KNIGHT CANCER Institute

OHSU

Grantee Orientation Webinar

Community Partnership Program
Grant Cycle 2022-2

Presented by: Blanca Cisneros, B.A and Amy Wilson, M.P.H

Click here to view recording

Password:CPP2022-2

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

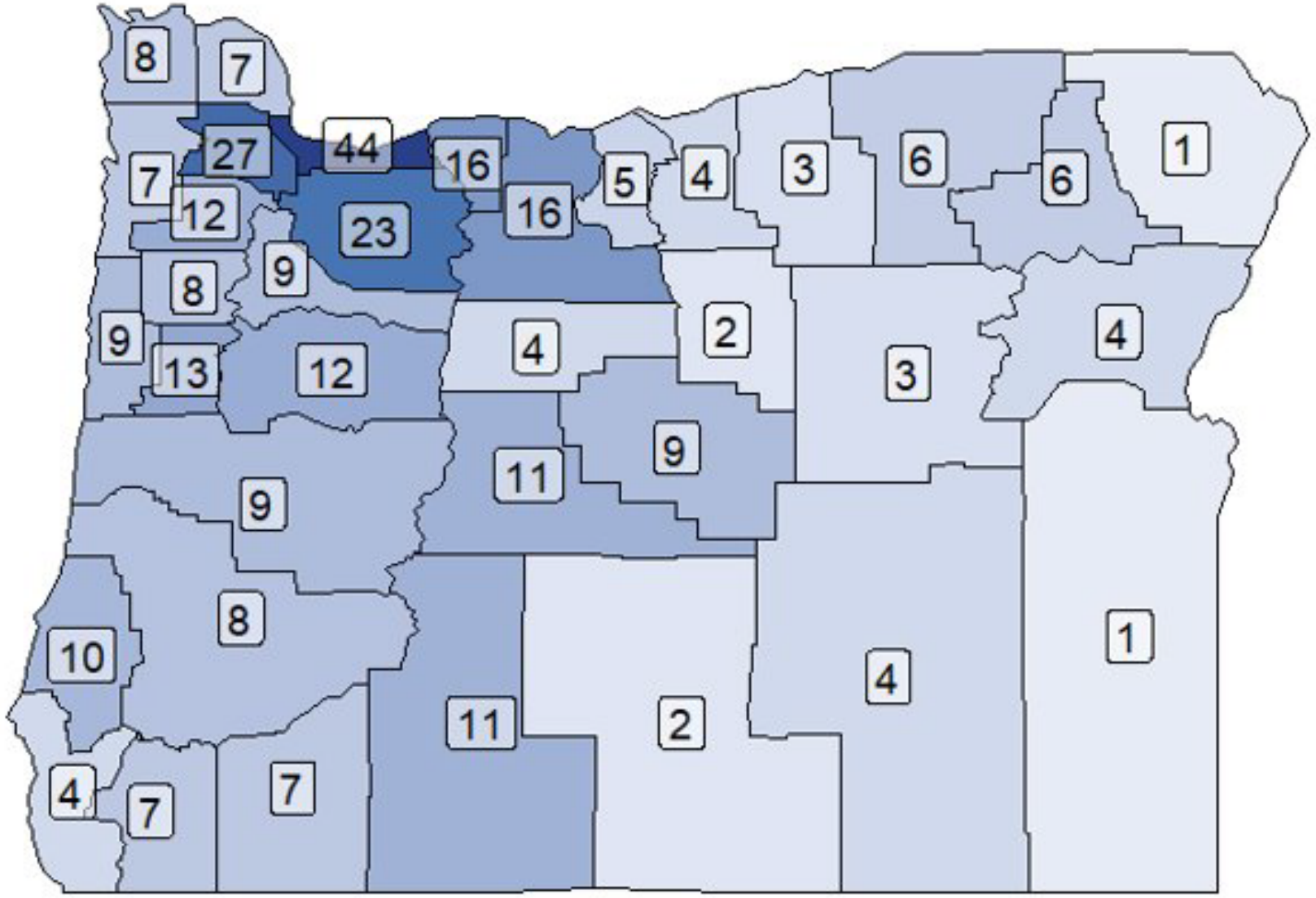
The mission of the Community Partnership Program is to work hand in hand with Oregon communities as allies in the Knight Cancer Institute's efforts to end cancer as we know it. We will:

Support	Enhance	Foster
• Oregon communities in understanding and addressing their most pressing cancer-related needs.	• Collaboration between Oregon communities and OHSU to address cancer in Oregon.	• Skills and abilities of communities to enhance long-term sustainability.

Congratulations!

