



Completing a Request for Determination

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Completing a Request for Determination Form

Request for Determination Form



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Community PI Name _____
Research Navigator Name Melissa Varnum
Project Title [CPP IRB Pilot]

PI (Principal Investigator): person who is responsible for oversight of project activities, including protection of human subjects (participants)

INSTRUCTIONS

Use this form when:

- You are not sure if your project requires human subjects' protection (Institutional Review Board=IRB) oversight, or
- You would like a formal determination from the IRB as to whether the project requires human subjects' protection oversight, or
- You are conducting genetic research with samples, information or data that are not individually identifiable to the research team.

Complete the entire form unless your response to a particular question instructs you to skip ahead.

Upload the form to the eIRB in place of, or in addition to, a protocol (your project's plan).

If your project meets the definition of Research (Section 1), includes Human Subjects (Section 2), and OHSU is Engaged in the research (Section 3), you should submit a new study with a full protocol instead of submitting this form.



RFD – Section One

Section One – Research | Evaluation | Study

Your project goal is to prove or study whether a new idea can help or improve something; this is research. Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

- This project is research. → Skip to Section Two.
- I don't think this project is research, or I am not sure. → Answer the questions below:

↑ 1.1. Is this a case study of a single patient or a case series of three or fewer patients? If so, describe. *Note: Inclusion of more than three patients is generally considered research.*

1.1.1. If yes, will it involve testing of biological specimens for non-clinical purposes? If so, describe.

1.2. Is this a quality improvement/quality assurance, program evaluation, or public health project? If so, explain. *(These types of activities may not meet the definition of research. See the [Quality Improvement or Research? Quick Guide on the IRB Policies and Forms](#) web page for more information.) The intent of this project is [quality improvement, program evaluation, program development, public health project, etc.].*

Here you can pull from proposal question 1. Description can be brief (3-5 sentences).

If this is a continuation, it's helpful to reference that this project builds on a previously funded CPP project.



Definition of Research

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

General Characteristics of Quality Improvement vs. Research

Quality Improvement

- Implement change according to mandates of hospital's Clinical QI program
- Improve process or delivery of care with established/accepted methods
- Implement systematic monitoring to ensure existing quality standards are met
- All participants receive standard of care
- Improve performance in a specific program

Research

- May be funded by an external research agency
- Answer a research question/tests a hypothesis
- Uses research design: Group comparisons, randomization, control groups, prospective comparison, cross-sectional, case-control, etc.
- Develops new paradigms or untested methods, establishes a new clinical practice standard
- Follows a protocol that overrides clinical decision-making
- Develop or contribute to generalizable knowledge

RFD – Section One

- 1.3. Will you be looking at **changes or differences** between groups? Will individuals, groups, or institutions/organizations be randomized or otherwise designated to receive different interventions that will be compared? Example; deciding whether there are changes between groups based on a Community Paramedic visiting a certain number of patients but not others. If so, explain. *Note: Randomization or comparison against a control tends to indicate a systematic investigation, which may be research.*
- 1.4. What are you hoping to **learn** from this project? Will the knowledge you gain be **generalizable** to other contexts or situations? Might you be interested in utilizing your knowledge in a proposal to a funder or are you being required to report your results to a funding agency?
- 1.5. **What will you do with the results?** Might you be interested in utilizing your knowledge in a proposal to a funder or are you being required to report your results to a funding agency? *Note: Whether you intend to publish does not itself determine whether your project is research. After describing what you will do with results, add the following: Findings will also be shared with the Knight Community Partnership Program in a final project report. Data and information provided on this report will not include any identifiable data.*

Example: publish in an academic journal, share results with other organizations, present at a national conference, prepare an internal report, etc.

Generalizable knowledge: results are intended to be generalized to a larger population beyond those involved in the project, or are intended to be replicated in other settings.

