How we'll spend our time today

1 **Welcome to the CEC**
Who we are, and how we can support your research during your EHSC Pilot Award and beyond

2 **Overview of Community-engaged research**
Benefits, challenges, and best practices

3 **Administering collaborative research**
Partnership agreements, payments, and IRB considerations

4 **Q & A and next steps**

Part 2: Date TBD

1 Common pitfalls and challenges in community engaged research + strategies for prevention & repair

2 Research team goal setting and support plans (small group discussions)

CALIFORNIA NATIVE LANDS ACKNOWLEDGEMENT

UC Davis Environmental Health Sciences Center,
Community Engagement Core

We acknowledge that we are gathering today throughout the unceded territory of California that is home to nearly 200 tribal nations. As we begin, we acknowledge and honor the original inhabitants of our various regions.

The work of the Environmental Health Sciences Center is based in Sacramento and Davis, on unceded lands stolen from Native peoples to form the University of California campuses.

To the original inhabitants of this land:

To the Nisenan people, To the Southern Maidu to the North, To the Valley and Plains Miwok/ Me-Wuk peoples to the south of the American River, To the Patwin Wintun peoples to the west of the Sacramento River, To the people of the Wilton Rancheria surrounding Elk Grove, To the Cachil Dehe Band of Wintun Indians of the Colusa Indian Community, To the Kletsel Dehe Wintun Nation, and To the Yocha Dehe Wintun Nation:

May we honor your ancestors who came before the colonizers and whose descendants still walk beside us today.

For the contribution of countless elders, activists, healers, families, loved ones, and Peoples in forming the history of the region where we reside today, we thank you.

In acknowledgement of the genocide and displacement of the indigenous peoples of California, we invite those who have benefited from the seizure of Native Lands to consider taking part in a form of financial reparation.

Nisenan Ancestral Homelands Reciprocity Program
https://chirpca.org/ancestral-homelands

Sacramento Native American Health Center
https://www.snahc.org/give-now/

News from Native California
https://newsfromnativecalifornia.com/about/support/

An initiative of the Nevada City Rancheria Nisenan Tribal Council, California Heritage: Indigenous Research Project (CHIRP), and current residents of the Bear and Yuba RIver Watersheds.

https://chirpca.org/ancestral-homelands

A choice between two worlds.
Alyssa Walz. www.minewatchnc.org

NEWS from NATIVE CALIFORNIA

35 YEARS

35 YEARS OF INDIGENOUS CALIFORNIA STORYTELLING

News from Native California is a quarterly magazine devoted to the vibrant cultures, arts, languages, histories, social justice movements, and stories of California's diverse Indian peoples.

We strive to preserve the cherished knowledge of an older generation, provide opportunities for a younger generation making a place for Indian ways in the modern world, and illuminate the beauty of Native cultures to all of California.

https://newsfromnativecalifornia.com/about/support/

The mission of the **Sacramento Native American Health Center**, Inc (SNAHC) is to carry out the legacy of a healthy American Indian and Alaskan Native community based on cultural values delivered through traditional, transformational, innovative, accessible, and self-sufficient systems of health care.

https://www.snahc.org/give-now/

1. **Welcome to the EHSC Community Engagement Core!**

Who are we?

What is our role at EHSC?

How can we support you?

Who are we?

The EHSC **Community Engagement Core** (CEC) helps researchers develop and maintain relationships with the stakeholders of their work, including impacted communities, public agencies, and other key decision makers.

Jonathan London

CEC Faculty Director

Professor
Department of Human Ecology, UC Davis

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Shosha Capps

CEC Associate Director

Department of Human Ecology, UC Davis

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CEC role in the Pilot Program

We provide **training and individualized assistance** in designing and conducting Community-Engaged Research, including **community partnership development**.

We facilitate EHSC's **Community Advisory Committee** (CSTAC), which sets research priorities for the Pilot program and reviews all proposals.

CEC Support Services

Pre-Award

- Facilitate partnerships and collaborative proposal development, including budgeting and developing formal agreements if needed
- Advise on community-engaged study design

During Award Period

- Assist in navigating administrative processes, including partner payments and IRB submissions involving a community partner.
- Quarterly consultations to support excellence in Community Engaged Research

Post-Award

- Assist with developing communications materials for general public and/or specialized lay audiences, such as study participants, impacted communities, and public sector decision makers.
- Assist in developing future community-engaged grant proposals related to the Pilot Award.

Values / theoretical framework

WHO

Who do we work with? Who are we accountable to?

WHY

Why do we do this work? What are our values and theories of change?

HOW

How do we do this work in alignment with our values? How do we operationalize our values in a research setting?

WHO

Who do we work with? Who are we accountable to?

Impacted communities: Those who are most impacted by environmental hazards, primarily in California's Central Valley.

Public agencies: Those who are charged with protecting public health from environmental hazards.

Academics: Environmental Health Science researchers, with a focus on Early Career Investigators and established investigators who are new to Environmental Health Science.

EHSC's Community Stakeholder Advisory Committee brings together

Community-Based Organizations

Representing stakeholders most impacted by environmental health issues

Public Agencies

Representing those charged with protecting public health from environmental hazards

Academic Researchers

Epidemiologists, Toxicologists, Exposure Scientists, Engineers, Clinicians, and more

Current members of EHSC's Community Stakeholder Advisory Committee

Californians for Pesticide Reform (CPR)
Jane Sellen

Central California Asthma Collaborative
Kevin Hamilton &
Tim Tyner

Central California Environmental Justice Network
Nayamin Martinez

Community Water Center
Ryan Jensen

Comité Civico del Valle
Luis Olmedo &
Christian Torres

Leadership Counsel for Justice and Accountability
Phoebe Seaton

Environmental Justice Coalition for Water
Espe Vielma

CA Department of Public Health
Dan Woo &
Dilhara Ranasinghe

CA Air Resources Board
Trish Johnson

CA EPA Office of Environmental Health Hazard Assessment
Lily Wu & Amy Budahn

CA Department of Pesticide Regulation
Andy Rubin

Marilyn Silva
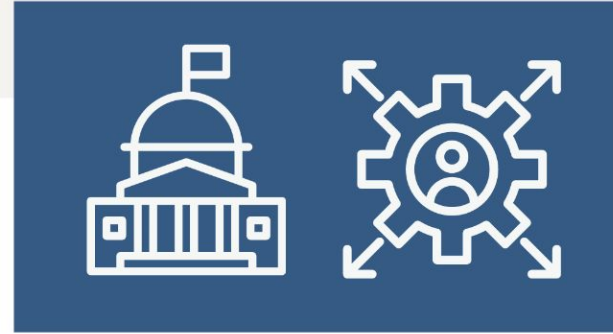Retired, Department of Pesticide Regulation

Jaymin Kwon
CSU Fresno Department of Public Health

CSTAC role at EHSC

The primary role of CBO members on the CSTAC is to ensure that **EHSC research is responsive and accountable to the priorities and perspectives of those who are most impacted** by environmental health issues across the state.

CBO and public agency members both help ensure that **EHSC research is timely, policy-relevant, and is communicated effectively to inform public policy.**

WHY

Why do we do this work? What are our values and theories of change?

The CEC's work is grounded in the values and theoretical frameworks of **Environmental Justice** and **Epistemic Justice.**

What is environmental justice?