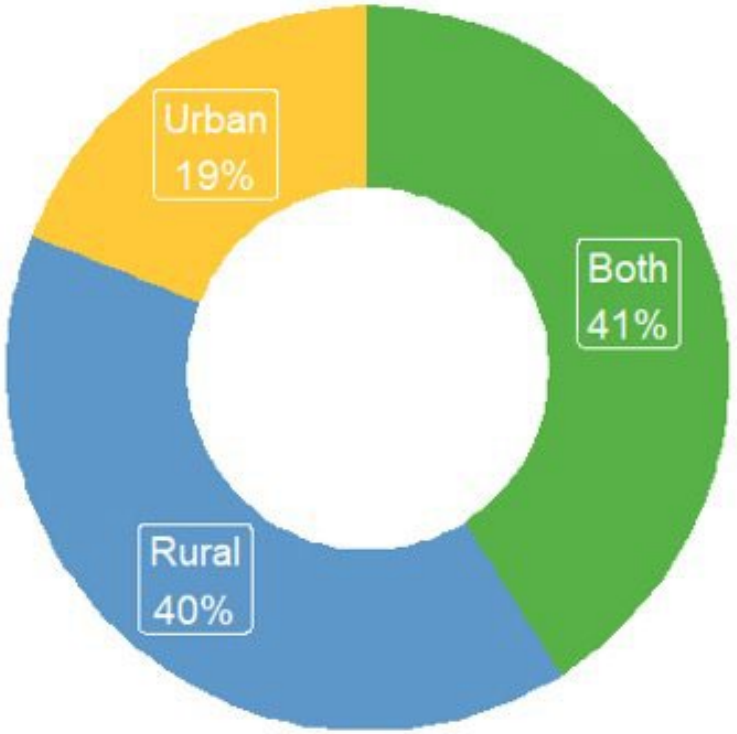
Organization	City
Center for African Health and Education	Portland
Centro de Servicios Para Campesinos	Woodburn
ICG Innovare Communication Group LLC	Hillsboro
Oregon State University – College of Public Health and Human Sciences	Corvallis

