Kick-Off Webinar
Community Partnership Program
2019-2

DATE: December 4, 2019
PRESENTED BY: Niyati Desai, Melissa Varnum
Click here to view recording.
Agenda  11:00am -12:30pm

• Part I – CPP Orientation
  • Overview of Community Partnership Program
  • Project Preparation Period activities
    • Skills-building workshop
    • 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
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>
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<tr>
<th>Support</th>
<th>Enhance</th>
<th>Foster</th>
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<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>
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</tbody>
</table>
Congratulations!

CPP has funded 119 proposals over 9 grant cycles

- 2015-1: Tier 1 2, Tier 2 10, Tier 3 4, Special call 4
- 2015-2: Tier 1 7, Tier 2 4, Tier 3 2
- 2016-1: Tier 1 4, Tier 2 4, Tier 3 4
- 2016-2: Tier 1 4, Tier 2 4
- 2017-1: Tier 1 2, Tier 2 6, Tier 3 3
- 2017-2: Tier 1 5, Tier 2 4, Tier 3 5, Special call 8
- 2018-1: Tier 1 5, Tier 2 7, Tier 3 6
- 2019-1: Tier 1 4
- 2019-2: Tier 1 4, Tier 2 9

Legend:
- Tier 1
- Tier 2
- Tier 3
- Special call
- Community Action Model
Potential Impact in Oregon

Funded projects have impacted all 36 Oregon counties
<table>
<thead>
<tr>
<th>Tier</th>
<th>Organization</th>
<th>Project Title</th>
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<tbody>
<tr>
<td>Tier 1</td>
<td>Douglas Public Health Network</td>
<td>Douglas County HPV Prevention Project</td>
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<td>Tier 1</td>
<td>Oregon State University, College of Public Health and Human Sciences</td>
<td>Women's experience with interval breast cancer</td>
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<td>Harney District Hospital</td>
<td>Harney County Cancer-Related Needs Assessment</td>
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<td>Tier 1</td>
<td>Southern Oregon Friends of Hospice</td>
<td>Active Cancer Patient Inquiry for Interest, Need and Form for End of Life Education and Counseling</td>
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<tr>
<td>Tier 2</td>
<td>Oregon State University, College of Public Health and Human Sciences</td>
<td>Well water remediation program with Oregon well owners to remove arsenic</td>
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<td>Tier 2</td>
<td>Samaritan Health Services</td>
<td>Feasibility of administering the evidence-based Exercising Together program at a community cancer center</td>
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<tr>
<td>Tier 2</td>
<td>Yamhill Community Care Organization (YCCO)</td>
<td>Tobacco Prevention Program for Youth</td>
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<td>Tier 2</td>
<td>Sky Lakes Medical Center Foundation</td>
<td>Fresh and Local: SLMC Outpatient Nutrition Outreach</td>
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<td>Tier 2</td>
<td>See You at the Summit</td>
<td>Therapeutic nature and adventure impact on adolescent oncology psychosocial health</td>
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<td>Urban League of Portland</td>
<td>Older Adult Cancer Coalition</td>
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<td>Tier 2</td>
<td>Native American Youth and Family Center (NAYA)</td>
<td>Cancer Prevention through Cultural Teachings</td>
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<td>Tier 2</td>
<td>Oregon State University Coos County Extension</td>
<td>WE CAN (Wellness Education for Cancer Nutrition)</td>
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<td>Tier 2</td>
<td>American Lung Association in Oregon</td>
<td>Reduce Tobacco and Nicotine Use Among Youth in Oregon</td>
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Geography

82% of funded projects include a focus on rural areas

- Rural: 43%
- Urban: 18%
- Both: 39%
Continuum and Tier

Funded projects span the cancer continuum

- **Prevention**
  - Tier 1: 18
  - Tier 2: 27
  - Tier 3: 14
  - Special call: 12
  - Community Action Model: 4

- **Screening/early detection**
  - Tier 1: 12
  - Tier 2: 8
  - Tier 3: 7

- **Survivorship (including treatment)**
  - Tier 1: 12
  - Tier 2: 18
  - Tier 3: 8
  - Special call: 8
36 proposals focus on specific cancers

- Colorectal: 11
- Breast: 11
- Skin/Melanoma: 5
- Gynecological: 5
- Lung: 4
- Sarcoma: 2
- Male reproductive system: 2
- Hematologic: 1
87 projects focus on at least one cancer topic