Defining Environmental Justice

Capabilities: Thriving/ Just Communities
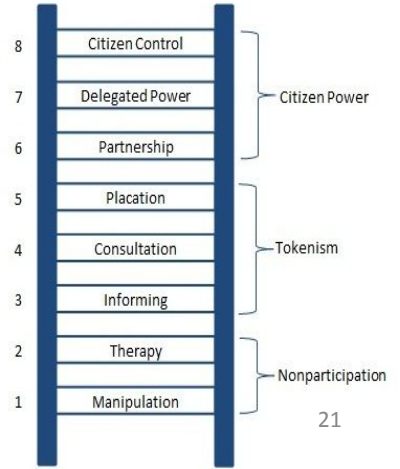
Equitable Distribution: Hazards/ Opportunities

Respect for different kinds knowledge and experiences (epistemic)

Democratic Process: "We speak for ourselves!"

8	Citizen Control	Citizen Power
7	Delegated Power	
6	Partnership	
5	Placation	Tokenism
4	Consultation	
3	Informing	
2	Therapy	Nonparticipation
1	Manipulation	

Core Concepts in Environmental Justice

- **Racial Capitalism**: Interdependence of racism and capitalism

- **White Supremacy:** Ideology of white racial superiority

- **Settler Colonialism**: Physical and cultural destruction of Indigenous people

- **Hetero-Patriarchy**: Domination by straight (typically white) men

- **Xenophobia/ Nationalism**: Marginalized/ vulnerable position of immigrants

- **OTHERS?**
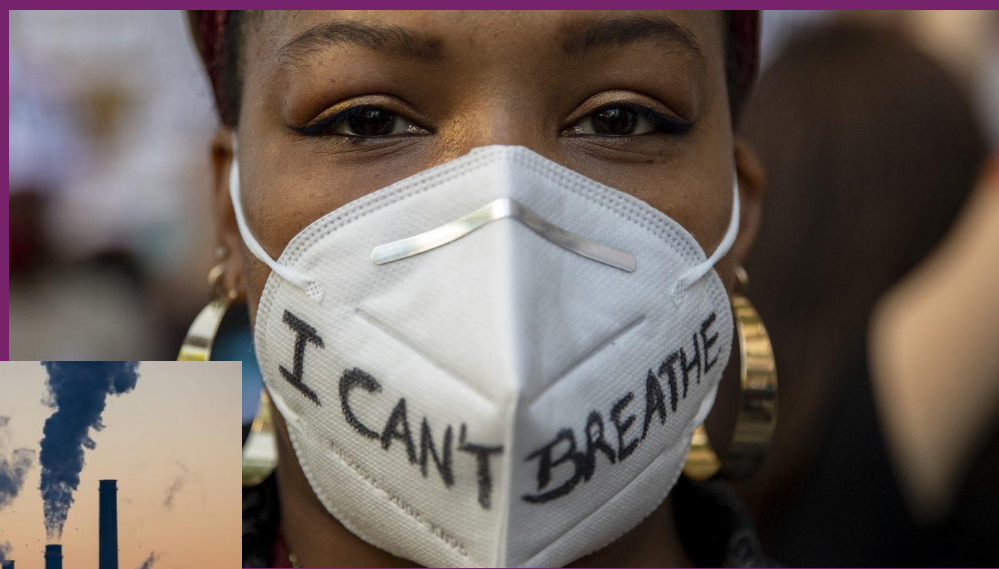
Racial Disposability vs. Racial indispensability. People of color are members of our society, are core participants in our social systems, and are members of our socio-ecological systems, and are therefore key to ensuring the continued functioning, sustainability, and resilience of our society and planet.

David Pellow: TOWARD A CRITICAL ENVIRONMENTAL JUSTICE STUDIES
Black Lives Matter as an Environmental Justice Challenge

WE, THE PEOPLE OF COLOR, gathered together at this multinational People of Color Environmental Leadership Summit, to begin to build a national and international movement of all peoples of color to fight the destruction and taking of our lands and communities, do hereby reestablish our spiritual interdependence to the sacredness of our Mother Earth; to respect and celebrate each of our cultures, languages and beliefs about the natural world and our roles in healing ourselves; to ensure environmental justice; to promote economic alternatives which would contribute to the development of environmentally safe livelihoods; and, to secure our political, economic and cultural liberation that has been denied for over 500 years of colonization and oppression, resulting in the poisoning of our communities and land and the genocide of our peoples, do affirm and adopt these Principles of Environmental Justice.

First National People of Color Environmental Leadership Summit
October 1991, in Washington DC.

Environmental Justice Principle

Environmental justice embraces the principle that all peoples and communities are entitled to equal protection of our environmental, health, employment, housing, transportation, and civil rights laws.

Source: 2nd People of Color Environmental Leadership Summit, 2002

Birth of a Movement: Kettleman City

EJ Signed into Federal Law

Federal: Executive Order 12898 (1994)

"...each Federal agency shall make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations..."

The Road to EO 12898

Environmental Health Disparities

Neweke et al 2011. Symposium on Integrating the Science of Environmental Justice into Decision-Making at the Environmental Protection Agency: An Overview

Holistic Environmental Health

Healthy Families

Considers those issues faced by families and individuals, with emphasis on what they can do to reduce harmful exposures.

Topics could include:
- Personal Care Products
- Indoor Air Quality
- Healthy Homes

Healthy Spaces

Focuses on those spaces where people interact outside their home.

Topics could include:
- Schools
- Work/Office
- Church
- Day Care
- Elder Care
- Hospitals
- Parks

Healthy Communities

Examines the complex interactions of different social and environmental elements that affect the health of community residents.

Topics could include:
- Water Quality
- Fish Consumption/Risk Communication
- EHD/EJ Issues

https://www.niehs.nih.gov/research/supported/translational/peph/resources/index.cfm

Key Sources

- Balazs, C. L., & Morello-Frosch, R. (2013). The three Rs: How community-based participatory research strengthens the rigor, relevance, and reach of science. *Environmental justice*, *6*(1), 9-16.

- Brulle, Robert J., and David N. Pellow. "Environmental justice: human health and environmental inequalities." *Annu. Rev. Public H*

- Cole, L. W., & Foster, S. R. (2001). *From the ground up: Environmental racism and the rise of the environmental justice movement* (Vol. 34). NYU Press.

- Morello-Frosch, R., & Lopez, R. (2006). The riskscape and the color line: examining the role of segregation in environmental health disparities. *Environmental research*, *102*(2), 181-196.

- Pulido, L. (1996). A critical review of the methodology of environmental racism research. *Antipode*, *28*(2), 142-159.

- Sze, J., & London, J. K. (2008). Environmental justice at the crossroads. *Sociology Compass*, *2*(4), 1331-1354.

- Taylor, D. E. (2000). The rise of the environmental justice paradigm: Injustice framing and the social construction of environmental discourses. *American behavioral scientist*, *43*(4), 508-580.

- Wilson, S. M. (2009). An ecologic framework to study and address environmental justice and community health issues. *Environmental Justice*, *2*(1), 15-24.

What is epistemic justice?

Epistemic injustice is "a wrong done to someone in their capacity as a knower."