Funded projects have impacted all 36 Oregon counties

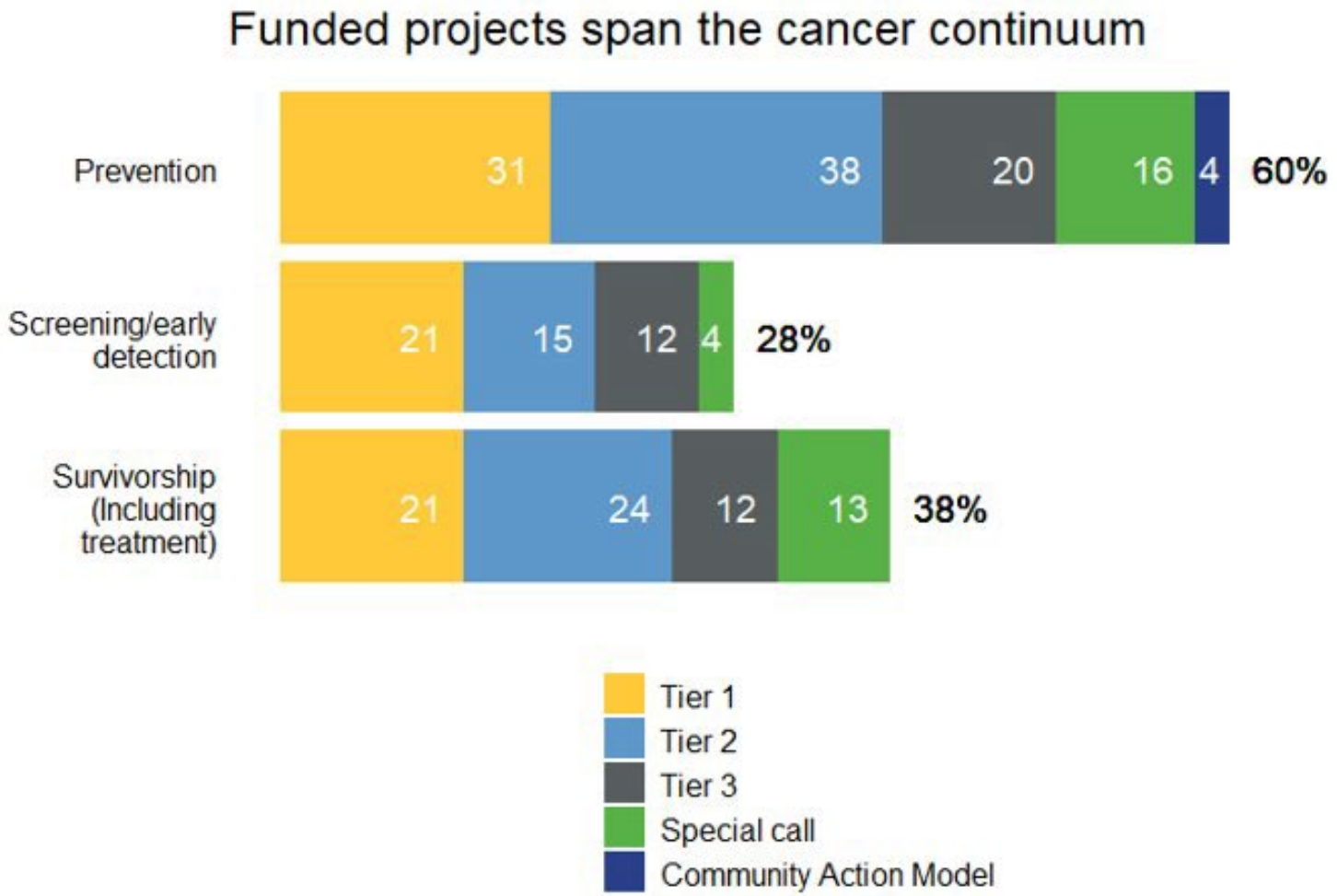


Geography

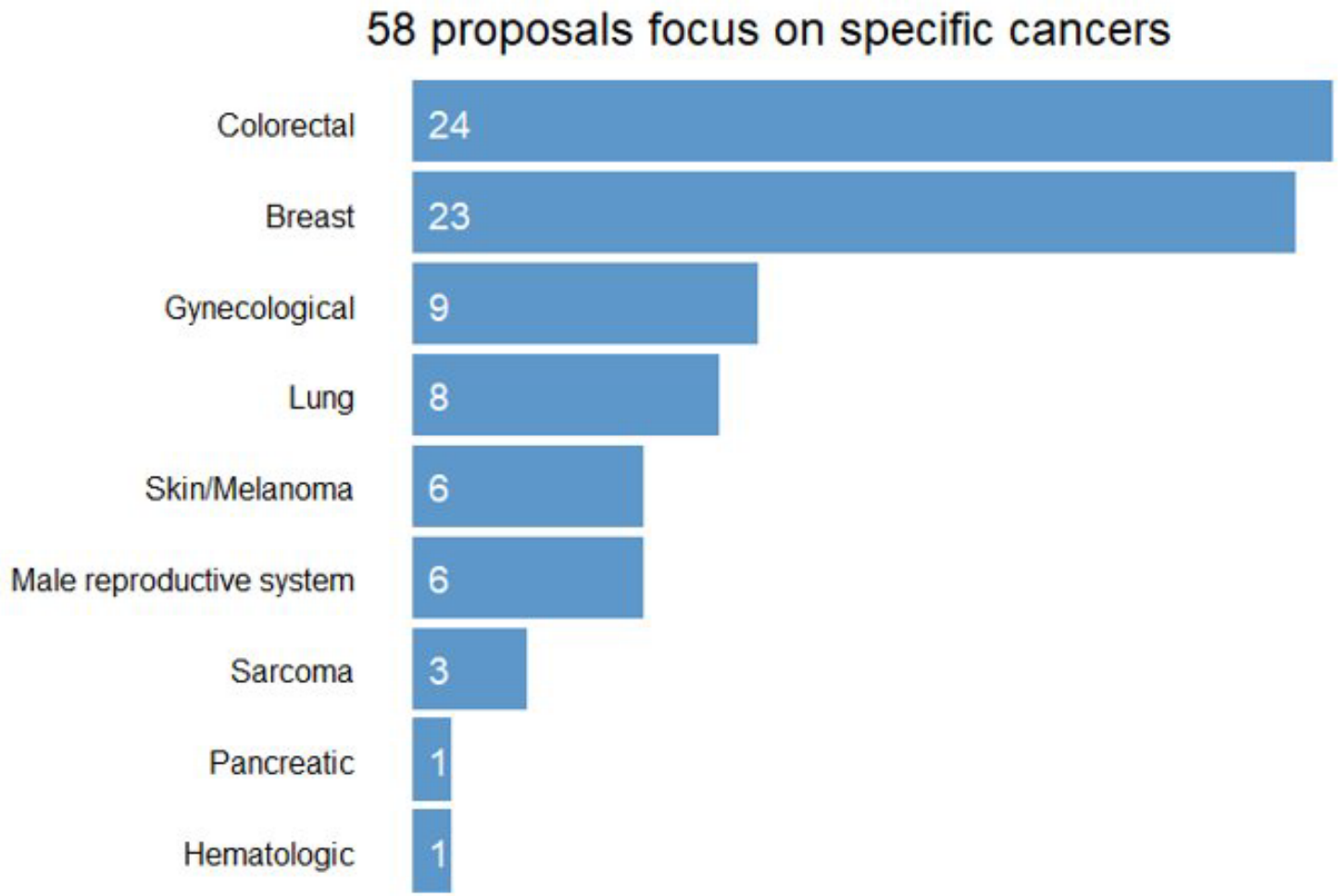
81% of funded projects include a focus on rural areas



