

Standard Operating Procedures for Researchers Conducting Community-Based Projects

Developed by the KRA-3 working group

This document is designed to meet a need for clear, consistent expectations for researchers in the Department of Epidemiology in their work with community partners. **Community partners** (CP) refers to individuals, informal groups, and incorporated organizations with stakes in the research process and/or findings, and that function independently of private companies or research institutions. CPs have special considerations in the research process that are distinct from those of external institutional or corporate partners common in research collaborations. Specifically, CPs typically do not come to a research partnership with the resources or infrastructure of institutional or corporate partners. In turn, CPs function and operate in the public health space on a smaller budget and with less formal structure. In the spirit of Community Engaged Research¹ and to apply anti-racist and equity principles to our CP collaborations, it is incumbent on the researchers in the Department to facilitate effective working relationships with CPs in research. These SOPs are meant to support researchers as they assume the role of institutional steward in their working relationships with CPs.

Additionally, working effectively with CPs as a Department aligns with the Strategic Plan’s third key result area (KRA-3), *conducting high impact research*, outcome 1: “the department has established a systematic process for getting community input on research priorities and activities.”

The SOPs outlined in this document will support effective, mutually beneficial, good-faith partnerships wherein CPs are provided clear expectations for the receipt of payment.

We present SOPs in three sections: 1) financial and institutional, 2) regulatory & ethical, and 3) CP relationship management.

Table of Contents

- Relationship Management & Maintenance2
 - 1.1. Identifying CP(s)2
 - 1.2. Communication2
- Regulatory & Ethical Considerations3
 - 1.3. Human Subjects Protection & HIPAA Privacy Protection3
 - 1.4. Confidentiality & Privacy4
 - 1.5. Records Storage & Retention4
 - 1.6. Ethical review4
 - 1.7. Regulatory review5
- Financial and Institutional Considerations5
 - 1.8. Decision-making/Signatory Authorities5
 - 1.9. Memorandum of Understanding5
 - 1.10. Determining the institutional role of the CP6
 - 1.11. Subawards6
 - 1.12. Payments6
 - 1.13. General Best Practices for Payment7
- Dissemination7
 - 1.14. Dissemination plan7
 - 1.15. After the research is complete7

¹Community-engaged research is a process that incorporates input from people who the research outcomes will potentially impact and aims to involve these individuals or groups as equal partners throughout the research process. This involvement may include co-designing research questions to solve problems, making decisions, influencing policies, and creating programs and interventions informed by their lived experiences. *Israel BA, Schulz AJ, Parker EA, Becker AB. Review of community-based research: assessing partnership approaches to improve public health. Annu Rev Public Health. 1998;19:173-202. doi:10.1146/annurev.publhealth.19.1.173*

Standard Operating Procedures for Researchers Conducting Community-Based Projects

Relationship Management & Maintenance

1.1. Identifying CP(s)

The selection of CP(s) for your research work depends on the principles you are using. For example, if you are conducting a formal CBPR project, it is likely that a CP approached you with the study idea. In other cases, you may be seeking CPs for a study concept you developed. Here, we provide considerations for this process. These items can be largely assessed by communicating with trusted key informants or by inviting a CP leader/member to an informational interview.

1.1.1. Mission, service, or product

The CP should have a mission, service, or product that directly relates to the study population or issue.

1.1.2. Established relationship and good reputation

The CP should have some established relationship and good reputation with a local study population or service community that has direct relevance to your work.

1.1.3. Structure

The CP may not have a formal structure, and indeed may be a single individual, but they should be a reliable study partner who can attend necessary meetings and deliver on study requirements.

1.1.4. Relationship to research

The CP should enhance the research approach, execution, and/or dissemination. In turn, the researcher should ensure that the CP is comfortable actively asserting their perspectives as appropriate.

1.1.5. Existing research/external partner processes

The CP may have existing research/external partner processes. Start with CP existing processes and preferences, then discuss how to integrate UW/research processes.

1.2. Communication

The timing, frequency, and form of communication should be established as early as possible with CPs. Some will prefer regular communication during conventional work hours, while others may be available only outside of work hours or are involved in roving work with little access to telephones or video calls. Here we provide key considerations:

1.2.1. Meetings

1.2.1.1. Regular team meetings:

Recurring calls at a mutually agreeable time.

1.2.1.2. Event-based meetings

Ad hoc calls that coincide with group efforts or study deliverable work deadlines.

1.2.1.3. Sub-team meetings

Recurring calls with specific team members based on their role(s) on the study team.

Standard Operating Procedures for Researchers Conducting Community-Based Projects

1.2.1.4. Written communication only

Some CPs will prefer email- or text-based communication.