Interpersonal Level: Testimonial Injustice

Exclusion of marginalised and oppressed people from being heard and understood

Occurs when identity-based prejudice undermines the credibility of the speaker/knowledge holder

Systemic Level: Hermeneutical Injustice

Exclusion of marginalized and oppressed people from contributing to understandings of the human experience and the natural world

Occurs as a result of systemic identity-based marginalization, which keeps whole groups of knowers from participating in shaping how the world is understood

What is epistemic justice?

Epistemic injustice produces two types of wrongs

An epistemic wrong

Important knowledge isn't shared

An ethical wrong

The knowers is harmed in a way that undermines what it is to be human

Source: Fricker (2007). Epistemic Injustice: Power and Ethics of Knowing

What is epistemic justice?

Epistemic JUSTICE takes two forms

Testimonial Justice

When knowledge is communicated interpersonally without identity-based bias in a way that affirms the credibility (and by extension the humanity) of the knower and builds the understanding of the knowledge receiver.

Hermeneutical Justice

When institutions and societies hold space for, and value, diverse ways of knowing how to make sense of the world and the human experience

Source: Fricker (2007). Epistemic Injustice: Power and Ethics of Knowing

HOW

How do we do our work in alignment with values of social, racial, and environmental justice?

How do we operationalize our values in a research setting?

- Community-Engaged Research
- Community-Driven Research
- Anti-racism / decolonization in research

EHSC's Community Engagement Core supports environmental health research that is...

COLLABORATIVE

Multidisciplinary

Co-created with impacted communities

Prioritizes reciprocity in research relationships

EMPOWERING

Builds capacity

Challenges power structures

Recognizes the expertise & moral authority of impacted communities

IMPACTFUL

Supports health-protective policy

Leads to reduced disparities in environmental exposures & health outcomes

COMMUNITY–ALIGNED

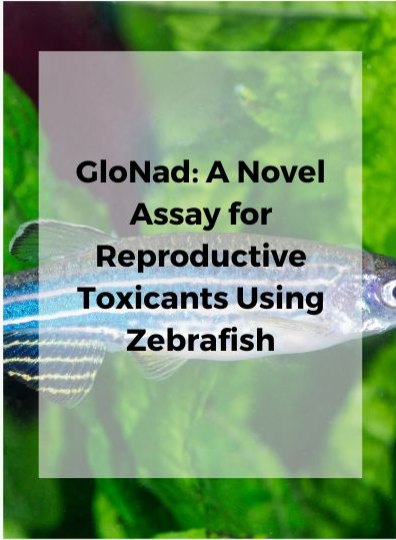Responsive to community-defined research priorities

Policy-relevant

Community Research Priorities

One way EHSC tries to center those most directly impacted by environmental health issues in research is to maintain an up-to-date list of **Community Research Priorities**.

These priorities synthesize high-priority, policy-relevant research needs identified by our **Community Stakeholder Advisory Committee (CSTAC)**.

These priorities are integrated into the EHSC's **Pilot Project Program** RFP to help scientists develop timely, policy-relevant environmental health research projects.

Introductions

GloNad: A Novel Assay for Reproductive Toxicants Using Zebrafish

Cortical Tri-Culture Platform for Environmental Neurotoxin Screening

Effects of Climate Change and Dietary Quality on Maternal-Infant Health Outcomes in the GROWell Trial

Mobile Source Monitoring Support for Environmental Justice Communities

PIs: Sean Burgess and Bruce Draper

PI: Erkin Seker
Community partners: Californians for Pesticide Reform, California Health Nail Salon Collaborative
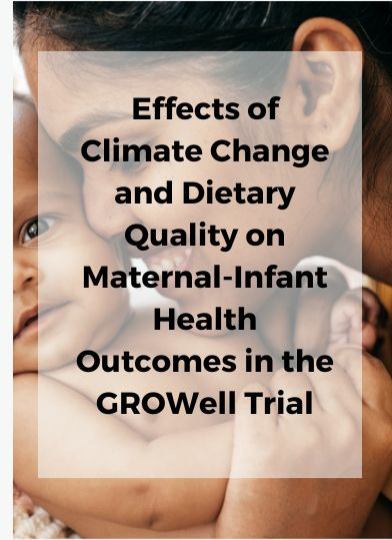
PI: Leigh Ann Simmons
Co-I: Clare Cannon

PI: Nicholas Spada
Community partners: Citizen Air Monitoring Network, Sustainable Solano

-Level of experience with community-engaged research
-Brief overview of your project and any community engagement components

3. Community-Engaged Research

What is community-engaged research?
What are its benefits and challenges?
How can your research integrate community engagement?

Research Stakeholders

Who – outside academia – has an interest in the outcome of your work?

Research Stakeholders

Anyone outside academia who has an interest in the outcome of your research

Anyone who might take different actions / make different choices as a result of your findings

Anyone who may be impacted (positively or negatively) by the actions/decisions that others take based on your findings

Those who are impacted by an exposure or health outcome

Who is impacted by the exposure and/or health outcome your research is relevant to?

Who, if anyone, is disproportionately impacted?

+

Those who produce or benefit from activities that lead to exposures

Does anyone currently benefit from the activities that lead to the exposure(s) most relevant to your work?

Typically an industry, e.g. agriculture, oil and gas, transportation, and the consumers of that good.

+

Those who can make (or block) change

Typically regulators, policy makers (big P and little P), administrators, clinicians, civic organizations, etc.

Often significant overlap with the previous two categories

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+

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Typically regulators, policy makers (big P and little P), administrators, clinicians, civic organizations, etc.

Often significant overlap with the previous two categories

Research Stakeholders: Toxicity of Pesticides

Anyone outside academia who has an interest in the outcome of your research

Anyone who might take different actions / make different choices as a result of your findings

Anyone who may be impacted (positively or negatively) by the actions/decisions that others take based on your findings

Those who are impacted by an exposure or health outcome

Disproportionately impacted:

- Agricultural workers
- Children
- Rural communities
- Disadvantaged communities of color, low income communities

+

Those who produce or benefit from* activities that lead to exposures

Beneficiaries of pesticide use:

- Farm and agribusiness owners
- Food sector (higher yields, lower costs)
- Food consumers (lower costs)

*often but not always a financial benefit = "profit from"

+

Those who can make (or block) change

- County Ag Commissioners
- Pesticide manufacturers
- CA Dept. of Pesticide Regulation
- OEHHA / EPA
- Governor's Office
- Community Organizations
- Farm and agribusiness owners

Research Action Potential

What might these stakeholders do differently (or try to get others to do differently) **based on what you learn?**

Point of emission

Point of exposure

Point of health impact
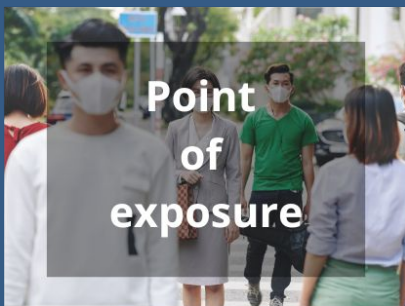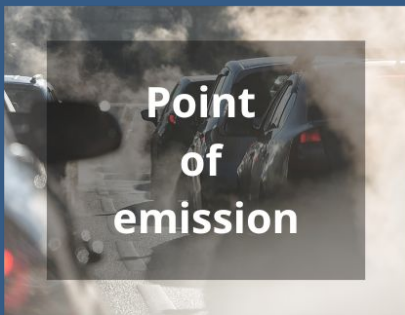
Prevention or reduction of exposure

