COALESCE

Research Application and Protocol Components

There are several components to research protocols that can be important for community partners to be familiar with. This way, they can make well informed decisions about whether:

- ✓ *a research opportunity is a **good match** with their organization's mission*
- ✓ *they have the **capacity** to carry out expected tasks*

Read further to find out more:

**Bolded items denote glossary terms*

- ## The "High-Level Requirements": Eligible Applicants, Funding Agency Information, Award Amount:

Many protocol applications (RFPs, "Requests for Proposals") begin with a high-level summary of the study being funded, including the study's aims, who is funding the study, what types of organizations are allowed (or not allowed) to apply, how much money is being awarded and to how many awardees. These are important details to know so you can decide if the project is a good fit for your organization.

- ## Application and Project Timelines:

Many research protocol applications spell out key dates that are important to the application process. This includes when the application opens, dates and times for informational calls when funders will answer applicants' questions about the application process, and dates when applications are due. They also spell out when the project itself is supposed to begin or end, and if there is an option to extend the timeline.

- ## Problem Statement/Background:

All research protocols are intended to answer a question or help solve a larger problem, like "Why are more young people not finishing college?" or "How can we contain air pollution to decrease respiratory illness in our city?" Your job as an applicant is to make sure your proposed research responds to this question and helps solve the problem.

- ## Research Purpose/Objectives:

The research purpose or objectives clearly state the purpose of your study and how it will address the problem statement. Typically, this section of the protocol is to the point and includes any strategies named by the funder to address the problem (e.g., building stronger partnerships within the community to identify at-risk youth, educating healthcare providers on how to integrate COVID-19 vaccinations into routine care)

- ## Allowable/Required Research Activities:

Funders often clarify which types of research activities they will allow or require as part of the proposed work and which types they will not allow. Engaging in non-allowable activities would weaken the proposal because it doesn't align with what the funder wants. It would also mean

more costs for whomever is carrying out the research because the funder will not reimburse unallowed costs. Take care that your study matches what the funder is asking for.

- ## Study Methods/Design:

This section of the protocol describes in detail what exactly will take place as part of the research study. This includes the research activities, such as:

- *Intervention or experiment* that takes place (e.g., diabetic participants were taught blood glucose level management skills, participants took either a medication being tested or placebo)
- *Data collected* (e.g., changes in blood glucose readings for diabetic patients, changes in illness and symptoms for participants taking medication or placebo)
- *Analysis plans:* how we make sense of the data collected and understand if our intervention had an impact, this could include observations, simple counts, or statistical analyses.

- ## Participants:

This section speaks to *who is eligible to participate* in the study, why this group is being targeted (e.g., are they at greater risk for a poor outcome, representative of the overall population, etc.) and why certain people are included or excluded from the study (e.g., do we focus on a certain age range because we are looking at adolescence as a developmental period).

This section also describes *how participants will be selected* (e.g., randomly ask people to get a cross section of the community, purposefully select participants based on a characteristic relevant to the study question, like gender, age or where they live), the *estimated number* of people we want to include in our study and *how they will be assigned* to a treatment or comparison group if our study includes these groupings.

- ## Recruitment Communication:

Protocols will outline what is approved or allowable to do in in terms of communicating with potential or enrolled participants. For example, a protocol may say that the researcher will call or email the participants to tell them about the study. Since it doesn't include text messaging, they can't send texts unless they want to submit an **amendment** to the protocol. You can always ask about recruitment procedures if you want clarification or if you have a suggestion of something that should be amended.

- ## Informed Consent Process:

Ensuring that a person understands what they are agreeing to by joining a study is a critical part of the work researchers do, this is called **informed consent.** There are three components that must be included in any informed consent. This includes 1) a *full description of the study*, what specifically is asked of the participant if they choose to participate, and any potential risks and rewards for participation, 2) ensuring that the participant is *competent to provide their own consent* or that their surrogate or guardian is (e.g. minors or cognitively impaired individuals may require the consent of a guardian/surrogate) and 3) ensuring the participant knows that their participation is completely *voluntary*, they don't have to do or say anything they don't want to, they can drop out at any time and it will not impact them negatively. Ask if you have any questions about the different sections of the consent form.

- **Workplan/Timeline/Budget:**

Research funders often ask for a plan of work, timeline in which this work will get done and budget needed to complete the work. Sometimes this is simply a high-level outline for the application and greater details will be requested when you win the research award. It's important for community partners to be familiar with these elements because they will be asked to carry out part of the work in accordance with the proposed timeline and budget. Make sure these elements are a realistic fit for your organization. If not, speak up and discuss with your research partner.

- **Applicant Capacity:**

Research funders don't want to waste their investment. They may ask research applicants to clarify why they are qualified to carry out the work. For example, have you done this type of work before? Do you as an applicant have enough staff, office space, equipment, experience, and training to carry out the work? Do you have the necessary relationships to recruit potential participants? If not, see how you can round out those necessary capacities across your research team.

- **Collaboration/Partnership Requirements:**

Community partners are often asked to collaborate on research projects given their deep ties and relationships to relevant communities and potential participants. It will be important as a community partner to understand what part you and your organization will play in recruiting and consenting participants, collecting data and the like. Make sure that you understand specifically what pieces of the work your organization is being asked to complete and that you feel you have the capacity to carry them out. Typically, these types of research collaborations are spelled out in writing and agreed to by both parties through a Memorandum of Understanding (MOU) before the work starts. It's OK to ask questions, seek clarification and fine tune the plan before your commit to it; this ensures that your organization can meet the demands of the study and that your staff have what they need to carry it out. Verify that what you are being asked to do is something your organization can do and is consistent with your organization's mission and values.

- **Communication/Dissemination of Findings:**

Finally, once the study is complete it will be important to share out what was learned. Typically, researchers will be required to submit periodic reports to their funder on project progress and outcomes. They likely will also write up research articles for peer reviewed journals to share findings within the scientific community. If you are interested in being a part of this process, let your research partner know. It also may be important to you that research findings are shared back with the participants themselves or the community impacted so they can know about the research findings and importance. Speak up and plan with your research partner if you want this included as part of the dissemination of findings.

- **Data Security:**

Research protocols spell out the processes researchers plan to use to secure Personally Identifiable Information (PII). Some of the important parts of data security and protecting participants privacy include *storing participant data separate from any information that identifies who they are.* For example, participants may be given an ID number rather than using

their name so that their name isn't associated with things they may have said, or health information gathered about them. Sometimes it's appropriate to collect data **anonymously** and that is one way of making sure participants' identities aren't tied to their statements. Data security plans also detail *how electronic data is kept safe* from being shared by mistake, e.g., the use of encryption, storage of data on non-networked computers, etc. Data security plans also clarify who does or does not have *access to the data*, if data will be available to researchers for future studies, as well as a *timeline for when data or specimens will be destroyed*.

Many research studies are **HIPAA compliant,** which means that that they follow the rules determined by the Health Insurance Portability and Accountability Act of 1996 and carefully protect every individual's private information. Many research studies include or even require training for all people working on the study to learn more about research ethics and safety issues like protecting sensitive data and proper informed consent procedures. You can always let a partner know if you don't feel equipped or have the level of expertise needed to carry out specific research tasks. Better to speak up so that the research leadership staff can assign tasks appropriately and provide necessary training; it's important that all research partners feel ready to carry out their roles.