1.2.1.5. Existing CP processes

Ask what existing communication processes (modality, interval, key attendees), and adjust/build on that. More communication/meetings than are CP norm may potentially become burdensome or poorly attended/responded.

1.2.2. Individuals

Depending on the composition of your CP, you may interact with multiple individuals within the CP. Decide the roles of each person and assess their communication preferences; it is not unusual for some individual CP to have disparate communication preferences and engagement.

Consider between CP individual relationships and potential hierarchy. For example, smaller and larger organizations may have supervisory staff that may appreciate or need to be copied and/or involved in smaller matters.

Regulatory & Ethical Considerations

1.3. Human Subjects Protection & HIPAA Privacy Protection

1.3.1. Human Subjects Protection (all research)

This is required for ALL research involving human subjects.

<https://www.washington.edu/research/hsd/training/required-training/human-subjects-protections-training/>

1.3.2. Human Subjects Protection (for CPs)

This is a "training program in human research protections that is tailored to the unique roles of community research partners." This training is not for UW researchers who need to satisfy the NIH training requirement.

<https://ccts.uic.edu/resources/cirtification/>

1.3.3. Good Clinical Practice (clinical research)

This is required or recommended for clinical research.

<https://www.washington.edu/research/hsd/training/required-training/good-clinical-practice-training/>

1.3.4. HIPAA (research involving health records access)

This is required for ANY research accessing health records and is administered by UW Medicine.

<https://www.uwmedicine.org/school-of-medicine/policies-procedures-reporting/hipaa-training>

1.3.5. Community-Engaged (CEnR) and Community-Based Participatory Research (CBPR) (optional)

UW offers this optional training course through the CITI Program. It introduces learners to CEnR and CBPR, and identifies the ethical and practical considerations particular to the design, review, and conduct of CEnR.

<https://www.washington.edu/research/hsd/training/required-training/web-based-citi-training/>

Standard Operating Procedures for Researchers Conducting Community-Based Projects

1.4. Confidentiality & Privacy

1.4.1. Confidentiality

Confidentiality may not necessarily be restricted to legal protections. Some CPs and communities may have additional concerns or preferences. If applicable, discuss, operationalize, and document with the CP whether additional extralegal protections or processes are necessary. For example, CPs may request sensitive data be redacted or destroyed sooner than legally required, that data to be stored by them and not shared with others including researchers, that they analyze data themselves or have the researcher sit with them and do the analyses, or that data destruction be documented.

1.4.2. Privacy

As with confidentiality, some CPs and communities may have additional concerns or preferences. If applicable, discuss, operationalize, and document with the CP. If additional concerns are noted, make sure you perform a privacy review of your final research procedures, to ensure all research procedures have been assessed. For example, communication with the CP or participant, and physical research setting.

1.5. Records Storage & Retention

1.5.1. CP practices

UW standards may not align with CP practices. Be sure to identify CP practices and determine if they align with the project overall compliance and data collection requirements.

1.5.2. UW/researcher SOP/rules

Your grants and fiscal contact can advise on general administrative requirements, and the UW records retention Web site covers research data.

<https://www.washington.edu/research/myresearch-lifecycle/closeout/records-retention/> .

1.5.3. What is stored

Even small projects collect a variety of records with different considerations. Be sure to assess storage and retention of each record type, for example, communication, study data, financial, contractual, etc.

1.5.4. Record types

Be sure to include all records in your review, for example, electronic, audio, video, paper, database, data sets, etc.

1.6. Ethical review

1.6.1. CP's IRB

The first step is determining if they have their own ethical review group(s). CPs may have their own IRB or rely on UW IRB. Regardless, UW IRB is always available for any questions (hsdinfo@uw.edu).

1.6.2. Researcher's IRB

Do not start your IRB application until you have established all necessary ethical reviews required.

Standard Operating Procedures for Researchers Conducting Community-Based Projects

1.7. Regulatory review

1.7.1. Applicable regulatory review

When discussing ethical reviews with the CP, be sure to also discuss any additional required regulatory or organizational reviews, for example, foreign nation governmental review or CP organizational approvals (grant/funder disclosures and documentation, etc.).

Financial and Institutional Considerations

1.8. Decision-making/Signatory Authorities

1.8.1. UW Personnel

We recommend beginning this process by notifying your department's grant administration staff as soon as possible so they can guide the identification of UW authorities. An individual from the UW must be able to execute a contract (or MOU) -- often UW Office of Sponsored Programs.

1.8.2. CP Personnel

In project discussions and planning, you should identify CP individuals that can make final decisions and authorizations, and review the scope of work.

1.8.3. Decision making authority

In a large non-profit organization, this may be the executive director or someone in a similar role. Initial discussions might include a delegate, but it is important that the decision making authority is copied since they will be the one providing final approval. If the CP is an informal, small group or an individual, it may be the person you work with most closely. As you begin your work with the CP, you will determine how they want to interact with the research project.