Categories of research:

→ Hazard identification (source, level, health impact)

→ Risk Assessment (dose, mechanism, vulnerabilities)

→ Risk Mitigation (behavioral, structural, contextual)

Action potential:

→ Policy change / investments reducing exposures (reduced emissions and/or mitigation/clean up strategies)

→ Develop/implement protections of vulnerable populations

→ Public health advocacy campaigns

Prevention or reduction of health impact

Categories of research:

→ Identification and assessment of strategies for reducing adverse health outcomes associated with exposures

Action potential:

→ Investments (education, resource allocations) in preventative public health measures

→ changes to clinical practices (early screening / ID of exposure-related health conditions, new preventative care options)

Improved management of associated health conditions

Categories of research:

→ Identification and assessment of strategies for managing health conditions associated with exposures

Action potential:

→ Changes in clinical practices to improve treatment/management of medical conditions associated with environmental exposures

ACTIVITY:

Who are the public stakeholders in your research?

What is the action potential of your research?

What is Community Engaged Research?

Collaboration with **community stakeholders** as full partners in the formation, implementation and application of research

Who are "community stakeholders" in this context?

We prioritize **community-based organizations** that work directly with communities facing environmental justice and health disparities.

As appropriate, other organizations (e.g., public agencies) may also be included.

Why (and when) do we engage different types of stakeholders?

Working with those who are impacted can improve the relevance, rigor and reach of projects.

Working with public agencies can enhance the policy impacts.

Working with both can improve multi-sector collaboration.

Why do we do community engaged research?

There are philosophical / values-based and practical reasons to pursue community engaged research.

"To make a difference" - sense of meaning, alignment of research to values.
In the conditions around the issue you study: Partnering with stakeholders increases the chances of impact outside academia – better and more action-oriented design, better implementation, better communication to those positioned to create change.
In how research is done / how communities experience research: To contribute to pushing back against history of exploitive research.

To increase the quality of research
Not all the benefits of CEnR translate to professional achievement within academia – can feel like unrewarded extra credit, depending on your field / career stage – but many do.

Benefits of Community Engaged Research to Academic Researchers

Gain firsthand knowledge and insight of local partners

Build bridges between the university and broader community

Develop interventions with greater relevance and feasibility

Support the self-empowerment of disadvantaged communities to take part in the production and application of knowledge

Expanded access to **large funding opportunities** that require meaningful community engagement, including those where a community organization must be the lead applicant.

NIEHS **Research to Action (R2A)** grant encourages multidisciplinary environmental health projects that employ community-engaged research methods & translate research findings into public health actions.

Community engagement can also **translate to higher significance scores** on other types of NIH grants, such as R01s.

Expanded opportunities beyond the Pilot

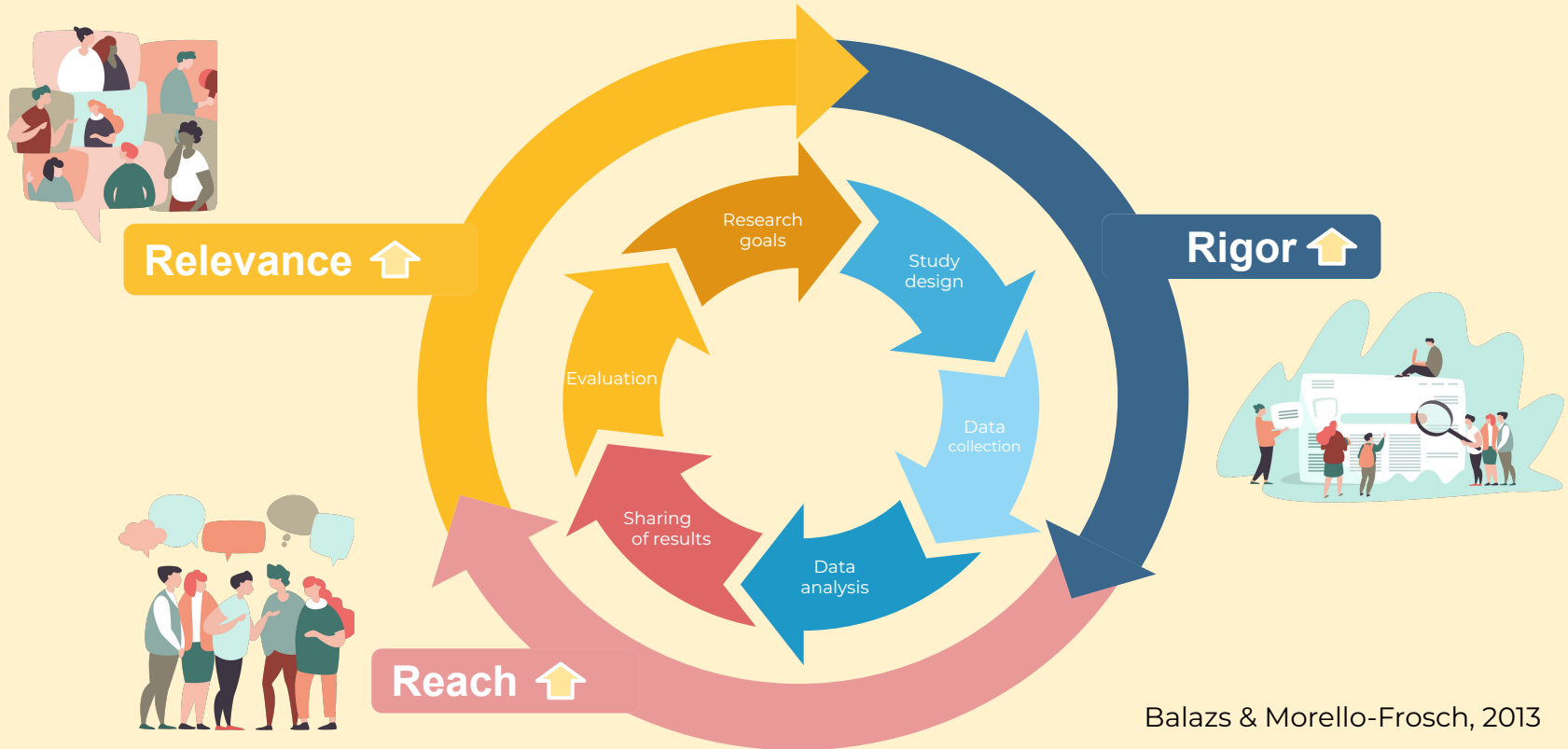# Benefits of Community Engaged Research to Community Partners

Access to scientific resources and knowledge that help inform community advocacy and bolster legitimacy in political and public discourse.

Help shape the research agenda of universities to respond to community priorities.

Community engagement can improve outcomes across the research cycle

Relevance ⬆

Rigor ⬆

Reach ⬆

Research goals
Study design
Data collection
Data analysis
Sharing of results
Evaluation

Balazs & Morello-Frosch, 2013

Community engagement on a continuum:
from participant to partner

"Helicopter Science"

Community stakeholders have **no influence** on study topic or design.