- Physical activity: 27
- Tobacco prevention and/or cessation: 24
- Diet/nutrition: 23
- Psychosocial support: 15
- Patient navigation: 12
- HPV prevention/vaccination: 8
Race

19 funded projects focus on a particular race

- American Indian/Alaskan Native: 8
- Black/African American: 7
- Asian: 4
- White/Caucasian: 3
- Native Hawaiian/other Pacific Islander: 1
Unique Populations

64 projects target at least one unique population

- Cancer patients/survivors: 53
- Immigrants and refugees: 12
- Persons with disabilities: 3
- LGBTQ: 2
- Veterans: 1
- Caregivers: 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
Grantee Resources

- Skill-Building
- Networking & Collaboration
- Technical Assistance
Project Preparation Period

Technical Assistance Support
Project Preparation Period

• Now through January 31, 2020!
  • Time dedicated to technical assistance and initiation of administrative requirements
  • Note: completion time varies from project to project

• Activities:
  • Sign Award Letters
  • Participate in kick-off call to:
    • Finalize evaluation tools and plans
    • Initiate Request for Determination and/or full study submission to IRB to determine if human subjects research
  • Tier 1: Create work plan/timeline
  • Tier 2/3: Attend Putting Public Health Evidence in Action - Training (if required)
Evaluation Core
Adrienne Zell, Liz Wenzel

• Conducts an initial assessment of each proposal to determine evaluation planning needs/gaps

• 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
  • Prepare plan description for Request for Determination submission
Human Subjects Protection Team
Melissa Varnum & Paige Farris

The Human Subjects Protection (HSP) team supports community grantees in protecting and minimizing risks to people who choose to participate in research projects.

*All grantees are required to obtain IRB approval or submit a Request for Determination to an IRB.*

*Stay tuned - Human Subjects Protection training is part two of this orientation*
Technical Assistance Triage

Proposals Reviewed

Evaluation team

Grantee completes draft Request for Determination; TA team to review and provide feedback

Outcomes:
- Final Evaluation Plan
- Data Collection Tools

Outcomes:
- Submit Request for Determination

Yes, human subjects research
- 10% funds distribution; Full study submitted & approved
- Full funds Distributed

No, not human subjects research

Human Subjects Protection (OHSU IRB)

Active grant period

Project Preparation Period
CPP Grantee Resources

- Skill-Building
- Networking & Collaboration
- Technical Assistance
Thursday, January 23, 2020:

Cancer Prevention And Control Network (CPCRN):

“Putting Public Health Evidence In Action”

Interactive workshop
• 10:00 a.m. – 4:00pm
• 4 modules covered
• Learn planning tools for communicating and evaluating community health interventions
• Pre and post work: Modules 1-3 completion (online) required prior to registration

Location: Eugene, Oregon

*One representative per grant required, 2 per organization
Continuing grants – new staff/partners welcome to attend
CPP Resources

Skill-Building

Networking & Collaboration

Technical Assistance
Networking & Collaboration

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

Peer-to-Peer
- In person regional grantee networking sessions
- Learning community webinars

CPP Program-wide
- Quarterly grantee newsletter
- Grantee conference (April 2020)
- 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
Regional grantee networking sessions

- Fall 2020
- Locations and dates to be determined
- Opportunities for grantees to plan/host if desired to meet more often!

Learning community webinars

- Virtual networking meetings highlighting grantee activities, successes, challenges, etc.
- Opportunities to connect with others working on similar:
  - **Cancer type**: (breast cancer, colorectal cancer, skin cancer)
  - **Other cancer-related topics**: (HPV, tobacco use, diet/physical activity, etc.)
  - **Activity** (needs assessments, education delivery, screening)
  - **Cancer continuum** (prevention, screening/early detection, survivorship)
  - **Population specific** (youth, women, AA, Hispanic/Latino...
Quarterly grantee newsletter

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

Grantee Conference April 29 and 30, 2020

- **Date/Location:** Welches, Oregon
- **Share your work!**
  - Tiers 1 and 2 (new projects): Poster presentations
  - Tier 2 (continuations): Grantee panel presentations
- **Networking**
- **Resource sharing**
- **Skills-building**

**Fees:** Knight funds registration & accommodations for up to two participants per funded project.
1. Orientation webinar
2. Communication Toolkit
3. Request for Determination guidance and templates
4. No cost extension and Final Report instructions
5. Grantee Conference
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

• You 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
Important to know

• **Project Start/End Dates**
  - Start: February 1, 2020
  - End: January 31, 2021

• **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

• **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

Melissa Varnum, MPH
Community Outreach Specialist
Agenda

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

• Protecting human subjects in research

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

• Completing a Request for Determination form
Defining Terms

• Research
  ➢ An organized, systematic way of finding answers to questions.

