Click here to view recording
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:

<table>
<thead>
<tr>
<th>Support</th>
<th>Enhance</th>
<th>Foster</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Oregon communities in understanding and addressing their most pressing cancer-related needs.</td>
<td>• Collaboration between Oregon communities and OHSU to address cancer in Oregon.</td>
<td>• Skills and abilities of communities to enhance long-term sustainability.</td>
</tr>
</tbody>
</table>
Congratulations!

**Tier 1:**

<table>
<thead>
<tr>
<th>Organization</th>
<th>City</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adventist Health Columbia Gorge</td>
<td>The Dalles</td>
</tr>
<tr>
<td>Oregon School-Based Health Alliance</td>
<td>Portland</td>
</tr>
<tr>
<td>Adventist Health Portland</td>
<td>Portland</td>
</tr>
<tr>
<td>Silver Years</td>
<td>Beaverton</td>
</tr>
</tbody>
</table>
Congratulations!

Tier 2:

<table>
<thead>
<tr>
<th>Organization</th>
<th>City</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tillamook County Health Department</td>
<td>Tillamook</td>
</tr>
<tr>
<td>2Live2Cure</td>
<td>Hood River</td>
</tr>
<tr>
<td>Centro de Servicios Para Campesinos</td>
<td>Woodburn</td>
</tr>
<tr>
<td>Southern Oregon Friends of Hospice</td>
<td>Medford</td>
</tr>
<tr>
<td>South Coast Rural Health Integrated Project Team</td>
<td>Coos Bay</td>
</tr>
</tbody>
</table>
Congratulations!

Tier 3:

<table>
<thead>
<tr>
<th>Organization</th>
<th>City</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hood River County Prevention Department</td>
<td>Hood River</td>
</tr>
<tr>
<td>Northwest Sarcoma Foundation</td>
<td>West Linn</td>
</tr>
</tbody>
</table>
Funded projects have impacted all 36 Oregon counties.
Cancer Continuum and Tier

Funded projects span the cancer continuum

Prevention
- Tier 1: 37
- Tier 2: 40
- Tier 3: 22
- Special call: 16
- Community Action Model: 4
- Total: 58%

Screening/early detection
- Tier 1: 27
- Tier 2: 19
- Tier 3: 12
- Special call: 4
- Total: 30%

Survivorship (including treatment)
- Tier 1: 25
- Tier 2: 30
- Tier 3: 15
- Special call: 13
- Total: 40%
80% of funded projects include a focus on rural areas
65 proposals focus on specific cancers

- Colorectal: 25
- Breast: 25
- Gynecological: 12
- Lung: 9
- Male reproductive system: 8
- Skin/Melanoma: 7
- Sarcoma: 4
- Pancreatic: 2
- Hematologic: 2
135 projects focus on one or more cancer-related topics

<table>
<thead>
<tr>
<th>Topic</th>
<th>Projects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical activity</td>
<td>35</td>
</tr>
<tr>
<td>Diet/nutrition</td>
<td>35</td>
</tr>
<tr>
<td>Psychosocial support</td>
<td>31</td>
</tr>
<tr>
<td>Tobacco prevention and/or cessation</td>
<td>28</td>
</tr>
<tr>
<td>Patient navigation</td>
<td>28</td>
</tr>
<tr>
<td>HPV prevention/vaccination</td>
<td>13</td>
</tr>
</tbody>
</table>
72 funded projects focus on a particular race and/or ethnicity

- Hispanic or Latino: 43
- Black/African American: 19
- American Indian/Alaskan Native: 15
- Asian: 7
- Native Hawaiian/other Pacific Islander: 3
- White/Caucasian: 1
106 projects target at least one unique population

- Cancer patients/survivors: 79
- Immigrants and refugees: 28
- Caregivers: 15
- Persons with disabilities: 4
- LGBTQ: 4
- Veterans: 1
Project Preparation Period

