Community Members’ Guide to Submitting A Community-Engaged Research Federal Grant Application

CONTRIBUTORS:

Tufts CTSI
Laurel K. Leslie, MD, MPH
Christina Mulé, PhD
Carolyn Rubin, EdD
Nathan Allukian, BA
Joe Hodgkin, BA
Marcia Izzi, MPH
Joseph Braitsch II, MRP

Community Partners
Chien-Chi Huang, MS
Megan Cheung, RN, LICSW
Vivien Wu, BA
Mei-Hua Fu, MS, MEd
Alex Pirie, BA

More information is available at www.tuftsctsi.org. If you have specific questions or would like to speak with one of our team members, please contact us at info@tuftsctsi.org.
Contents

Overview ......................................................... 4
Glossary ........................................................ 5
Helpful Acronyms ............................................. 10

INTRODUCTION 11
What Is Community-Engaged Research?
Models of Community-Engaged Research ......................... 12
Examples of Community-Engaged Research ........................ 14

COMMUNITY-ACADEMIC PARTNERSHIPS 16
How to Build Community-Academic Partnerships
Aspects of Community-Academic Partnership Development ............... 16
Learning about the Possibilities of Community-Academic Research Partnership .................... 17
Establish Guidelines and Strategies to Guide Interactions with Academic Researchers ............. 18
Build and Maintain Relationships .................................. 19
Establish a Clear Community-Academic Research Partnership ........................................... 20

COMMUNITY-ENGAGED RESEARCH APPLICATION 23
Administrative Logistics
Application Process Checklist ....................................... 23
Pre-application Process ............................................. 23
Application Process ................................................ 23
Pre-Application Process ............................................. 24
Tax Exemption ............................................................. 24
Data Universal Numbering System (DUNS) .............. 24
eRA Commons Identification Number .................. 25
Facilities and Administration (F&A) Rates .............. 26
Application Process ....................................................... 26
Knowing the Landscape of Potential Funding ............ 26
Letter of Intent (LOI) .................................................. 27
Negotiating Roles ...................................................... 28
Human Subjects Research Ethics Requirements ........ 29
Memorandum of Understanding ............................... 29
Conflicts of Interest (COI) .......................................... 30
Budget & Budget Justification ....................................... 30
Biosketches ................................................................. 30
Letter of Support (LOS) ............................................. 30
Grant Text ................................................................. 31
Conclusions for Administrative Logistics ................. 31

ETHICS & BEST PRACTICE IN RESEARCH 33
Why Is Research Ethics Important?
Institutional Review Board (IRB)
& Federalwide Assurance (FWA) ....................... 33
Conflicts of Interest (COI) .......................................... 36
Health Insurance Portability and Accountability Act (HIPAA) . 36

RESEARCH BUDGET & BUDGET JUSTIFICATION 38
Developing a Research Budget & Justification
How to Develop a Budget ........................................... 39
Existing Resources ..................................................... 39
Needed Resources ..................................................... 39
Facilities and Administration (F&A) Rates ............... 40
Understanding Your Specific Role in the Grant Process 40
Sharing Grant Funds .................................................. 41
How to Develop a Budget Justification ...................... 42
Successfully Collaborating:
The Critical Role of Communication ..................... 45

CONCLUSION 46
This guide is intended for community-based organizations that are interested in community-based research partnerships with academic researchers (defined herein as researchers affiliated with academic universities and academic medical centers). It was developed after community-based organizations and academic researchers expressed interest in having a resource that outlines the steps required to submit a federal grant application to funding agencies such as National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Agency for Healthcare Research and Quality (AHRQ), and Patient Centered Outcomes Research Institute (PCORI).

One of the primary goals of this guide is to help streamline the process of meeting federal research grant application requirements for collaborations between community members and researchers. In this guide, you will find:

- Information about community-engaged research
- Information you need to build community-academic research partnerships
- Information you need to prepare a federal community-engaged research application
- Useful tips and examples to guide you through federal grant submissions.

The guide is a product of the Center for Aligning Researchers and Communities for Health (ARCH) of Tufts Clinical and Translational Science Institute (CTSI). If after reading this guide you are interested in pursuing a community-academic research partnership, please contact Tufts CTSI for more information. If you would like specific consultation, please complete a request form: http://informatics.tuftsctsi.org/pims/request.htm.

We encourage you to explore our website: www.tuftsctsi.org.
Glossary

**501(c)(3):** An organization with this status is exempt from some forms of federal income tax. This status is reserved for organizations working for “religious, charitable, scientific, testing for public safety, literary, or educational purposes, or to foster national or international amateur sports competition (but only if no part of its activities involve the provision of athletic facilities or equipment), or for the prevention of cruelty to children or animals” [26 USC 501(c)(3)]). Organizations with 501(c)(3) status are not allowed to campaign for political candidates or legislation. Doing so will result in their tax-exempt status being revoked. More information about 501(c)(3) tax exempt status can be found at [http://www.irs.gov/Charities-&-Non-Profits/](http://www.irs.gov/Charities-&-Non-Profits/).