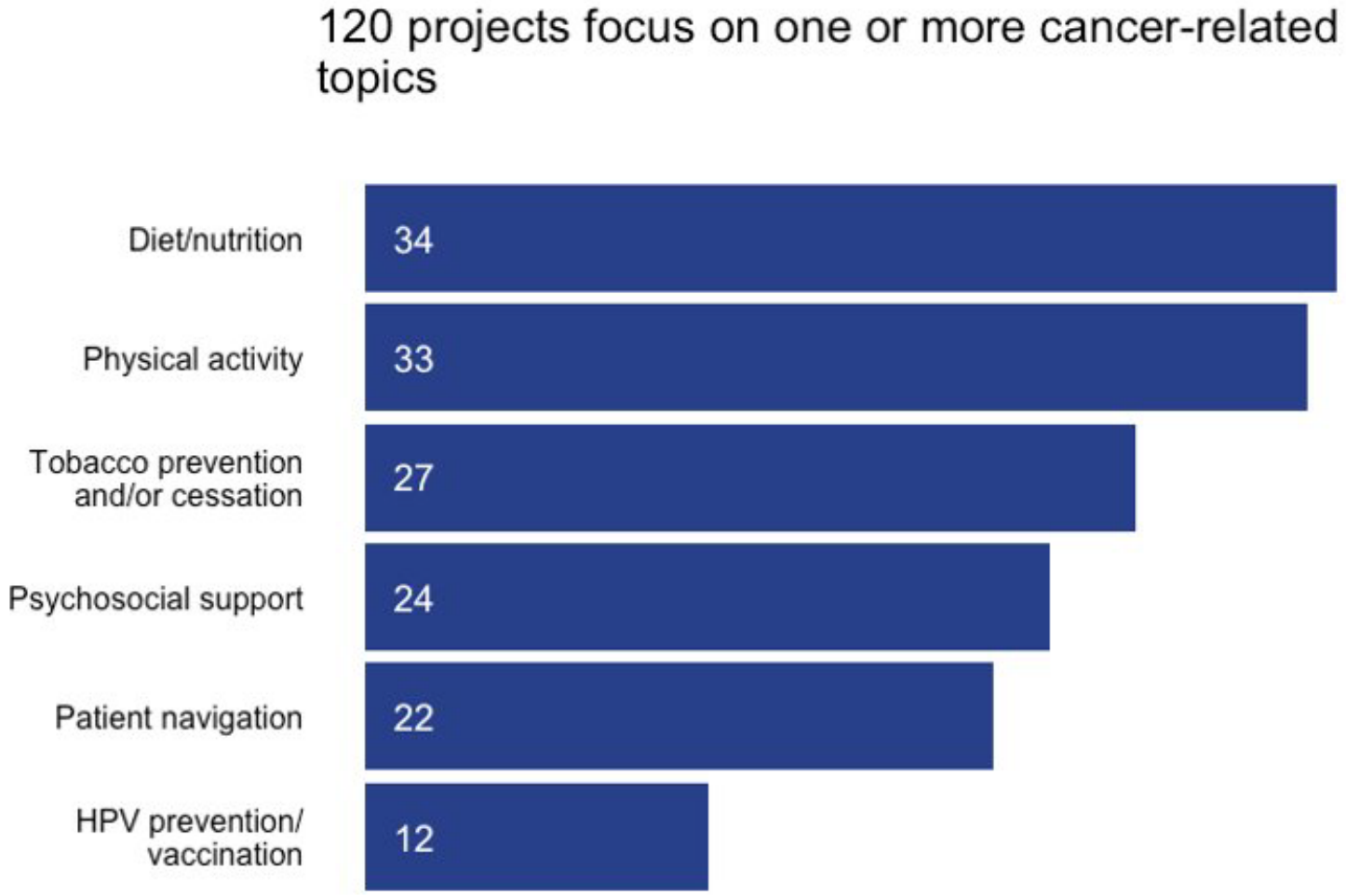
Cancer Continuum and Tier



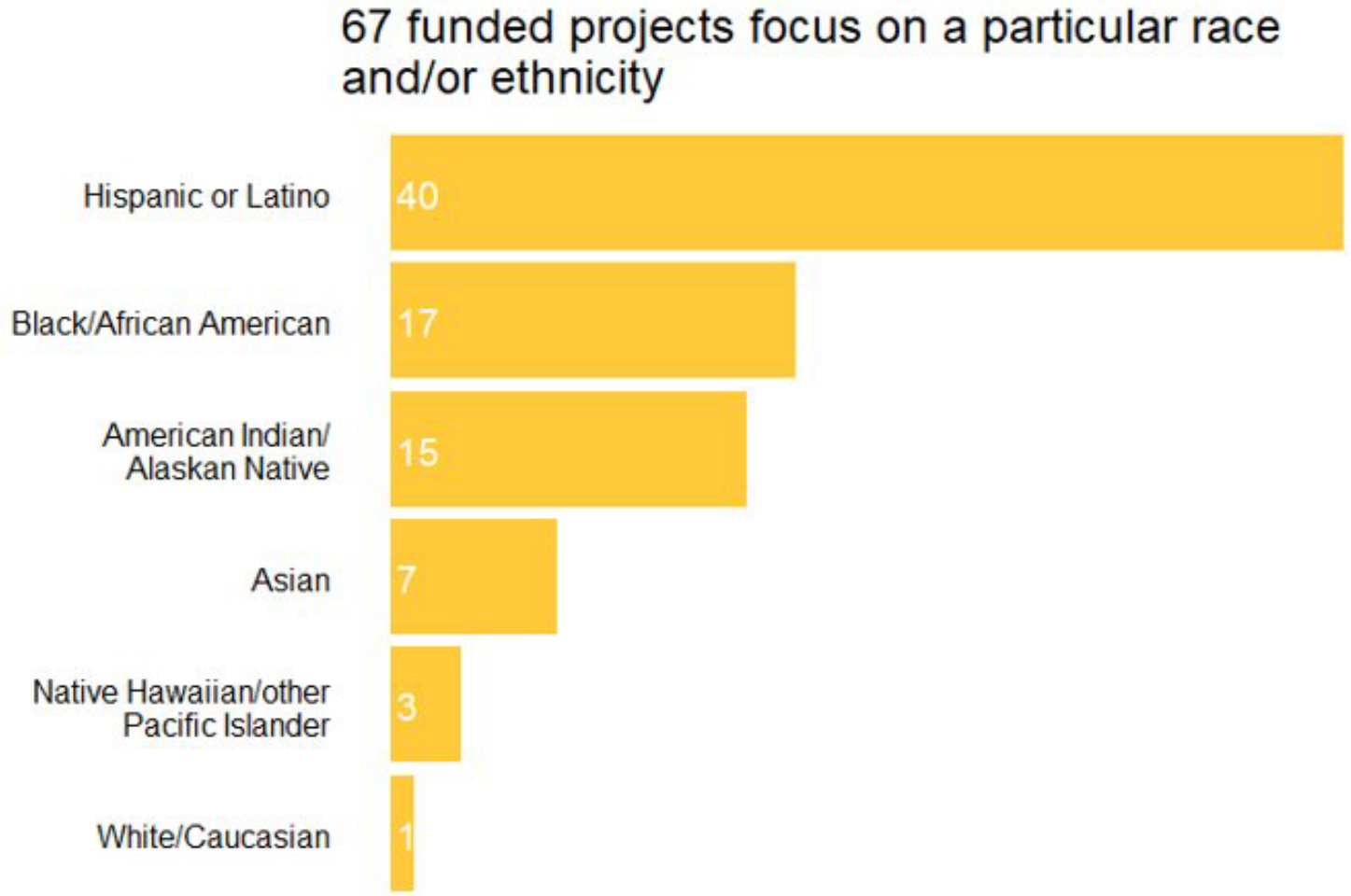
Cancer Type


58 proposals focus on specific cancers
Colorectal
24
Breast
23
Gynecological
9
Lung
8
Skin/Melanoma
6
Male reproductive system
6
Sarcoma
3
Pancreatic
1
Hematologic
1

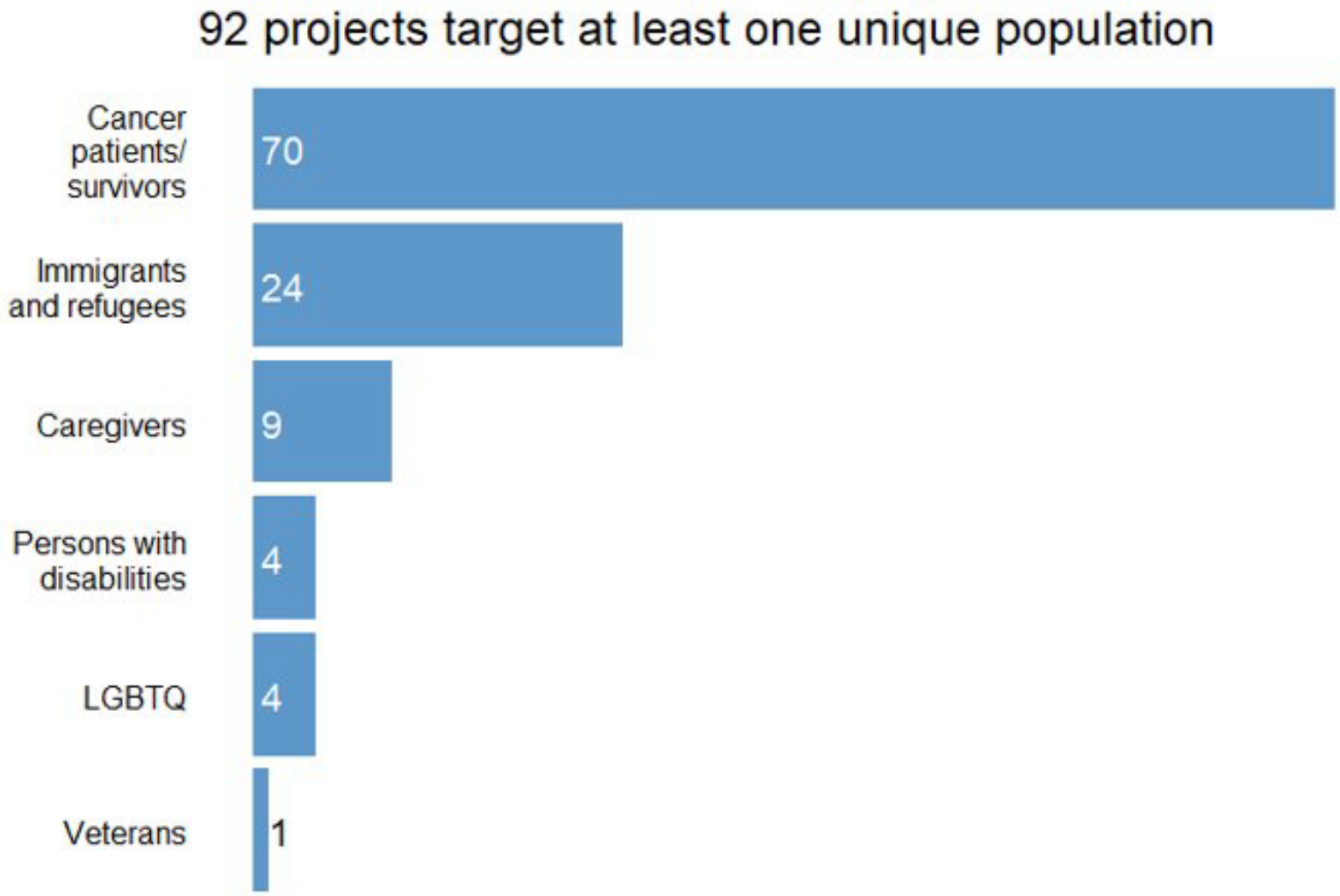
Cancer-related Topic



Race and/or Ethnicity



Unique Populations



Project Preparation Period

Technical Assistance Support

Project Preparation Period

- Now through February 1, 2023
  - —Time dedicated to technical assistance and initiation of administrative requirements
  - —Completion time varies from project to project