Technical Assistance Support
Project Preparation Period

• Now through January 19, 2024
  — 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 meeting to:
    — Finalize evaluation tools and plans
    — Discuss training topics of interest
    — Initiate Research Determination Checklist to CPP and/or Request for Determination to IRB to determine if human subjects research; full study submission if applicable
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
Skill-Building

- Trainings opportunities will be available to grantees throughout the project period.
- During kick-off meetings, 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.
Networking & Collaboration

Individual Projects
- Mid-project check-ins

Peer-to-Peer
- Grantee networking sessions
- Grantee workshops

CPP Program-wide
- Quarterly grantee newsletter
- Grantee conference (Oct. 1-2 Corvallis, Oregon)
- Grantee resources page
Individual Projects

Mid-project check-ins
• 5-6 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.

Grantee networking sessions
• Quarterly sessions
• Opportunities for grantees to plan/host if desired
Quarterly grantee newsletter

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

Grantee Conference (required)

Tuesday and Wednesday, Oct. 1-2, 2024, at The LaSells Center, located on the campus of Oregon State University in Corvallis, Oregon.

• Share your work! (poster or grantee presentations)

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 CPP 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
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
1. Orientation webinar
2. Communications toolkit
3. Research Determination Checklist and Request for Determination guidance and templates
4. No cost extension and final report instructions
5. Grantee conference
Important Information

• **Project Start/End Dates**
  • Start: February 1, 2024
  • End: January 31, 2025

• **Funds Distributions**
  • Dependent on research determination and if applicable, 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

Chelsea Ruder & Gina Beer
Evaluation Research Data Analysts
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 Research Determination Checklist and/or Request for Determination submission process
- Facilitate evaluation-related trainings and resources to grantees
- Evaluation drop-in hours:
  - As needed before deadlines
Agenda

- How to use evaluators
- Human subjects protection and the Institutional Review Board (IRB)
- What to expect in the Human Subjects Protection process for your project
- Completing a Research Determination Checklist and/or 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
HSR Key Components for CPP Projects

Purpose

Generalizability

Does your project aim to address a need within your specific community and/or organization?

Is it your intention that the results of this project be applicable only to your community and/or organization?

OHSU Involvement
“What about the data we collect?”

Only collect data necessary to accomplish your project aims

Store all information securely and give access to those that need it

**And just a note**

Anonymous vs confidential does not impact whether or not it is research

- **Anonymous**: no identifiable is collected and linked to responses
- **Confidential**: identifiers collected and may be linked to responses but not reported or shared
### QI/Evaluation or Research

What is the difference?

#### 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

<table>
<thead>
<tr>
<th>Quality Improvement</th>
<th>Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Implement change according to mandates of hospital’s Clinical QI program</td>
<td>• May be funded by an external research agency</td>
</tr>
<tr>
<td>• Improve process or delivery of care with established/accepted methods</td>
<td>• Answer a research question/tests a hypothesis</td>
</tr>
<tr>
<td>• Implement systematic monitoring to ensure existing quality standards are met</td>
<td>• Uses research design: Group comparisons, randomization, control groups, prospective comparison, cross-sectional, case-control, etc.</td>
</tr>
<tr>
<td>• All participants receive standard of care</td>
<td>• Develops new paradigms or untested methods, establishes a new clinical practice standard</td>
</tr>
<tr>
<td>• Improve performance in a specific program</td>
<td>• Follows a protocol that overrides clinical decision-making</td>
</tr>
<tr>
<td></td>
<td>• Develop or contribute to generalizable knowledge</td>
</tr>
</tbody>
</table>
Human Subjects Protection Process

**Research Determination Checklist**
- Checklist document completed by grantee and returned to CPP staff to determine if further action is needed, or if project is not research.

**Request for Determination form (RFD)**
- OHSU IRB 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.

**Full IRB Review**
Completing the Research Determination Checklist

Project Purpose

☐ This project is a public health project, program evaluation, and/or quality improvement/quality assurance project.

Generalizability

☐ This project aims to address a need within my specific community and/or organization.
☐ We do not intend for the results of this project will be applicable in other communities and/or organizations.