Community **context influences** study design and research questions

Community stakeholders are **consulted,** may participate in **translation and dissemination of results**

Community stakeholders **frame questions and set research priorities.**

Community stakeholders **leverage study results & partnerships to promote social change**

CBPR

Community stakeholders are **full partners** in research, protocol design, fundraising, and data ownership

Balazs & Morello-Frosch, 2013

Principles of CBP(A)R

BUILD
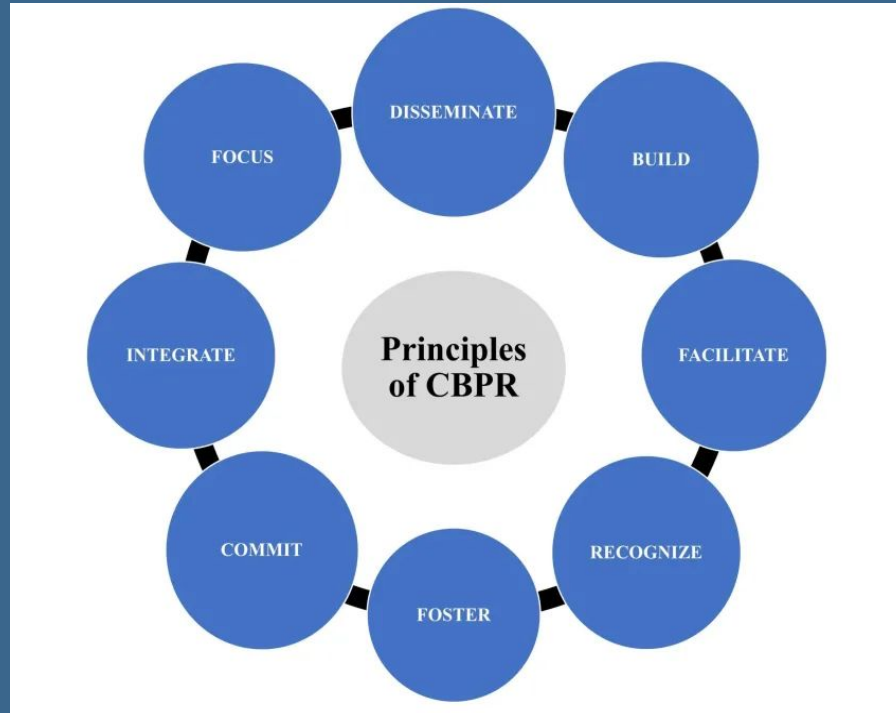on strengths and expertise within the community

FACILITATE
an equitable partnership in all phases of the research that aims to both empower and share power

RECOGNIZE
the community as a unity of identity with shared experiences related to environment, race, socioeconomic status, occupation, etc.

FOSTER
co-learning and capacity building among all partners

FOCUS
on public health issues relevant to stakeholder communities, including those influenced by social and economic determinants

COMMIT
to a sustainable, and when possible, long term investment in the partnership

DISSEMINATE
results to all partners and identify stakeholders who can influence change

INTEGRATE
knowledge generation with community action!

Adapted from: https://medicine.yale.edu/intmed/genmed/eric/cbprguidebook/principles/

Community-Based Participatory Action Research (CBPAR)

"Community-based participatory action research (CBPAR)
is **an applied collaborative approach that enables community
residents to more actively participate in the
full spectrum of research...**

(from conception – design – conduct – analysis – interpretation –
conclusions – communication of results)

...with a **goal of influencing change in community health,
systems, programs or policies.**"

Community-Based Participatory Action Research

CBPR **helps address concerns of exploitation and research fatigue** among members of disadvantaged, marginalized, stigmatized, and underrepresented communities **who have often been the subject of research** studies.

CBPR promotes **"research with" rather than "research on"** these communities and their members.

The EHSC's intention is that the PPP will support both new science and new collaborations -- both of which we hope will continue beyond the grant term.

You're not just piloting the science, you're piloting the relationship to build into larger projects over time.

Pilots are short and budgets are small - think creatively about reciprocity and shared goals in both the short and long term.

If your pilot project doesn't currently include community collaboration, **we can help you develop relationships during your pilot award to support community engagement in your next steps.**

Partnership beyond the Pilot

Successful partnerships are long term investments in relationship- and trust-building.

Challenges of Community Engaged Research to Academic Researchers

Disincentives for engaged scholarship in academia: Work seen as "less legitimate/objective" (especially for pre-tenure faculty, women, academics of color)

Can be time and resource intensive

But, things are changing...

Challenges of Community Engaged Research to Community Partners

Over-extension in time and effort

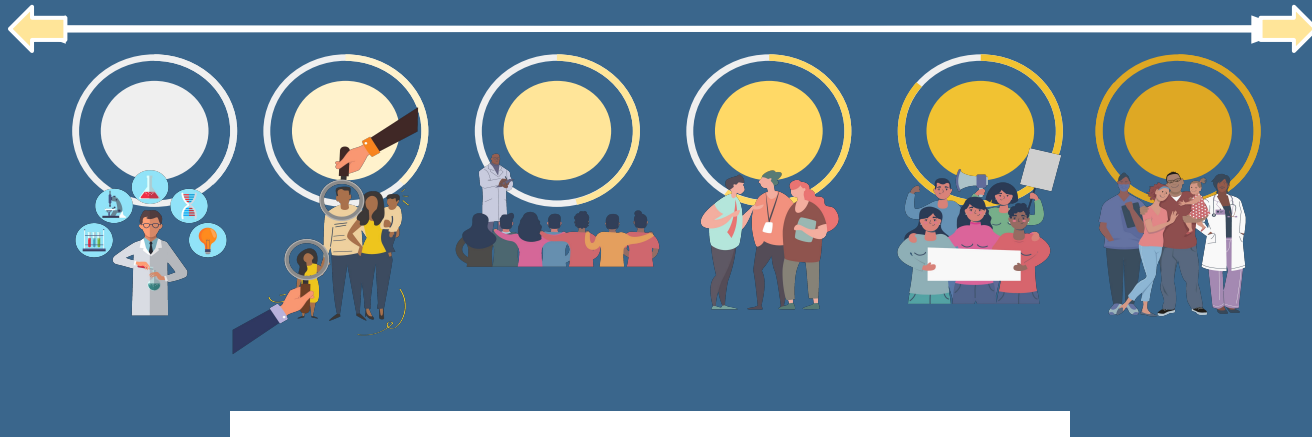Reduction of available resources for community organizing/ advocacy

Potential for negative community impacts of the research based on negative/ inconclusive results

Assessing Community Engaged Research

Extent of community participation:
The quality and quantity of roles that community partners play in the project

Assessing Community Engaged Research

Alignment
of the project
to its context

London, Jonathan K., et al. "Aligning community-engaged research to context." *International journal of environmental research and public health* 17.4 (2020): 1187.