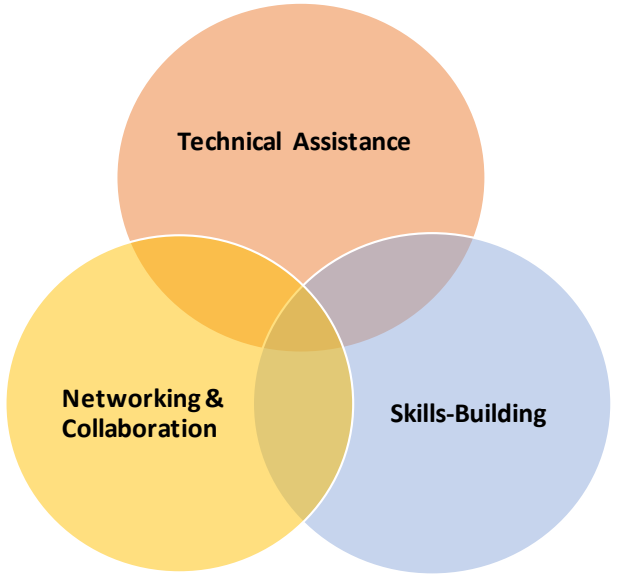
- **Activities:**
- Sign award agreement and submit current W-9
  - Participate in individual kick-off call to:
    - —Finalize evaluation tools and plans
    - —Discuss training topics of interest
    - —Initiate Research Determination Checklist to CPP and/or Request for Determination to IRB to determine 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



Evaluation Team

Amy Wilson, M.P.H.
(she/her)

Alex Dest, M.P.H.
(she/her)

- 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:
  - First Tuesday of month, 2-3pm
  - Third Thursday of month, 10-11am

Skill-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.

Networking & Collaboration

Individual Projects

- Mid-project check-ins/site visits

Peer-to-Peer

- Regional grantee networking sessions
- Grantee workshops

CPP Program-wide

- Quarterly grantee newsletter
- Grantee conference (Fall 2023)
- 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

- Details to be determined
- Opportunities for grantees to plan/host if desired to meet more often!

All Grantees

Quarterly grantee newsletter

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

Grantee Conference

Date/Location: Fall 2023

- Share your work!
- Poster presentations
- Grantee panel presentations
- Networking
- Resource sharing
- Skills-building

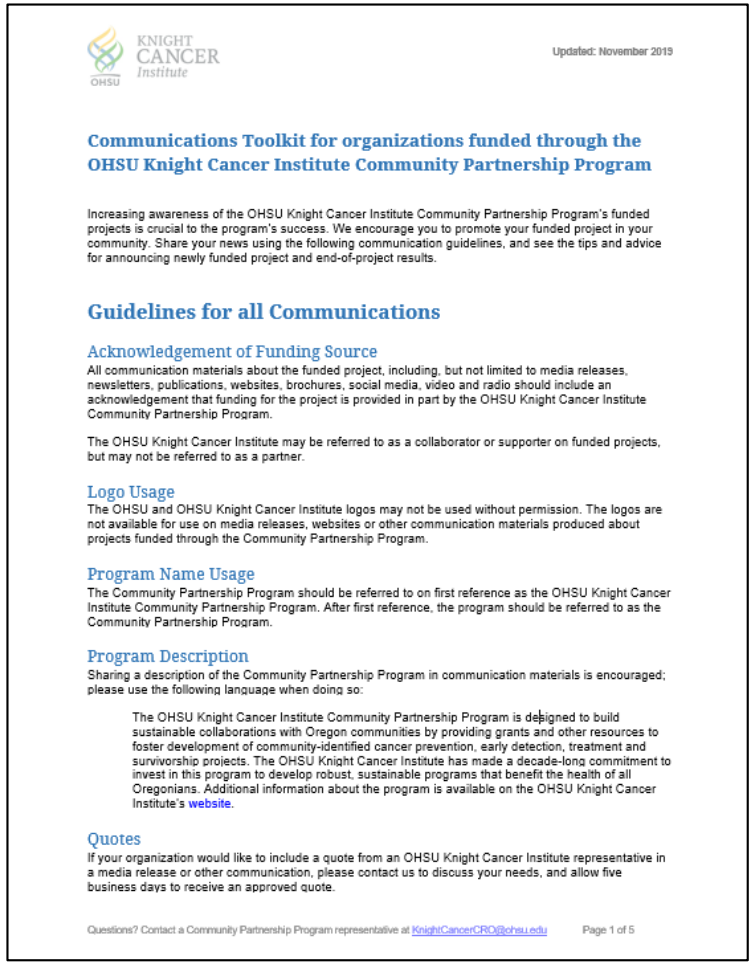
Fees: Knight funds registration & accommodations for up to two participants per funded project.

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!



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Updated: November 2019

Communications Toolkit for organizations funded through the OHSU Knight Cancer Institute Community Partnership Program

Increasing awareness of the OHSU Knight Cancer Institute Community Partnership Program's funded projects is crucial to the program's success. We encourage you to promote your funded project in your community. Share your news using the following communication guidelines, and see the tips and advice for announcing newly funded project and end-of-project results.