OHSU Involvement

☐ OHSU will act as a funder and provide general technical assistance (e.g., evaluation support) via the Knight Cancer Institute Community Partnership Program.
☐ OHSU will not intervene or interact with human subjects or participants for the project.
☐ OHSU will not obtain individually identifiable private information about human subjects or participants for the project.
☐ OHSU will not obtain informed consent of individuals for participation in the project.

Protected Health Information

☐ This project may collect health information and/or identifiable information (including but not limited to name and contact information) of participants. Only data necessary to accomplish project aims will be collected. All information will be securely stored and managed by our organization, in accordance with any applicable HIPAA regulations.

If all of the above statements apply to your project, no further oversight is needed.

Any changes to your project may require a submission to the Institutional Review Board (IRB). It is normal for the scope and/or direction of a grant-funded project to change. We encourage all grantees to adapt project activities as needed and to collect the data necessary to successfully meet their objectives. Our intent is to support organizations by ensuring the appropriate level of protection and oversight from OHSU’s IRB throughout the duration of the project.

Examples that may require a reassessment include but are not limited to:

- Changing the overall intent of the project (e.g., from quality improvement to research)
- Changing plans around how results will be used and/or shared

If you’re proposing a change to your project’s design, scope, and/or data collection methods, follow the steps below:

- Contact the CPP team at KnightCancerCRO@OHSU.edu to discuss the change. They can help determine whether additional steps need to be taken.
- Project activities involving human subjects (including participant recruitment, data collection, etc.) must wait until it is determined whether the project needs to go through further OHSU IRB determination. You will be notified when your project activities can resume by CPP staff.

Name of Primary Contact

Signature of Primary Contact

Date
Possible Checklist Outcomes

➢ **No**, your project is not considered human subjects research based on what you reported to CPP
  • No further IRB action needed, unless project design changes

➢ **Potentially**, your project may be considered human subjects research or it is unclear based on what you reported to CPP
  • Submit a Request for Determination (RFD) form to the OHSU IRB
  • You will receive a formal determination from the IRB whether the project is considered research or not

*We will support your team through this multi-step process!*
Completing the Request for Determination 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. \(\rightarrow\) 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. \(\rightarrow\) 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 proposals). 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.
Possible RFD Outcomes

➢ **No**, your project is not considered human subjects research by OHSU IRB
   • No further IRB action needed, unless project design changes

➢ **Yes**, your project is considered human subjects research by OHSU IRB
   • Submit additional documents and information about project to the IRB

*We will support your team through this multi-step process!*
Follow Up and Payment

Project Changes

- If you plan to make changes to the design or intent or your project, reach out to us. Depending on the changes, you may need to complete an RFD, but we will support you through this process.

To move forward for payment:

- Must confirm project (via checklist) does not meet definition of research involving human subjects OR receive IRB approval OR a not human subjects research determination from the IRB
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 scheduling email
   - Review and draft Research Determination Checklist
   - Review Communications Toolkit
   - TA team will support you to finalize plan & tools
## Team contact info:

<table>
<thead>
<tr>
<th>Technical Assistance Team</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Chelsea Ruder</td>
<td><a href="mailto:ruderc@ohsu.edu">ruderc@ohsu.edu</a></td>
</tr>
<tr>
<td>Gina Beer</td>
<td><a href="mailto:beerg@ohsu.edu">beerg@ohsu.edu</a></td>
</tr>
<tr>
<td>Blanca Cisneros</td>
<td><a href="mailto:cisnerbl@ohsu.edu">cisnerbl@ohsu.edu</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>OHSU Knight Cancer Institute's Communications Team</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="mailto:KnightCancerCom@ohsu.edu">KnightCancerCom@ohsu.edu</a></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CPP General Support</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="mailto:knightcancercro@ohsu.edu">knightcancercro@ohsu.edu</a></td>
<td></td>
</tr>
<tr>
<td>(503) 418-8077</td>
<td></td>
</tr>
</tbody>
</table>
Any Questions?

Thank you!