Grantee Orientation Webinar
Community Partnership Program
2021-2

PRESENTED BY: Melissa Varnum, MPH and Alex Dest, MPH
Click here to view recording
Password: Knightcpp1!
Agenda

• Part I – CPP Orientation
  • Overview of Community Partnership Program
  • Project Preparation Period Activities
    • Technical assistance overview
  • Networking & Collaboration Opportunities
  • Communications Toolkit
  • Grant Reporting Guidelines
  • Important Updates
  • Next Steps

Part II – Human Subjects Protection Overview
Community Partnership
Program Overview
Program Mission

The mission of the Community Partnership Program is to work hand in hand with Oregon communities as allies in the Knight Cancer Institute’s efforts to end cancer as we know it. We will:

**Support**
- Oregon communities in understanding and addressing their most pressing cancer-related needs.

**Enhance**
- Collaboration between Oregon communities and OHSU to address cancer in Oregon.

**Foster**
- Skills and abilities of communities to enhance long-term sustainability.
## Congratulations!

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<tr>
<th>Tier</th>
<th>Organization</th>
<th>City</th>
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<tr>
<td>Tier 1</td>
<td>South Coast Rural Health Integrated Project Team</td>
<td>Coos Bay</td>
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<td>Access Care Anywhere</td>
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<td>Tier 1</td>
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<td>Virginia Garcia Memorial Health Center &amp; Foundation</td>
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<td>Umatilla County Public Health</td>
<td>Pendleton</td>
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<td>Mid-Columbia Medical Center</td>
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Program Impact

Funded projects have impacted all 36 Oregon counties
Geography

82% of funded projects include a focus on rural areas
Cancer Continuum and Tier

Funded projects span the cancer continuum

- **Prevention**: 26 Tier 1, 37 Tier 2, 17 Tier 3, 12 Special call, 4 Community Action Model (59%)
- **Screening/early detection**: 16 Tier 1, 14 Tier 2, 10 Tier 3 (24%)
- **Survivorship (including treatment)**: 16 Tier 1, 23 Tier 2, 11 Tier 3, 11 Special call (37%)
Cancer Type

49 proposals focus on specific cancers

- Colorectal: 18
- Breast: 18
- Lung: 6
- Gynecological: 6
- Skin/Melanoma: 5
- Sarcoma: 3
- Male reproductive system: 2
- Pancreatic: 1
- Hematologic: 1
113 projects focus on at least one cancer topic

- Diet/nutrition: 33
- Physical activity: 31
- Tobacco prevention and/or cessation: 26
- Psychosocial support: 23
- Patient navigation: 20
- HPV prevention/vaccination: 11
Race

30 funded projects focus on a particular race

- Black/African American: 13
- American Indian/Alaskan Native: 13
- Asian: 6
- Native Hawaiian/other Pacific Islander: 2
Unique Populations

80 projects target at least one unique population

- Cancer patients/survivors: 63
- Immigrants and refugees: 19
- Caregivers: 6
- Persons with disabilities: 3
- LGBTQ: 2
- Veterans: 1
Grantee Resources

- **Technical Assistance**: OHSU-supported assistance to build capacity of grantees in evaluation planning and human subjects protection oversight

- **Skills-Building**: Opportunities to increase knowledge of best practices for community cancer research and programming

- **Networking & Collaboration**: OHSU-hosted opportunities for collaboration and peer-to-peer learning
Project Preparation Period

Technical Assistance Support
Project Preparation Period

• Now through Jan. 31, 2022
  —Time dedicated to technical assistance and initiation of administrative requirements
  —Completion time varies from project to project

• Activities:
  • Sign award agreement and submit current W-9
  • Participate in individual kick-off call to:
    —Finalize evaluation tools and plans
    —Discuss training topics of interest
    —Initiate Request for Determination to IRB to determine if human subjects research; full study submission if applicable
  • Tier 1: Create work plan/timeline (optional)
Evaluation Core
Amy Wilson, Alex Dest

• Assigned evaluator will work closely with you and your team to:
  • Ensure outcomes are feasible and measurable
  • Identify/recommend tools for collecting data (evaluation)
  • Modify proposed approach, if applicable
  • Supporting the Request for Determination submission process
Human Subjects Protection

Human subjects protection supports community grantees in protecting and minimizing risks to people who choose to participate in research projects.

All grantees are required to submit a Request for Determination to an IRB and/or obtain IRB approval if needed.

*Stay tuned for more!*
Skills-Building

• Trainings opportunities will be available to grantees throughout the project period.

• During kick-off calls, TA team will ask questions about training topic interests/needs, preferred format/timing, etc.

• Based on grantee feedback, planned trainings and technical assistance opportunities will be shared in February, 2022.
Networking & Collaboration

Individual Projects
- Mid-project check-ins/site visits

Peer-to-Peer
- In person regional grantee networking sessions
- Grantee highlight webinars

CPP Program-wide
- Quarterly grantee newsletter
- Grantee conference
- Grantee resources page
Individual Projects

Mid project check-ins/site visits
• 5-7 months into project
• Projects in action: let us know of scheduled grantee activities we can attend/observe

Peer-To-Peer

Grantee workshops
• Virtual trainings with dedicated time for grantee networking to discuss common successes, challenges, etc.

Regional grantee networking sessions (possible)
• Details to be determined
• Opportunities for grantees to plan/host if desired to meet more often!
Quarterly grantee newsletter

- Updates on upcoming networking opportunities, trainings, funding opportunities, etc.

Grantee Conference

- **Date/Location:** May 10-11, 2022 in Portland, OR
- **Share your work!**
  - Poster presentations
  - Grantee panel presentations
- Networking
- Resource sharing
- Skills-building

**Fees:** Knight funds registration & accommodations for up to two participants per funded project.
Communications Toolkit

An opportunity to promote the work your organization will be doing in your community. We want your hard work to be recognized!