Assessing Community Engaged Research
From the community perspective
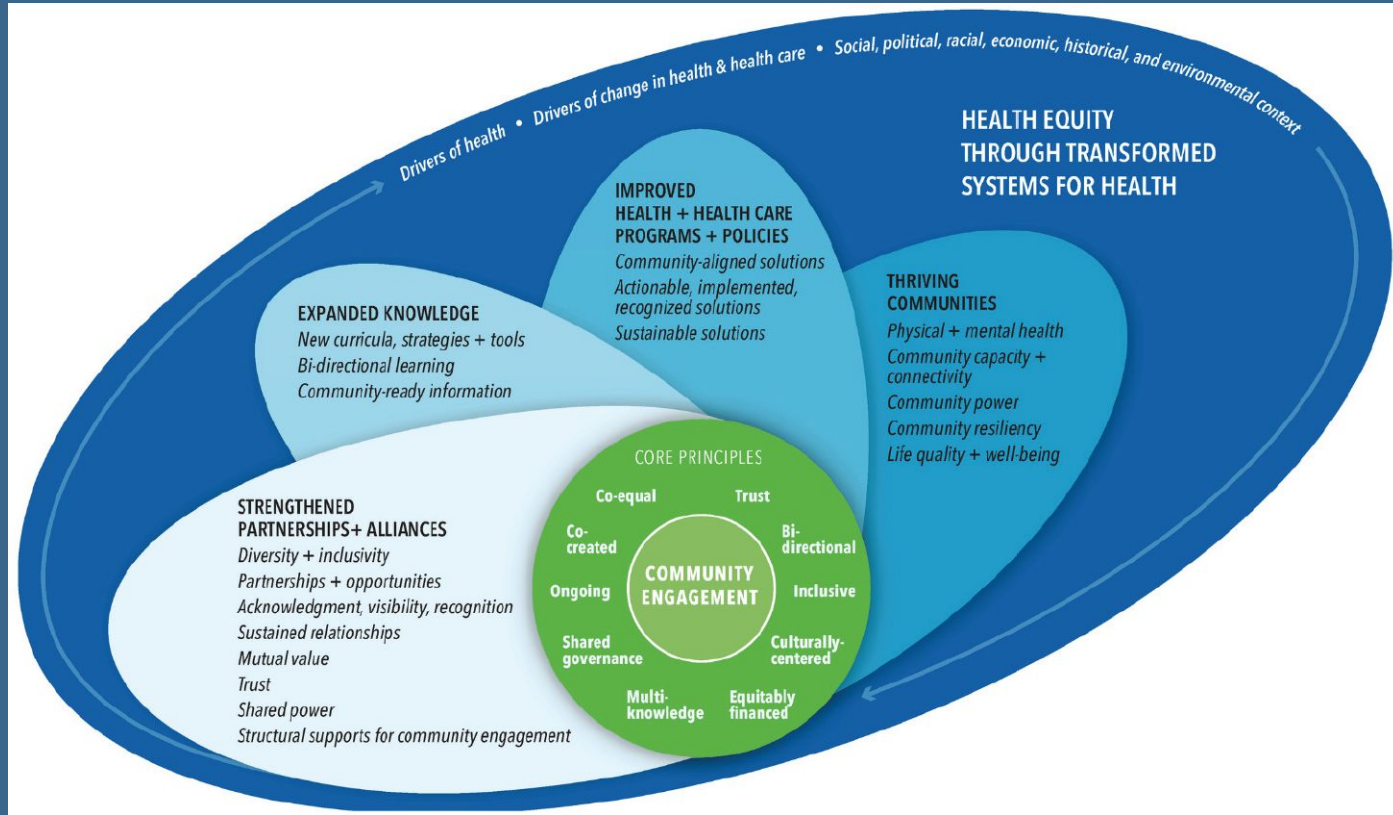
ACTIVITY:
What does the community engagement look like in your current project?

Discussion / Sharing Experiences

4. Administering community engaged research

Partnership agreements
Payments to community partners
Going through IRB with a community partner

Partnership agreements

We strongly recommend written agreements for all projects

A written agreement is **required** if the community partner is either:

- included as a researcher on the IRB application

- getting paid

Partnership agreements

The CEC can help you negotiate and write up your partnership agreements.

We request that you provide the CEC with copies of your partnership agreements and notify us of any modifications.

Partnership agreements

Types of partnership agreements include:

- Informal partnership agreement / Scope of Work

- Budget / contract / subaward

- Formal MOU
    - The terms of formal MOUs must be aligned with IRB requirements
    - ~4 month UCD approval timeline

Partnership agreements

Components of partnership agreement:

- Decision making process
- Nature of relationship
- Communication
- Ownership of data
- Timeline
- Roles and responsibilities
- Budget, if applicable

Payments to community partners

PIs are solely responsible for getting community partners paid

- EHSC / CEC cannot pay community partners directly

- Payments will go through your standard departmental accounting procedures

- Community partners will need to be added to the UCD system and issued POs or subaward agreements **before they can start work**

Payments to community partners

Payments may be issued to <u>contractors/vendors</u>, <u>consultants</u>, and <u>subrecipients</u>.

- Which category a community partner falls into is determined by nature and scope of their contributions to the work

- Each designation involves different administrative processes for payment

- UC Davis provides guidance on what types of work fall into each category

Payments: Vendor Status

A community collaborator is considered a <u>vendor/contractor</u> if all of the following are true:

- They do not collaborate on the design of the project/proposal, including the design of their own scope of work.
- Their work is measured against contract deliverables rather than project objectives.
- They do not make or contribute to project decisions.
- They are not expected to create or co-author publications.

Payments: Vendor Status

Documentation required for university to issue a PO:

- IRB Approval from UC Davis (if human subjects)
- IRB Approval from NIEHS (if human subjects)
- Community partner scope of work
- Community partner budget
- Payment term (default is 60 days, can request shorter)
- Any specific qualifications / resources of the community group

Payments: Subrecipient Status

A community collaborator is considered a <u>subrecipient</u> if any of the following is true:

- They collaborate on the design of the project/proposal, including the design of their own scope of work.
- Their work is measured against the project objectives, rather than contract deliverables.
- They make decisions as part of the project team.
- They create or co-author publications.

Payments: Subrecipient Status

A grant received by a UCD PI with a community subrecipient is referred to as an "outgoing subaward."

UC Davis provides a toolkit with guidelines, tutorials, and a formal training for processing outgoing subawards. This will be handled by the PI's accounting staff.

The CEC can help a community collaborator with their portion of the paperwork.

Payments: Subrecipient Status

Prior to receiving an outgoing subaward, community collaborators must be compliant with federal regulations.