• Human subjects research
  ➢ Research that involves interacting with people or their identifiable information.

• Generalizable knowledge
  ➢ Results intended to be generalized to a larger population beyond those involved in the project, or are intended to be replicated in other settings
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.
Why is Human Subjects Protection important & regulated?

**Historical events:**

Nazi human experimentation in WWII (1940s)
- Series of medical experiments by Nazi doctors on large numbers of prisoners without their consent.

Willowbrook State School, New York (1956-1963)
- Institutionalized children with disabilities exposed to hepatitis A.

Tuskegee Syphilis Study, Alabama (1932-1972)
- 400 African-American men with syphilis never told they had syphilis and were not treated for their syphilis once treatment became available.
Result: laws and ethical codes developed that still guide us today

• The Belmont Report

- and -

• The Institutional Review Board (IRB) system
# The Belmont Report (1978)

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<tr>
<th>Principle</th>
<th>Applications</th>
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<tr>
<td><strong>Respect for Persons</strong></td>
<td>• People participate voluntarily</td>
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<td></td>
<td>• Informed consent</td>
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<td></td>
<td>• Privacy (confidentiality and/or anonymity)</td>
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<td><strong>Beneficence</strong></td>
<td>• Protecting research participants from harm</td>
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<td></td>
<td>• Maximize potential benefits and potential minimize risks</td>
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<td></td>
<td>• Well developed project design</td>
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<td><strong>Justice</strong></td>
<td>• Choosing research participants fairly and equally</td>
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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.
Protecting human subjects in research

Requires an *informed consent* process, which includes:

- A description of the risk of harm and potential benefits of the research
- The alternatives to participation
- An explanation that participants have the right to refuse to participate
- An explanation that participants retain the right to withdraw from the research at any time without consequence

This process ensures participants know they have the right to be heard, the right to be respected and the right to their opinions.
Human Subjects Protection Process

Next steps:

IRB approval
- If your project has IRB approval, send us documentation

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: 
Research Navigator Name: 
Project Title: 

INSTRUCTIONS:

Use this form when:
- You are not sure if your project requires human subjects’ protection (institutional review board [IRB]) oversight.
- You would like a formal determination from the IRB as to whether the project requires human subjects’ protection oversight.
- 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 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 in this research. Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contributes 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 Process 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 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?
RFD – Section One

Asks about:

- The goal/intent of your project
  - Is the intent research, project program evaluation, quality improvement, etc.?

- 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
  - Tools – specific or general (e.g. survey, interviews, etc.)
  - Types of questions being asked
  - Will data be anonymous or identifiable?

- Who will you be collecting data from?
- How will the data be collected?
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 – Section Four

Asks about:

- Whether your project involves genetic research
RFD – Section Five

Asks about:

- Protected Health Information (PHI) and HIPAA requirements
- Does your project include access to identifiable information?
- Support available to discuss which option may be the best fit for your project
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 Letter**: Receive, sign and return along with current W-9 form in online portal

2. **Technical Assistance Support**
   - View video tutorial on *Completing a Request for Determination* (RFD) and begin draft
   - Participate in a kick-off call with your TA team
   - Identify who you want to be your Project Lead (PI)
   - Evaluation team will support you to finalize plan & tools
   - Begin drafting your projects RFD (**draft due Jan. 10, 2020**)
   - TA team will review and submit your RFD

3. **Training**:
   - Register for and attend 1/23 “Putting Public Health Evidence in Action” workshop in Eugene, OR
**Team contact info:**

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<thead>
<tr>
<th>Role</th>
<th>Name</th>
<th>Email</th>
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<tbody>
<tr>
<td>Manager, Community Outreach &amp; Engagement</td>
<td>Niyati Desai</td>
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<td>Human Subjects Protection Team</td>
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<tr>
<td>Communications – Social Media</td>
<td>Amanda Gibbs:</td>
<td><a href="mailto:gibbam@ohsu.edu">gibbam@ohsu.edu</a></td>
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<tr>
<td>General Support</td>
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<td></td>
<td><a href="mailto:knightcancercro@ohsu.edu">knightcancercro@ohsu.edu</a></td>
<td>503 418-8077</td>
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Questions?

Thank you!