- Guidelines for funding announcements and sharing project results
- OHSU branding logistics
- Social media prompts
- Acquiring quotes + approvals from OHSU
- Assistance from Knight Cancer Institute Communications

Are there opportunities to share about your work through local media? Contact us with ideas/questions!
Final Project Report (FPR) Guidelines

The report is a three-step process:

1. Contact evaluation specialist to set up a FPR consult (30 days prior to due date)

Online Portal

2. Submit the final project report in the online portal.
3. Submit all supporting documents
   a. Evaluation tools
   b. Data summaries
   c. Outreach and engagement materials
Final Project Report Guidelines

Projects are required to report on:
• Objectives
• Reach (participants)
• Evaluation/assessment (tools used, associated preliminary findings)
• Collaboration/partnerships
• Strengths, successes and benefits
• Barriers, challenges, lessons learned
• Sustainability & future plans
• Participation in technical assistance support

Report guidelines available on Grantee Resources webpage
• Online form available 90 days prior to project end date
• Final reports due 30 days after project period end date
Grantee Resources Page

1. Orientation webinar
2. Communications toolkit
3. Request for Determination guidance and templates
4. No cost extension and final report instructions
5. Grantee conference
**Important to know**

- **Project Start/End Dates**
  - Start: Feb. 1, 2022
  - End: Jan. 31, 2023

- **Funds Distributions**
  - Dependent on IRB approvals – *this can take up to several weeks/months*
  - If not research - payment processed upon this designation
  - If human subjects research - 10% funds payments distributed; remaining balance submitted upon receipt of IRB approval documentation
  - If you hold two active grants, one must end before initiation of/payment for this newly funded project

- **No Cost Extensions**
  - Available to all grantees in good standing
    - *We will notify you when time to apply (90 days prior to end date)*
Part II: Human Subjects Protection

Alexandra Dest, MPH
Evaluation Research Data Analyst
Agenda

• Human subjects protection and the Institutional Review Board (IRB)

• What to expect in the Human Subjects Protection process for your project

• Completing a Request for Determination form
Human Subjects Protection

What is it?

The steps taken to be sure people who choose to participate in a research project are protected from any potential harm that may result from their participation.
Institutional Review Board (IRB)

Among other things, IRBs are responsible for:

- Protecting the rights and welfare of all human subjects or research participants.
- Providing approval and oversight for all projects determined to be human subjects research.
- Ensuring compliance with federal regulations.
Human Subjects Protection Process

Request for Determination form (RFD)

- Determines the project’s intent and level of engagement in research
- Our team will support you in completing and submitting this form for your project

To move forward for payment:

- Must receive IRB approval or a not human subjects research determination from the IRB
Completing the Request for Determination Form

Request for Determination Form

Community PI Name: [Input]
Research Navigator Name: [Input]
Project Title: [Input]

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 stop ahead.

Upload this form to the IRB 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 ONH 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 in this 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. 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. 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.)

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 leads to 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?
Completing the Request for Determination Form

### Request for Determination Form

<table>
<thead>
<tr>
<th>Community PI Name:</th>
<th>Add name of person responsible for project oversight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Navigator Name:</td>
<td>eIRB</td>
</tr>
<tr>
<td>Project Title:</td>
<td>[CPP IRB PIot] Add project title</td>
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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.

#### 1.1.
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.

1.1.1. 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 webpage 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.
Completing the RFD Form

- **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.

- **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.
Completing the RFD Form

- As you respond to questions, please remove the yellow CPP guiding text.

- No CPP text will be included in the version submitted to the IRB.

- The IRB will not have background information on your project beyond what is provided here.
Completing the RFD Form

The RFD form has check box questions to prompt you on which sections/questions need to be completed.

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.
RFD – Section One

Asks about:

- The goal/intent of your project
- Are you looking at changes or differences between groups?
- What are you hoping to learn? What do you plan to do with results?
RFD – Section Two

Asks about:

➢ The data you’ll be collecting
➢ Who will you be collecting data from?
➢ How will the data be collected?

2.2. 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.
RFD – Section Three

Asks about:

- OHSU and other institutions’ role in the project
- Template language available if OHSU is not engaged in the project

RFD – Sections Four and Five

Asks about:

- Whether your project involves genetic research
- Protected Health Information (PHI) and HIPAA requirements (does your project include access to identifiable information?)
Possible RFD 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!*
Next Steps

1. **Award Agreement**: Receive, sign and return along with current W-9 form in online portal

2. **Technical Assistance Support**
   - Respond to kick-off call scheduling email
   - View video tutorial on *Completing a Request for Determination* (RFD) and begin draft
   - TA team will support you to finalize plan & tools
# Team contact info:

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<tr>
<th>Technical Assistance Team</th>
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<tbody>
<tr>
<td>Amy Wilson</td>
</tr>
<tr>
<td><a href="mailto:wilamy@ohsu.edu">wilamy@ohsu.edu</a></td>
</tr>
<tr>
<td>Alex Dest</td>
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<tr>
<td><a href="mailto:dest@ohsu.edu">dest@ohsu.edu</a></td>
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<tr>
<td>Melissa Varnum</td>
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<td><a href="mailto:varnum@ohsu.edu">varnum@ohsu.edu</a></td>
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<tr>
<td>Dustin Hawes</td>
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<td><a href="mailto:hawesdu@ohsu.edu">hawesdu@ohsu.edu</a></td>
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<tr>
<td><a href="mailto:knightcancercro@ohsu.edu">knightcancercro@ohsu.edu</a> 503 418-8077</td>
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Questions?
Thank you!