This includes:
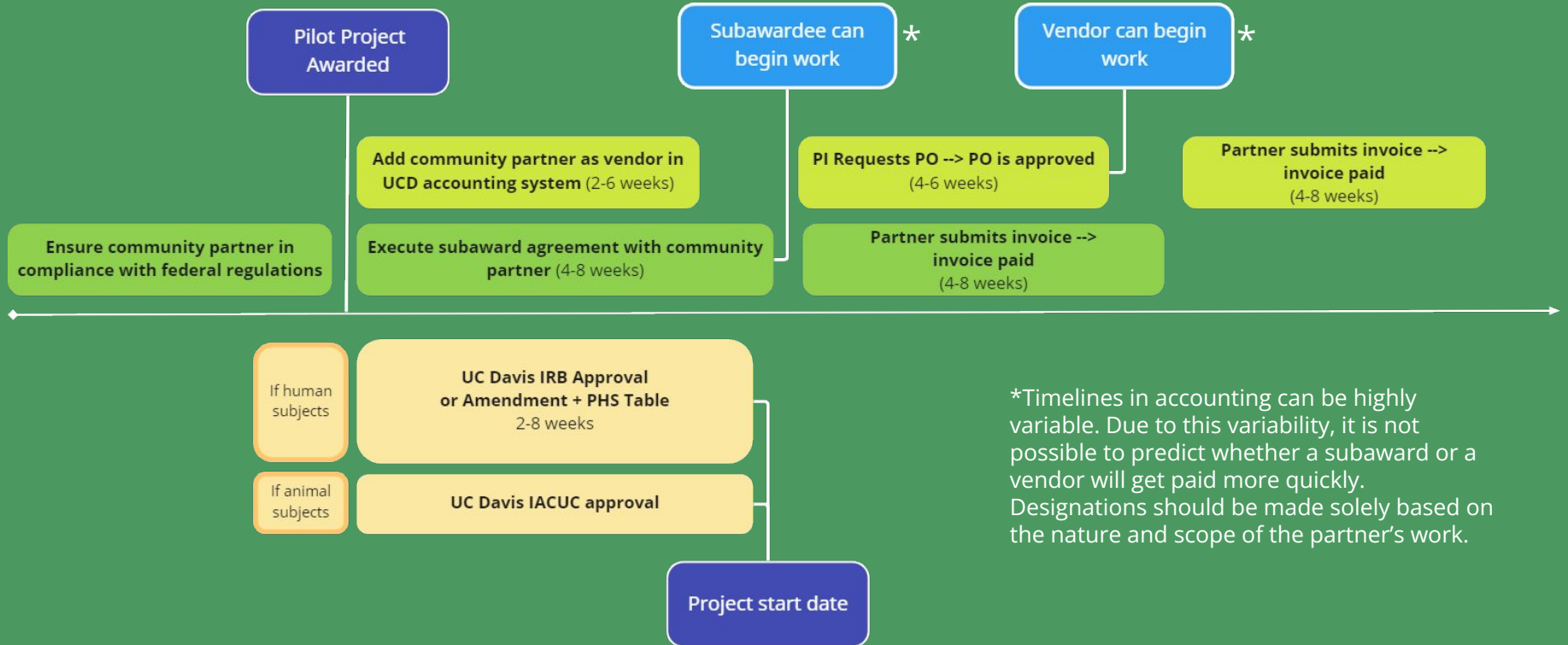- Registration in System for Award Management (SAM)
- A Unique Entity Identifier (UEI), which is requested through SAM
- Registration in eRA commons
- Any individual listed as key personnel must also have an eRA commons ID

Many larger community-based organizations will already be compliant or have a fiscal sponsor who is. **For those who don't, the EHSC can support them in applying.**
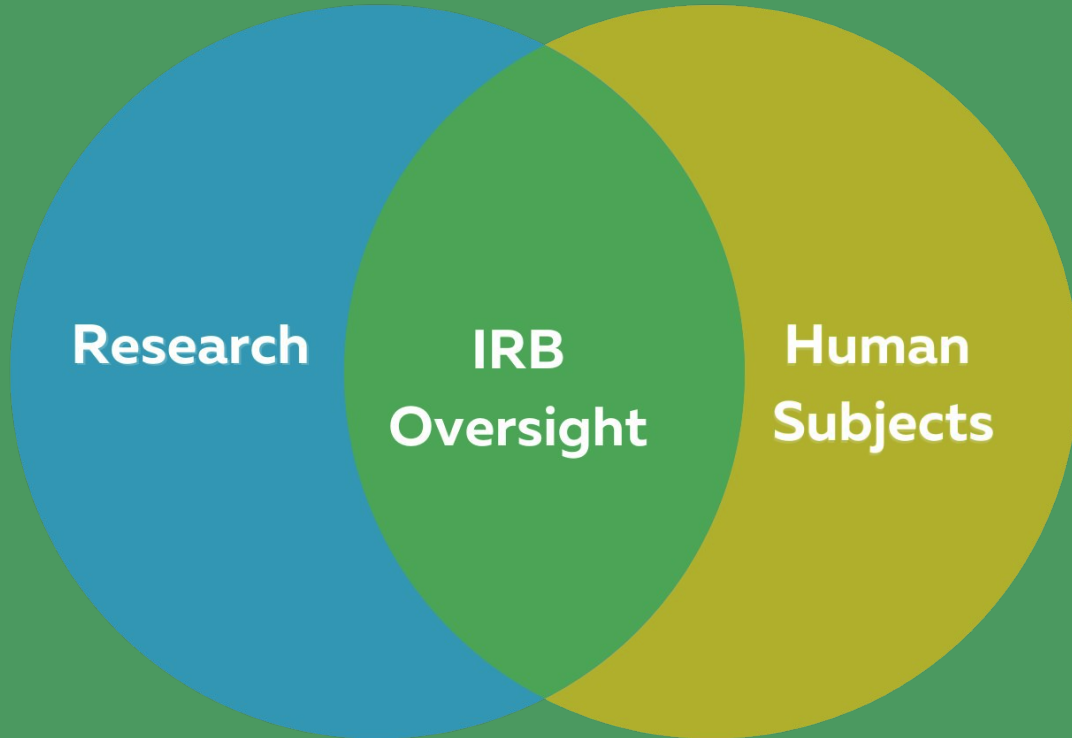
Payments: Timeline

Pilot Project Awarded

Subawardee can begin work *

Vendor can begin work *

Add community partner as vendor in UCD accounting system (2-6 weeks)

PI Requests PO --> PO is approved (4-6 weeks)

Partner submits invoice --> invoice paid (4-8 weeks)

Ensure community partner in compliance with federal regulations

Execute subaward agreement with community partner (4-8 weeks)

Partner submits invoice --> invoice paid (4-8 weeks)

If human subjects

UC Davis IRB Approval or Amendment + PHS Table 2-8 weeks

If animal subjects

UC Davis IACUC approval

Project start date

*Timelines in accounting can be highly variable. Due to this variability, it is not possible to predict whether a subaward or a vendor will get paid more quickly. Designations should be made solely based on the nature and scope of the partner's work.

IRB with a community partner

3 types of IRB review

Full board review

Expedited review

Exempt review

Studies involve more than "minimal risk"

Examples:

Interventions involving physical or emotional discomfort or deception

Studies involving sensitive data or vulnerable populations

Not greater than "minimal risk:

Examples:

Collection of biospecimens by non-invasive means

Studies that do not involve vulnerable populations

Studies involve less than "minimal risk"

Example:

Research with de-identified records or anonymous surveys

Studies that involve normal educational settings using normal practices

What is research?

Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge

If the intent of an activity is to contribute to testing a hypothesis, drawing conclusions, and contributing to generalizable knowledge, **these activities are categorized as research.**

Translating and disseminating findings alone is not "research."

What is human subjects research?