RFD – Section Two

Section Two – Human Subjects and their Identifiable Private Information

A **human subject** is a **living individual** about whom an investigator conducting research obtains:

- Data through **intervention** or **interaction** (including surveys, questionnaires, providing educational materials or testing home visits) with the individual, or
- **Identifiable private information** (*information is identifiable [includes medical record numbers, addresses, names; any of the [18 HIPAA identifiers](#)] if the identities of the subjects are **readily ascertainable** to the investigator, either directly or indirectly through a coding system)*)

This project involves human subjects. → **Skip to Section Three.**

This project is not research. → **Skip to Section Five.**

This project is or may be research, but I don't think it involves human subjects, or I am not sure. → **Answer the questions below.**



2.1. Are all of the subjects in the research known to be deceased? *Note: Decedents are not considered human subjects.*
No.

2.2. Describe the information, data and/or specimens to be used for the project. **Data to be collected during this project include:**

- **Data collection tool 1 (e.g. literature review)**
 - Describe tool
 - Will results be identifiable?
 - Specific data points to be collected:
 - XYZ
- **Data collection tool 2 (e.g. online survey)**
 - Same secondary questions as above.
- **Data collection tool 3 (e.g. process data)**
 - Same secondary questions as above.



Here you can pull from your:

- Tier 1 – methodology section
- Tiers 2, 3 – methodology and evaluation sections, project objectives template

Example

2.2. Describe the information, data and/or specimens to be used for the project. **Data to be collected will include:**

Type of data collection tool



Process data

- # of “ready” OHP patients referred to Behavioral Health
- # of Quit Line referrals through Oregon Health Authority
- # of providers/clinics contacted about available training to implement adapted evidence-based smoking cessation intervention
- # of trainings held for clinic staff
- # of training participants

Anonymous?
Coded?
Identifiable?



- **Anonymous pre/post survey for training participants**
 - Training to support clinics in effectively implementing the adapted evidence-based smoking cessation intervention using the Behavioral Health referral process
 - Survey to measure training effectiveness
- **Anonymous survey of clinic staff**
 - Will identify current workflows and process for tobacco cessation from their perspective
- **Anonymous patient survey**
 - Survey of those accepting referral to Behavioral Health to assess satisfaction with program
 - Administered by behavioral health staff or referral coordinator
 - Measuring satisfaction with: length of time from referral to appointment, level of support offered, cessation plan, etc.

Detail around what is being measured, how, and from who?



RFD – Section Two

2.3. Are all of the information, data and/or specimens pre-existing or going to be collected for some purpose other than for this project?

If yes:

2.3.1. What is the original source of the information, data and/or specimens? How will they be provided or transferred to the investigators?

2.3.2. Are all of the information, data and/or specimens de-identified such that none of the investigators working on the project could readily ascertain the identities of the subjects, either directly or indirectly through a coding system? Explain. *Note: If investigators have a way of identifying individual subjects or linking the code to identifiable information stored elsewhere, the project likely involves human subjects.*

If no:

2.3.3. How will the investigators (at OHSU or another institution) collect the information, data and/or specimens? *Note: If investigators will intervene (including both physical procedures and manipulations of the subject or subject's environment) or interact (including all forms of communication or interpersonal contact) with individuals in order to collect information about them, this project likely involves human subjects. Data will be collected through use of [process data, surveys, interviews, etc.] as described in question 2.2.*

RFD – Section Three

Section Three – Engagement in Research

OHSU is **engaged** in a research project if **OHSU employees, students, or other agents** do any of the following:

- **Intervene or interact** with human subjects for the research,
- Obtain **individually identifiable private information** about human subjects for the research, or
- Obtain the **informed consent** of individuals for participation in the research.

There are exceptions for certain recruitment activities and for performance of some protocol-required procedures as a commercial service or on an emergency or temporary basis.

- This project is research and OHSU is engaged in the research project. → **Skip to Section Four. If the project also involves human subjects, STOP and complete a new study submission.**
- This project is not research, or it is research that does not involve human subjects. → **Skip to Section Four.**
- This project is or may be human research, but I don't think OHSU is engaged in the project, or I am not sure. → **Answer the questions below:**
 - 3.1. Describe OHSU's and any other institutions' roles in the research, including which investigators will interact with human subjects, obtain subjects' identifiable private information, or obtain informed consent for the research. *Note: If OHSU investigators will do any of these things, OHSU is probably engaged in the research.*

If OHSU is not engaged in the project's activities, data collection, or data analysis, sample language is provided on the template.

RFD – Section Four

Section Four – Oregon Genetic Privacy Law

Genetic Research is research using human DNA samples, genetic testing, or genetic information. **Genetic information** is information about an individual or the individual's blood relatives obtained from a genetic test. For more details, see our [Genetic Research](#) web page.

- This project does not involve genetic research. → **Skip to Section Five.**
- This project involves genetic research. → **Answer the questions below.**

Select the first box unless your project involves genetic research. If selecting this box, you can skip the rest of section four questions.

RFD – Section Five

Section Five – HIPAA

Protected Health Information (PHI) = health information + one or more of the 18 identifiers. See our [HIPAA and Research](#) web page for more details.

Even if your project is not human research or OHSU is not engaged in the research, you may have requirements under HIPAA if you are using, obtaining, or releasing/disclosing PHI.

All HIPAA forms linked below are available on the [IRB Policies and Forms](#) web page. Upload them on the **Recruitment, Consent and Authorization** page of the IRQ.

- This project does not collect any health information. → **Stop here, no HIPAA requirements.**
- This project collects health information, but does not involve access to or recording of any of the 18 individual identifiers, and therefore does not involve PHI. → **Stop here, no HIPAA requirements.**
- Investigators on this project will only have access to data/specimens already at OHSU and that meet the definition of a Limited Data Set (*no direct identifiers such as name, MRN, initials, or street address, but may include dates and geographic subdivisions smaller than a state*), and the Limited Data Set will not be sent outside OHSU. → **Stop here, no additional HIPAA requirements.**
- PHI will be accessed, used, and/or sent outside OHSU, but not for research purposes. → **Stop here, comply with OHSU HIPAA policies for non-research activities.**
- PHI will be accessed only for purposes preparatory to research, such as preparing a protocol or compiling a recruitment list, and the PHI will not be released outside OHSU. → **Prep to Research form required.**
- This project is research and will collect and use PHI, but all subjects are known to be deceased. → **Decedents Representation form required.**
- This project is research and will collect PHI, but only for the purpose of preparing a Limited Data Set to send outside OHSU. → **Data Use Agreement required.**
- This project is research and OHSU will receive a Limited Data Set from another institution for this project. → **Data Use Agreement may be required by the other institution.**
- This project is research, PHI will be accessed, used, and/or sent outside OHSU for purposes of this study, and none of the above options apply. → **You most likely need a Waiver or Alteration of Authorization. Any disclosures outside OHSU must be tracked in the Accounting of Disclosures System.**
- Other – Explain:

A list of the 18 identifiers is provided on the RFD template.

RFD – Section Five

If none of the provided options fit, select ‘Other’ and describe.

Analysts will want to see detail around:

- Access to protected health information (PHI)
- If you are with a health system or clinic, describe whether project staff have access to PHI within regular scope of clinical practice. How will data collection for this project be different?
- How will PHI be used specifically for this project (identifying and recruiting participants, tracking screening completion, etc.)?

Next Steps

- Complete RFD draft for your project and work with our team to finalize
- Once submitted to the IRB, two possible outcomes:
 - *No, your project is not considered human subjects research*
 - No further IRB action needed, unless project design changes
 - *Yes, your project is considered human subjects research*
 - Submit additional documents and information about project to the IRB

We will support your team through this multi-step process!



Thank You!