Guidelines for all Communications

Acknowledgement of Funding Source

All communication materials about the funded project, including, but not limited to media releases, newsletters, publications, websites, brochures, social media, video and radio should include an acknowledgement that funding for the project is provided in part by the OHSU Knight Cancer Institute Community Partnership Program.

The OHSU Knight Cancer Institute may be referred to as a collaborator or supporter on funded projects, but may not be referred to as a partner.

Logo Usage

The OHSU and OHSU Knight Cancer Institute logos may not be used without permission. The logos are not available for use on media releases, websites or other communication materials produced about projects funded through the Community Partnership Program.

Program Name Usage

The Community Partnership Program should be referred to on first reference as the OHSU Knight Cancer Institute Community Partnership Program. After first reference, the program should be referred to as the Community Partnership Program.

Program Description

Sharing a description of the Community Partnership Program in communication materials is encouraged; please use the following language when doing so:

> The OHSU Knight Cancer Institute Community Partnership Program is designed to build sustainable collaborations with Oregon communities by providing grants and other resources to foster development of community-identified cancer prevention, early detection, treatment and survivorship projects. The OHSU Knight Cancer Institute has made a decade-long commitment to invest in this program to develop robust, sustainable programs that benefit the health of all Oregonians. Additional information about the program is available on the OHSU Knight Cancer Institute's website.

Quotes

If your organization would like to include a quote from an OHSU Knight Cancer Institute representative in a media release or other communication, please contact us to discuss your needs, and allow five business days to receive an approved quote.

Questions? Contact a Community Partnership Program representative at KnightCancerCRO@ohsu.edu

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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:

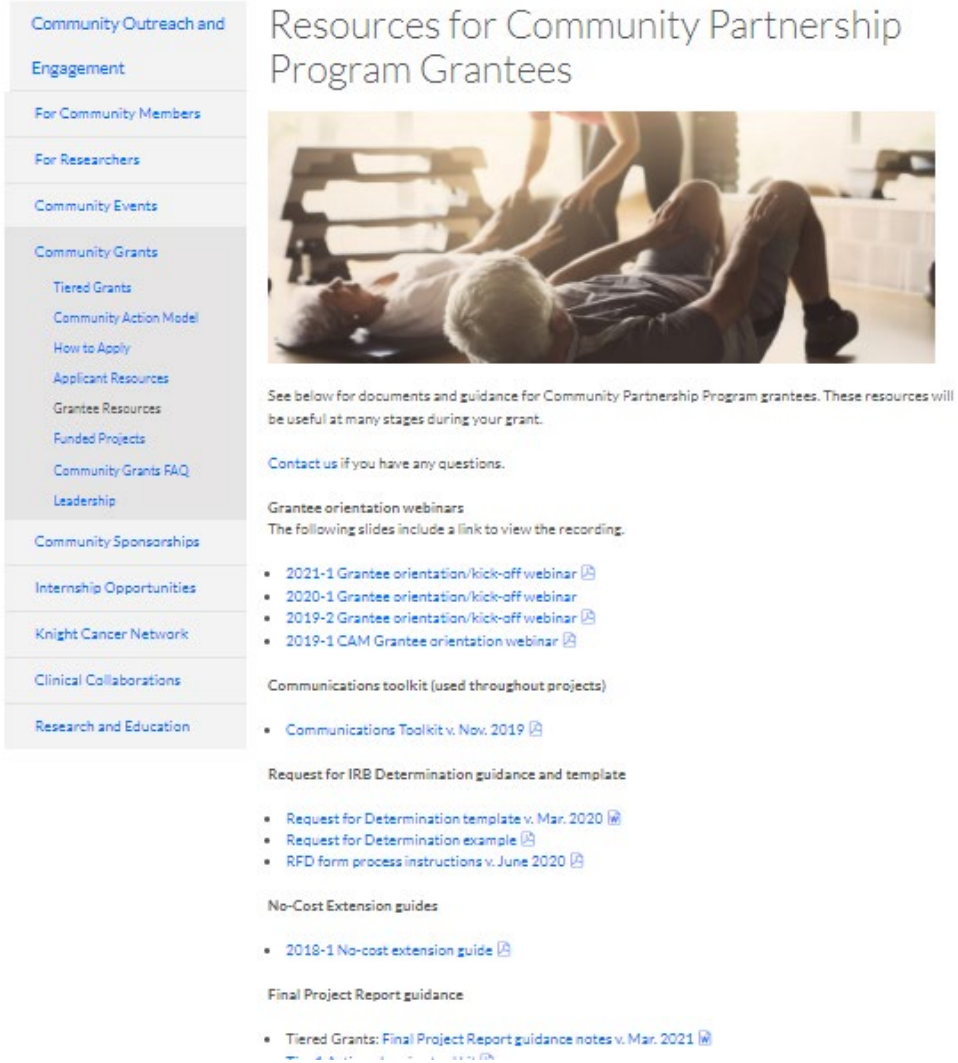
- Objectives
- Reach (participants)
- Evaluation/assessment (tools used, associated preliminary findings)
- Collaboration/partnerships
- Strengths, successes and benefits
- Barriers, challenges, lessons learned
- Sustainability & future plans
- Participation in technical assistance support

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

Grantee Resources Page

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



Community Outreach and Engagement
For Community Members
For Researchers
Community Events
Community Grants
Tiered Grants
Community Action Model
How to Apply
Applicant Resources
Grantee Resources
Funded Projects
Community Grants FAQ
Leadership
Community Sponsorships
Internship Opportunities
Knight Cancer Network
Clinical Collaborations
Research and Education

Resources for Community Partnership Program Grantees

See below for documents and guidance for Community Partnership Program grantees. These resources will be useful at many stages during your grant.

Contact us if you have any questions.

Grantee orientation webinars
The following slides include a link to view the recording.

- 2021-1 Grantee orientation/kick-off webinar
- 2020-1 Grantee orientation/kick-off webinar
- 2019-2 Grantee orientation/kick-off webinar
- 2019-1 CAM Grantee orientation webinar

Communications toolkit (used throughout projects)

- Communications Toolkit v. Nov. 2019

Request for IRB Determination guidance and template

- Request for Determination template v. Mar. 2020
- Request for Determination example
- RFD form process instructions v. June 2020

No-Cost Extension guides

- 2018-1 No-cost extension guide

Final Project Report guidance

- Tiered Grants: Final Project Report guidance notes v. Mar. 2021

Important Information

- **Project Start/End Dates**
  - Start: February 1, 2023
  - End: January 31, 2024
- **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

Amy Wilson, 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 Research Determination Checklist and/or Request for Determination form

Human Subjects Protection

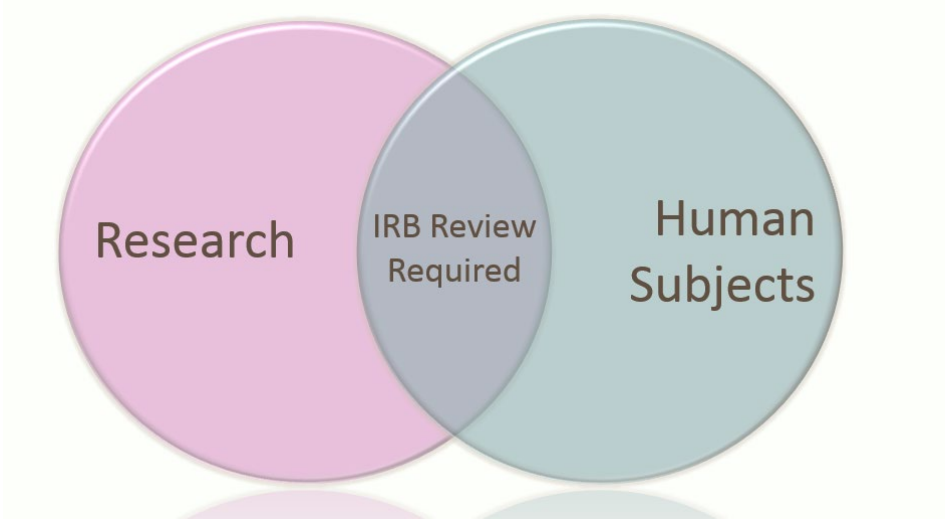
What is it?

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

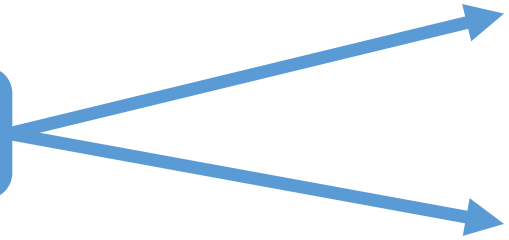


HSR Key Components for CPP Projects

Purpose

Generalizability

OHSU Involvement



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?

“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

Quality Improvement

- Implement change according to mandates of hospital's Clinical QI program
- Improve process or delivery of care with established/accepted methods
- Implement systematic monitoring to ensure existing quality standards are met
- All participants receive standard of care
- Improve performance in a specific program

Research

- May be funded by an external research agency
- Answer a research question/tests a hypothesis
- Uses research design: Group comparisons, randomization, control groups, prospective comparison, cross-sectional, case-control, etc.
- Develops new paradigms or untested methods, establishes a new clinical practice standard
- Follows a protocol that overrides clinical decision-making
- Develop or contribute to generalizable knowledge

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

KNIGHT CANCER Institute
OHSU

COMMUNITY PARTNERSHIP PROGRAM (CPP)
RESEARCH DETERMINATION CHECKLIST

CPP Staff Use Only
Organization: _____
Submission ID: _____
Staff Reviewed: _____
☐ No RFD required
☐ RFD required

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

Request for Determination Form

Version PEFarris-OCTRI+Knight Tool
Publish date March 27, 2020

OREGON HEALTH & SCIENCE UNIVERSITY
Research Integrity Office
Mail Code L106-RI
Portland, Oregon 97239-3098
Phone: 503.494.7887
Fax: 503.346.6808

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.

1.1. 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 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.

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 call scheduling email
   - Review and draft Research Determination Checklist
   - Review Communications Toolkit
   - TA team will support you to finalize plan & tools

Team contact info:

Technical Assistance Team	
Alex Dest • ICG Innovare Communication Group • Centro de Servicios Para Campesinos	dest@ohsu.edu
Amy Wilson • Oregon State University • Center for African Health and Education	wilamy@ohsu.edu
Blanca Cisneros	cisnerbl@ohsu.edu
OHSU Knight Cancer Institute's Communications Team	
KnightCancerCom@ohsu.edu	
CPP General Support	
knightcancercro@ohsu.edu (503) 418-8077	

Questions?

Thank you!