

**OREGON CLINICAL & TRANSLATIONAL**

**RESEARCH INSTITUTE**

Knight CPP Grantee Instructions

The document below is a template designed by the OHSU Institutional Review Board. Please reach out to your assigned evaluator with any questions or concerns.

Yellow text: **additional information** from Knight CPP team designed to help you better respond the question. This text also includes references to the Knight CPP proposal where you may have already provided the details requested. All yellow text will be deleted prior to submission.

Blue text: indicates a field where you need to **replace** the existing text with the information requested.

Green text: this is **sample language** that you should include *if relevant****.*** Yellow text will provide context as to whether or not this text is relevant.

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| **Request for Determination Form** | |  | | | | | |
| Version **PEFarris-OCTRI+Knight Tool**  Publish date March 27, 2020 | | Research Integrity Office  Mail Code L106-RI  Portland, Oregon 97239-3098  Phone: 503.494.7887  Fax: 503.346.6808 | | | | | |
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|  | | | | | | | |
| Community PI Name: | Add name of person responsible for project oversight | | | | eIRB |  |  |
| Research Navigator Name: |  | | | | | |  |
| Project Title: | [CPP IRB Pilot] Add project title | | | | | |  |
|  |  | |  |  | | | | |
| ***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**. Only select this box if the intent of your project is specifically research.

I don’t think this project is research, or I am not sure. 🡪 **Answer the questions below:** Select this box if you aren’t sure and would like the IRB to make this determination. This is the recommended option to select.

* 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.* The answer here is typically ‘No,’ unless your project will involve three or fewer participants.
     1. If yes, will it involve testing of biological specimens for non-clinical purposes? If so, describe.
  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?*](http://www.ohsu.edu/xd/about/services/integrity/policies/upload/Quality-Improvement-or-Research-Quick-Guide.pdf) *Quick Guide on the* [*IRB Policies and Forms*](http://www.ohsu.edu/xd/about/services/integrity/policies/all-irb-documents.cfm) *web page for more information.*) Briefly describe the overall intent of your project (can pull from question 1 on CPP proposal). If this is a continuation, reference that this project builds on a previously funded CPP project. The CPP team will then add the IRB number for your previously reviewed project.
  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.* If your project will compare differences between groups or will compare results from different interventions, describe here. Otherwise, indicate “No.”
  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? Describe what your team hopes to learn from this project. Include detail around whether you want to generalize findings beyond those in your local community. This may include things like publishing findings in an academic journal, developing a program/model that can be implemented at other agencies, or generalizing findings to other populations beyond who participates in this project. Include the following template language if you do not intend to generalize findings: “Results of our team’s needs assessment are intended to be used for future program development, and it is not the intention to generalize findings more broadly.”
  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.* If you intend to publish findings, share results with other organizations, present findings at a conference, prepare an internal report, etc. include these details here. 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.”

**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*](http://privacyruleandresearch.nih.gov/pr_08.asp)*] 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:** By selecting this option (recommended), you are able to provide the IRB with additional detail about the types of data being collected.

* 1. Are all of the subjects in the research known to be deceased? *Note: Decedents are not considered human subjects.*
  2. Describe the information, data and/or specimens to be used for the project. For Tier 1 grantees, you can pull this information from methodology section of the proposal. For tiers 2/3, you can pull from the methodology and evaluation sections of the proposal and the project objectives template.

Data to be collected during this project include:

* Add name of data collection tool (e.g., literature review, survey, process data, interviews)
  + Add description of tool
  + Add how the tool will be administered (e.g., online, in person)
  + Add who the target audience will be and how they will be recruited
  + Add whether data collected will be identifiable (name, date of birth, etc.) or anonymous
  + Add information about the types of questions you plan to ask. You do not need to add the specific questions; high level overview is fine.

Include all the above information for **EACH** data collection tool

* 1. Are all of the information, data and/or specimens pre-existing or going to be collected for some purpose other than for this project? Is the data to be used for this project already collected (e.g. literature review, chart review, etc.)? Is data being collected only to be stored for future use? If the answer to either is yes, describe. Otherwise, indicate ‘No’ (this is the most typical response).

**If yes:**

* + 1. What is the original source of the information, data and/or specimens? How will they be provided or transferred to the investigators?
    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:**

* + 1. 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.

**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 andOHSU 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:**

* 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.* Will OHSU or other academic institutions will participate in this project? If yes, describe here. Otherwise, you can enter the following language: OHSU is not engaged in this project other than by acting as a funder and providing general technical assistance (e.g. evaluation support) via the Knight Cancer Institute Community Partnership Program. [Your organization] is responsible for this project, including analysis of any collected data.
  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.*
  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.*

**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](http://www.ohsu.edu/xd/research/about/integrity/irb/genetic.cfm) web page.

This project does not involve genetic research. 🡪 **Skip to Section Five.** Select this box unless your project involves genetic research. If selecting this box, skip the rest of section four questions.

This project involves genetic research. 🡪 **Answer the questions below:**

* 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)

* 1. 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](http://www.ohsu.edu/xd/about/services/integrity/policies/upload/HRP-461-WORKSHEET-Oregon-Genetic-Research-Anon-Coded-ohsu.pdf) on the [IRB Policies and Forms](http://www.ohsu.edu/xd/about/services/integrity/policies/all-irb-documents.cfm) web page for specific criteria regarding coded genetic research.)
  2. 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](http://www.ohsu.edu/xd/research/about/integrity/irb/genetic.cfm) 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](http://www.ohsu.edu/xd/research/about/integrity/irb/hipaa_research.cfm) 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](http://www.ohsu.edu/xd/about/services/integrity/policies/all-irb-documents.cfm) web page. Upload them on the ***Recruitment, Consent and Authorization*** page of the IRQ.

The 18 identifiers are listed below. If any health information will be collected with one or more of these, you are collecting protected health information (PHI).

Names

All geographical subdivisions smaller than a State

All elements of dates (except year) for dates directly related to an individual

Phone numbers

Fax numbers

Email addresses

Social Security numbers

Medical record numbers

Health plan beneficiary numbers

Account numbers

Certificate/license numbers

Vehicle identifiers and serial numbers, including license plate numbers

Device identifiers and serial numbers

Web Universal Resource Locators (URLs)

Internet Protocol (IP) address numbers

Biometric identifiers, including finger and voice prints

Full face photographic images and any comparable images

Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)

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**](http://www.ohsu.edu/xd/about/services/integrity/policies/upload/HIPAA-Prep-to-Research-Form-FINAL-3-5-2014.docx) **form required.**

This project is research and will collect and use PHI, but all subjects are known to be deceased. 🡪 [**Decedents Representation**](http://www.ohsu.edu/xd/about/services/integrity/policies/upload/HIPAA-Decedent-Representation-Form-rev-12-17-2014-2.docx) **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**](http://www.ohsu.edu/xd/about/services/integrity/policies/upload/HIPAA-Data-Use-Agreement.doc) **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**](http://www.ohsu.edu/xd/about/services/integrity/policies/upload/HIPAA-Waiver-or-Alteration-of-Authorization-rev-12-17-2014.doc)**. Any disclosures outside OHSU must be tracked in the Accounting of Disclosures System.**

Other – Explain:

If none of the above options fit, select ‘Other’ and describe. Analysts will want to see information on:

* + Access to PHI
  + If a health system or clinic, can describe whether project staff have access to PHI within regular scope of clinical practice. How will data collection for this project be different? Will PHI be used specifically for this project (identifying participants, tracking screening completion, etc.)?
  + Provide as much detail as possible in this section, reinforcing points from questions above around data collection and sharing of results.