

Request for Determination Form



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

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.

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. N/A

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.)* **This intent of this public health project is quality improvement/program evaluation; Blanks Health Department is aiming to build on their previously funded Community Partnership Program project; they will be expanding the pilot program focused on primary care medical home providers and staff utilizing evidence-based tobacco cessation interventions in their clinic workflows. Clinics in Blanks County will participate. Training will be provided for clinic staff, which will include an anonymous pre/post survey to measure training effectiveness.**

Patients who report they are ready to stop using tobacco will be offered behavioral health and/or Quit Line support (patient to decide which services to access, if any). Patients who accept the referral to Behavioral Health will have the option to participate in anonymous surveys to measure satisfaction with the cessation services offered. A referral coordinator will follow up with patients who are referred but do not accept the referral to identify whether other cessation options were accessed, barriers to accessing services, etc.

All information transmitted from participating clinics to Blanks County will be de-identified, and a data use agreement is in place.

- 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.* **No.**
- 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? **Blanks Health Department is hoping to assess satisfaction among patients referred to Behavioral Health services in support of tobacco cessation and the effectiveness of a training for clinic staff around implementation of an adapted evidence-based cessation intervention.**
- 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.* **Analyzed results from patient satisfaction surveys will be shared back to participating clinics in aggregate form. Survey results will be used as quality improvement to adjust, modify, and or/change the overall project for future implementation. Results from training pre/post surveys will serve as program evaluation for the staff training. Results will 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.**

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 will include:**
- **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 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.

Note: only de-identified patient data provided by participating clinics to Blanks Health Department. No PHI will be shared and a data use agreement will be in place.

- 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? **No.**

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 and anonymous surveys as described in question 2.2.*

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. OHSU is not engaged in this in this project other than by acting as a funder via the Knight Community Partnership Program. Blanks Health Department is responsible for this project, including the analysis of any data collected.*
 - 3.2. Will OHSU employees, students, or agents obtain **only de-identified data or specimens** (that is, the data/specimens are completely anonymous or the data/specimens are coded and OHSU investigators will not have access to the key to the code)? *If so, OHSU is probably not engaged in the research. N/A*
 - 3.3. Will OHSU employees, students, or agents **only release pre-existing data or specimens** to investigators at another institution (that is, OHSU investigators will have no part in testing of specimens or data analysis)? *If so, OHSU is probably not engaged in the research. N/A*

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:**
 - 4.1. The specimens/data are (check one):
 - Anonymous (meaning the identity of the individuals or their blood relatives cannot be determined by the investigator, including through a code or other means of linking the information to a specific individual)
 - Coded (meaning that a link to identifiers exists that would allow re-identification of the data/specimens, even if the OHSU investigators will not have access to it)
 - 4.2. For coded data/specimens, describe the method of coding and steps you will take to ensure data security. (See [HRP-461 WORKSHEET – Oregon Genetic Research – Anon-Coded](#) on the [IRB Policies and Forms](#) web page for specific criteria regarding coded genetic research.)
 - 4.3. In Oregon, the individuals who originally provided the data/specimens must have consented to genetic research, or you must verify that the individuals have not “opted out” of genetic research at OHSU (see our [Genetic Research](#) web page for more information). Indicate how your project complies with this requirement (check one):

- Subjects consented for this project specifically
- Subjects consented for future genetic research generally
- Subjects did not consent, but we will exclude any subjects who opted out of coded/anonymous genetic research – Describe your plan to verify opt-out status:

- None of the specimens/data are from subjects in Oregon
- Other – Describe:

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: