor IRB

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2. Student Investigator Information (if applicable)

If you are a student, you will first be prompted to enter your faculty sponsor's name (start by typing their last name), then click Continue. Next, enter the title of your study, and then click Save.

TC IRB Walkthrough for Submitting a Research Determination Form in Mentor IRB

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Select Faculty Sponsor	Cancel X
() If you are unable to locate your faculty sponsor, then contact IRB office at IRB@tc.columbia.edu.	
Select your Faculty Sponsor by typing the first letters of their last name in the Lookup field below. Then select Faculty Sponsor Lookup Continue Close	ct their name from the pop-up list.
Create NHSR NHSR Application	Cancel X
Important Notice: Completion of this form initiates a formal review by the IRB to determine whether your proj human subjects research. Please do not begin any research activities involving data collection or participant in formal determination from the IRB.	ject meets the definition of nteraction until you receive a
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On "Save" of this form, you will be presented with a set of questions designed to help determine if your project meets the criteria for Not Human Subjects Research. Once you have completed these questions, you will will be prompted to sign your submission electronically (at the bottom of the questionnaire). If you are a student, your Faculty Sponsor will be notified automatically when you submit your electronic signature.	
Save Cancel O	

3. Review Pre-Submission Guidance

Before the questionnaire begins, you'll see an important notice:

Do not begin research activities until the IRB has reviewed and issued a formal determination.
 The IRB cannot make retrospective determinations for projects already started or completed.

You'll also find links to:

- OHRP Human Subject Regulations Decision Charts
- TC IRB's What is Human Subjects Research? guide
- 4. Complete the Questionnaire

	Research Determination Form
	This form is intended to help you determine if your proposed project meets the federal definition of research involving human subjects and requires oversight from the IRB.
	For support in determining whether your study includes human subjects, please refer to the U.S. Department of Health and Human Services' Human Subject Regulations Decision Charts.
_	Please also refer to our What is Human Subjects Research? Guide for additional detailed examples of what studies are considered human subjects research and which are not.
()) After reviewing your submission, the IRB will provide you with a written determination. This determination can be used to provide to sponsors, collaborators, journal editors, and others who need verification from impartial source that the proposed activities do not require IRB approval.
	Important Notice: Please do not begin any research activities involving data collection or participant interaction until you receive a formal determination from the IRB. The IRB cannot make retrospective determinations when the project has already started or has been completed.
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Section A – Project Overview

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You will answer three open-ended questions:

- Brief description of your project
- Goals or objectives
- Description of the human population involved (or confirm that none are)

Section B – Research Classification Questions

These determine if your activity qualifies as human subjects research. You'll be asked:

- Is your activity a systematic investigation?
- Is it intended to contribute to generalizable knowledge?
- Is it a quality improvement or quality assurance activity?
- Is it a program evaluation?

You will also address:

- Whether results are intended to remain organization-specific
- Whether the project involves public benefit or service programs

Answer **Yes/No** for each item based on your study.

Section C – Human Subjects Triggers

This section is critical. You'll be asked:

- Will you interact or intervene with living individuals?
- Will you obtain or use identifiable private information or biospecimens?
- Are you using coded data where you have access to the link?
- Will your data come entirely from public sources?
- Is your dataset **completely de-identified**?
- Will you merge datasets that could re-identify subjects?

Each answer impacts whether IRB oversight is required.

Section D – Funding Source

Indicate whether your project is:

- Unfunded
- Funded by a **non-federal** source

Federal funding may trigger review even if the project doesn't involve human subjects.

5. Upload the Research Proposal or Protocol Description (Optional)

You may upload a brief proposal or protocol description, **though it is not required**. This is helpful for context but not mandatory for NHSR applications.

Choose File	No file chosen			
Display Name				
Rename File to				
eave blank to	use original file name			

6. Electronic Signature

Once all required fields are completed:

• Click "Sign Electronically" at the bottom of the form.



• Then, complete the submission attestation and proceed with signature.



• If you're a student, the form will be routed to your Faculty Sponsor for review and approval before submission to the IRB.

7. Faculty Sponsor Review (Students Only)

Faculty sponsors must log in and select an action (Accept, Revisions Required, Not Yet Accepted, or Rejected). They are responsible for ensuring:

- The project is accurately described
- Any future changes are reported
- The student adheres to the parameters of NHSR status

Faculty Sponsor Action Cancel x	Acceptance Status
By "Accepting" this Not Human Subjects Research application, you are verifying that the information provided by the student investigator is true and accurate and that any changes to the conduct of this project that may impact the NHSR determination will be submitted to this record as a modification prior to implementing those changes.	Accepted ~
Acceptance Status Accepted I Not Yet Accepted Faculty Sponsor Revisions Required Accepted Rejected	Update Status ✓ Cancel ⊗

8. Await IRB Determination

Once submitted, the IRB will review your responses. You'll receive a formal written determination that can be provided to:

• Sponsors

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• Journal editors

- Academic departments
- Collaborators

9. Reminders

- **Do not** begin research until a determination letter is issued.
- NHSR determinations **do not require** a full protocol or consent documents.
- If your project changes, you may need to **resubmit** for reevaluation.
- For questions, submit a ticket via <u>AskIRB</u> or contact <u>irb@tc.edu</u>.