



Request a Determination

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Why? What? When? Who?

- If you are not sure if your project is research.
- If you are not sure if your research involves human subjects.
- It will help you determine if your project requires IRB review.
- Start the eIRB application prior to starting your project.
- Anyone can submit a request.

Research

The Code of Federal regulations defines **Research** as:

"A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." [45 CFR 46.102(d)]

Human Subjects

The Federal regulations defines **Human Subjects** as:

"...living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual , or (2) identifiable private information." [45 CFR 46.102(f)(1-2)]


How?

Check the correct box:

* **Short Study Title:**

Enter a short study title for your study. Use the short study title to identify your study in the system. If the NIH requires a short title for your study, use the same short study title here.

* Please select one of the following:

- New Study
- Request Waiver of Oversight to Another IRB
- Future Human Subjects
- Request a Determination 
- Repository Only (data/biological specimen registries, repositories, data banks or libraries)

[Clear](#)

How? continued

- Do you know you are doing research?

1.

YES — I am conducting research ⇒ Go on to human subject determination

I am not sure if my activity meets the definition of research

[Clear](#)

- If yes, hit continue

2. Does the research involve obtaining information about living individuals?

No — All subjects are dead, therefore no research involving human subjects. HIPAA and Oregon Genetic Privacy Act requirements may apply. Go to question 4.

Yes — Go to question 2.1.

[Clear](#)

2.1. If Yes, does the research involve intervention or interaction with the individuals?

No — Go to question 3.

Yes — Activity is likely to be determined to be human subject research.

[Clear](#)

How? continued

3. If there is no interaction or intervention, this must be data-only research or research involving tissue samples. Is the data or sample existing or will it be created or collected for non-research purposes? Pick One.

- Data/samples already exist
-
- Data/samples will it be created/collected for non-research purposes
-
- Other

[Clear](#)

3.1. If Other, please describe.

4. Does the research involve obtaining information from genetic tests or performing genetic tests?

- Yes — Genetic Opt out requirements may apply.
-
- No

[Clear](#)

5. Is the data/information/sample individually identifiable and/or being anonymized by the research team? Pick One.

- No — not individually identifiable and therefore not likely to be determined to be human subject research.
-
- Yes — individually identifiable

[Clear](#)

Check if being anonymized by research team (may qualify for exemption)

How? continued

5.1. If No, not individually identifiable, please specify:

-
- Data/sample is anonymous – no code exists
-
- Data/sample is coded, but PI will receive data/sample without identifiers and code will not be shared with PI.

[Clear](#)

5.2. If Yes, individually identifiable, is the information Private?

-
- No — Not likely to be determined to be human subject research.
-
- Yes — Human Subject Research

[Clear](#)

6. Describe the interaction or data that will be involved in the activity.

7. Describe who created or will create the data and who, if applicable, will be sharing the data with the research team.

8. Describe how data is transferred or shared with the research team.

9. Describe any plans to de-identify or anonymize data.

- Not sure if your activity meets the definition of research?

1.

YES — I am conducting research ⇒ Go on to human subject determination

I am not sure if my activity meets the definition of research

[Clear](#)

1.1 Please describe your activity. Provide detail regarding the intent or primary purpose for implementation of the activity.

1.3 What will you do with the results of the activity?



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