A human subject is **a living individual**

- about whom an investigator conducting research obtains, uses, studies, or analyzes **data or biospecimens** through an intervention or interaction with the individual

-OR-

- whose **identifiable, private information** is used, studied, analyzed, generated

Examples of human subjects research

- Collecting blood
- Conducting a survey
- Changing participants' environment
- Administering medicine
- Interviewing

- Collecting data
- Conducting a focus group
- Testing a new educational technique
- Administering a psychological test

HUMAN SUBJECTS RESEARCH ACTIVITIES

VERSUS

NON-HUMAN SUBJECTS RESEARCH ACTIVITIES

Recruitment

Obtain informed consent

Inform potential participants about a study, including:

- Providing potential participants with IRB-approved materials, including copies of informed consent documents
- Providing potential participants with information about contacting investigators, or obtaining permission for investigators to contact them

Data handling

Access to identifiable private information

Access to coded, de-identified data

HUMAN SUBJECTS RESEARCH ACTIVITIES

VERSUS

NON-HUMAN SUBJECTS RESEARCH ACTIVITIES

Data collection

Perform an intervention (i.e. take measurements, administer a treatment, collect a biospecimen, or alter the environment for research purposes)

Engage in protocol-dictated communication or contact (i.e. asking someone for a specimen, conducting interviews, or administering questionnaires)

Obtain identifiable private information

Permit the use of facilities for an intervention or interaction with subjects (i.e. provide a location for conducting surveys or collecting blood samples)

Release identifiable private information to investigators

Dissemination

Author a paper, journal article, or presentation describing a human subjects research study

IRB with a community partner

If a community partner will be engaging in human subjects research, they must be included on the researcher's IRB.
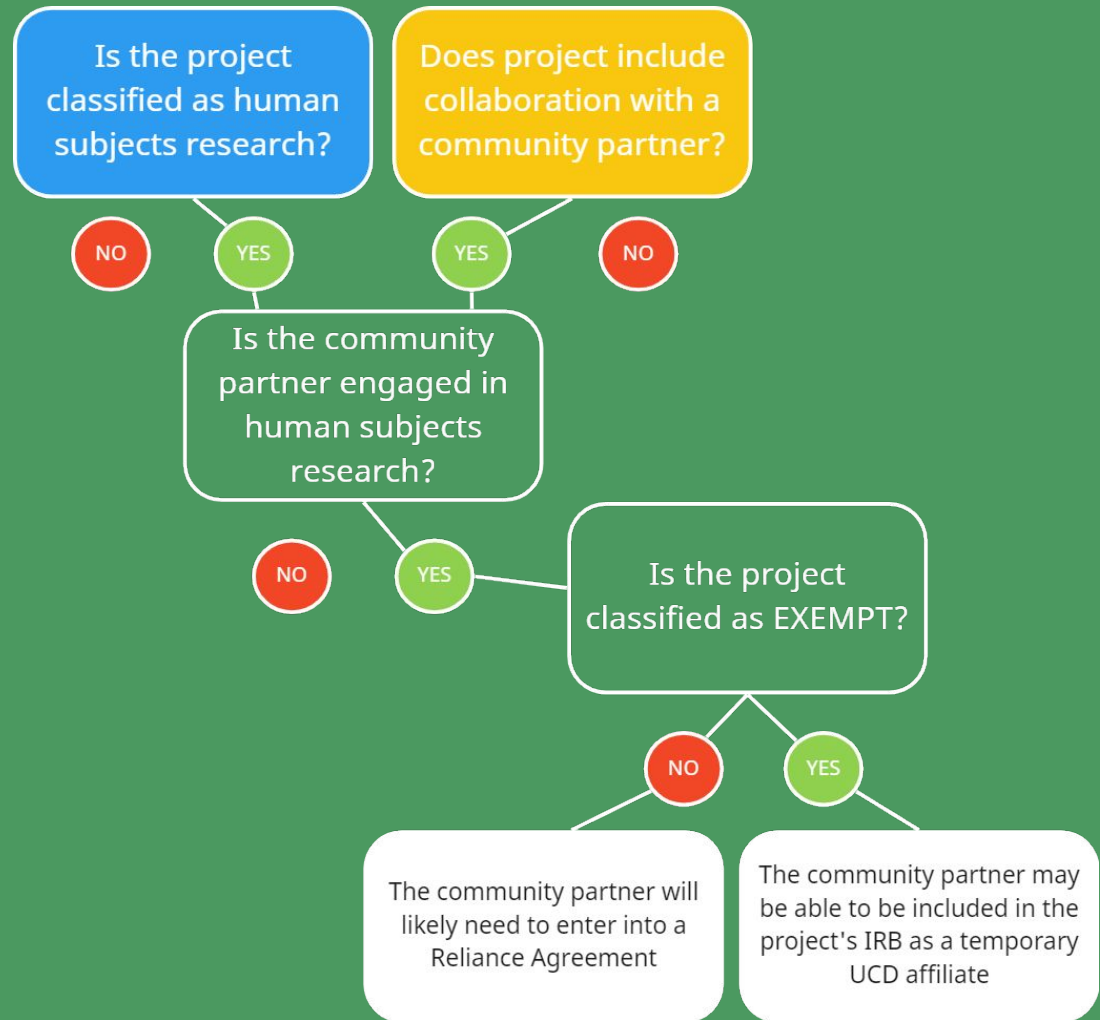
UC Davis IRB Policy is to not allow non-university employees on the Research Personnel List.

Available options for including a community partner on an IRB:

Temporary Affiliate Form (TAF)

Reliance Agreement

IRB with a community partner

Is the project classified as human subjects research?

NO — YES

Does project include collaboration with a community partner?

YES — NO

Is the community partner engaged in human subjects research?

NO — YES

Is the project classified as EXEMPT?

NO — YES

The community partner will likely need to enter into a Reliance Agreement

The community partner may be able to be included in the project's IRB as a temporary UCD affiliate

Temporary Affiliate Form (TAF)

Can only be used for projects classified as EXEMPT by IRB.

Cost: Free

TAF is a process created to grant external constituents (visiting faculty, concurrent students, vendors, and others) access to UC Davis computer resources.

By registering for temporary access, affiliates have access to the UC Davis network, a ucdavis.edu email address, and a unique username and password which is used to verify identity and enable subsequent access privileges to various parts of the network.

Term: 1 year, renewable

TAF (Temporary Affiliate Form): https://servicehub.ucdavis.edu/servicehub?id=it_catalog_content&sys_id=e729e15d1b9798103f4286ae6e4bcb3e
To create a TAF: https://computingaccounts.ucdavis.edu/cgi-bin/taf/index.cgi

Reliance Agreements

Reliance Agreements allow **independent investigators** partnering with UC Davis researchers to rely on UC Davis IRB for review and oversight of **non-exempt human subjects research.**

Reliance Agreements

An **Independent Investigator** is one whose home institution <u>does not</u> have an IRB.*

Cost:
$2974 for initial review
$1620 for continuing review

Contact: <u>hs-irbreliance@ucdavis.edu</u>

*An **external investigator** is one whose home institution <u>does</u> have their own IRB.

Special Considerations for IRBs with Community Partners

- Importance of intentionality around power imbalances

- Include community partner in assessing risk, particularly community-level risk and risks associated with dissemination of findings

- Planning for modification is important but also introduces potential uncertainty around informed consent and predicting risk

Special Considerations for IRBs with Community Partners

- Start early, as the process can take longer with multiple collaborators

- Some non-academic entities may have their own ethics review process that the research will need to go through

- Consult with CEC and IRB if you need to go through the IRB process before you have a partner identified

5. Q & A and next steps

- Please fill in training evaluation (sent by email)
- CEC will reach out to set up quarterly check-ins for individualized, project-specific support
- Supplemental support materials will be provided before Part 2