1.8.4. Financial authority/signatory

This is the individual that will sign and review financial agreements and/or decisions. This may be the decision making authority in a small group or a separate person in a large organization.

1.8.5. Key implementation stakeholders

These are the individual(s) that will be overseeing and/or conducting the activities, and whom initial or detailed discussions involve. In a small group, this individual may serve as the decision making authority and the financial authority. In larger groups where roles are split, it is critical that at least final decisions involve all parties to ensure the work is both supported and agreeable by both leadership and those directly performing study activities.

1.9. Memorandum of Understanding

A Memorandum of Understanding (MOU) is a brief document that functions like a contract between parties involved in the research. Typically, it is short and contains straightforward language, in contrast with a contract that often is long and contains legal or complicated language. We provide an MOU template adapted from CDC in Appendix I. This tool will support the establishment of these norms:

Standard Operating Procedures for Researchers Conducting Community-Based Projects

1.10. Determining the institutional role of the CP

The UW Office of Research provides [guidance](#) on defining the role of a non-UW affiliate in a research project. In most cases, CPs will function as either a *Contractor/Vendor* role or a *Consultant* role. Refer to the linked resource to determine the role of your CP (also provided in Appendix II). This institutional role of the CP may be of no importance to the CP and institutional language and practices associated with this determination may be alienating. You should consult the financial point-person for the CP to ensure that communication is straightforward and clear on how the role is defined.

1.11. Subawards

Information needs to be conveyed to small CPs at the grant proposal stage regarding what entering into a Subaward with the UW entails, especially on Federal awards with many compliance requirements. Contact your grants team as early as possible in the process to assist with this.

1.12. Payments

CPs may receive one-time or multiple payments for their involvement in the research. Regardless, contact your grants team as early as possible since a variety of payment mechanisms and regulations apply, regardless of frequency or quantity of payments. For example, the practical and institutionally defined role of the CP affects the entire payment process, including setup, initiation, payment, and accounting.

1.12.1. Sample payment types

1.12.1.1. Initial payment

Agreements in place and filed (UW and CP), confirmation of payment receipt

1.12.1.2. Milestone payments

Submission and milestone requirements, expected turnaround time for payments, confirmation of payment receipt, research team check-in reminders regardless of submission

1.12.1.3. Time point payments

Clearly documented/communicated payment intervals, expected payment windows (range of time for payment execution), confirmation of payment receipt, study team payment reminders

1.12.1.4. Final payment/close-out

Final invoicing and payment, confirmation of payment receipt

1.12.2. Considerations for multiple payments

If more than a one-time payment will be made, ensure that payment requirements, amounts, and timing are clearly documented and understood. Example considerations include:

1.12.2.1. Clear expectations

A clear list of payment frequency, amount, and corresponding tasks/deliverables

Standard Operating Procedures for Researchers Conducting Community-Based Projects

1.12.2.2. Contingency planning

A contingency plan for potential delayed/late payments to the CP

1.12.2.3. Point-person identification

Point-person(s) for the CP(s) to communicate with directly. Consider including financial, administrative, and/or faculty point-persons depending on your project needs and scope.

1.12.2.4. CP's UW role

The role of the CP in terms of University policy (see next section)

1.13. General Best Practices for Payment

Although you may not have an institutional role in remitting payment to the CP, you can take steps to advocate for the CP and prevent delayed or missed payment.

1.13.1. Plan a payment execution timeline.

Payments take time to process on both researcher, UW and CP ends. Document an internal estimated SOP for payments and timing. This does not have to be formal. It could be a folder with all email contacts involved in a payment.

1.13.2. Set early reminders

Holidays, staff vacations, and other events often result in delays. Set a reminder 1-2 weeks prior to when you expect to request/initiate a payment.

1.13.3. Ensure CP understanding

Make sure the CP understands the RANGE of time to expect from payment request to receipt. This doesn't need to be a detailed technical document, but can be as simple as a gentle reminder of the process at initiation/receipt of payment request, e.g., "... I requested the payment today. As a reminder, this should take about x days since this gets processed by y..."

Dissemination

1.14. Dissemination plan

In most forms of community-involved research work, the CP should be closely involved in the dissemination plan. Many subject matters that indicate community-based research have sensitive considerations, so we encourage referencing the Trauma and Resilience Informed Research Principles and Practice (TRIRPP). The CP can provide valuable input in the approach to results dissemination.

1.15. After the research is complete

Some CPs will want to stay in touch following the conclusion of work, while others will not. We encourage establishing corresponding norms as early as possible in the work and including expectations in the MOU. Post-conclusion calendar reminders can be useful to ensure this is not forgotten as you move on to other projects or after funding expires.