**Allowable Costs:** Allowable costs are expenses that are reasonable and necessary.

**Award:** Federal funding granted in the form of an award is generally granted in annual installments and allows for more flexibility and adjustment than federal funding granted in the form of a federal contract. A team is held to less specific expectations and consequences for changes in the project when it is funded through an award.

**Biosketch:** A form submitted with an application for funding that summarizes the education and experience of a researcher. This is short and should aim to highlight the experience that makes the researcher a strong applicant for the grant in question. The template for the National Institutes of Health (NIH) biosketch and a sample can be found at [http://grants.nih.gov/grants/funding/phs398/phs398.pdf](http://grants.nih.gov/grants/funding/phs398/phs398.pdf).

**Budget Justification Form:** A form that provides a narrative explanation for each of the components mentioned in the budget; it explains, or “justifies,” the cost of the work. Each item should be
explained by its necessity to achieve the aim of the project, provide sufficient detail that describes the work, how it relates to the cost, and links to the aim.

**Commons ID:** A Commons ID or “eRA Commons ID” is an identification number required of all investigators submitting application to NIH. It is important to request an ID well in advance of your grant submission deadline because the process of obtaining a number can take weeks. For more information on eRA Commons ID number, visit [http://era.nih.gov/commons/faq_commons.cfm](http://era.nih.gov/commons/faq_commons.cfm).

**Conflict of Interest:** A situation in which investigators in a research study have a relationship or interest that may conflict with the goals of the project. Conflicts of interest should be avoided at all costs or accounted for in project proposals.

**Consultant:** In a grant application, a consultant is an independent (i.e., he/she is unaffiliated with another institution) individual from outside the applying institution who will be participating in the research and who will be paid for his or her services.

**Contract:** Federal funding granted in a contract is contingent upon meeting very specific requirements. Often the funding will be delivered in installments as the group meets benchmarks established in the contract. If the project does not proceed as promised, the team will be subject to legal or financial consequences. Contracts are usually paid for on a cost reimbursement basis.

**Cost Principles:** Cost principles are charges that cannot be charged to grants and are considered unallowable expenses (e.g., alcohol).

**Data Universal Numbering System (DUNS):** This is a registration system for businesses that is used by governments around the world, including the U.S. government. Funding sources usually require applicants to have a DUNS number. An organization can obtain a unique, nine-digit DUNS number by applying to Dun & Bradstreet, the group that assigns them, at [http://www.dnb.com/get-a-duns-number.html](http://www.dnb.com/get-a-duns-number.html).

**Direct Costs:** When applying for funding for a project, direct costs make up the portion of your grant that is spent solely on the cost of that project. Examples include the salaries and benefits of staff members who work full time on that project, the cost of supplies that are used exclusively for that project, or travel for the purpose of working on that project.
**Electronic Research Administration (eRA) Commons:** This is an online portal administered by the U.S. Department of Health and Human Services (HHS). Its function is to move the grant application and approval process (the “grant life cycle”) online, making it more efficient. Applicants for grants can submit materials and review their progress through the tool, while grantees can update applicants and request further information. The eRA commons can be accessed at https://commons.era.nih.gov/.

**Facilities and Administration (F&A):** A funding application must also account for indirect costs, which come from spending that supports your project, but not exclusively. For example, if your team is sharing a building with people working on other projects, then the heat, rent, electricity, and phone bills for that building, as well as salaries of maintenance staff, are supporting your project, but not exclusively. Rate agreements have formulae for calculating the indirect cost of a project. Institutions negotiate these rates with the federal government.

- Foundations often set an indirect rate at a percent of the total project award (0, 10, 12, 15%). These may range from 0 to 100%.
- Community-based organizations can also request indirect costs—it is important to decide as an organization.

**Federalwide Assurance (FWA):** An agreement with the government to comply with federal standards for ethical research with human subjects. An FWA is required for organizations that conduct human subjects research supported by or paid for by any agency of the U.S. Department of Health and Human Services (HHS). A project conducted at an organization with an FWA is approved by an Institutional Review Board, which helps research stay in compliance with federal regulations and protect human subjects. Instructions for obtaining an FWA number can be found at http://ohrp.nih.gov/efile/FwaStart.aspx.

**Health Insurance Portability and Accountability Act (HIPAA):** This 1996 federal law put in place a system for the protection of patient privacy. Healthcare providers must be trained by their institutions in these privacy practices. A summary of the HIPAA Rule can be found at http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html.
Human Subjects Training Requirements: The curriculum an institution requires researchers to complete if they are working with human subjects. These requirements are designed to be in compliance with the regulations regarding human subjects research laid out by the U.S. Department of Health and Human Services (HHS), including HIPAA.

Inflation: If a project will take place over years, the researchers and funders may take the increase in prices over that time (inflation) into account when planning funding. Adjusting for inflation increases the projected cost of a project; however, some funding agencies have discontinued inflationary increases. It is important to consider this when you draft your initial budget.

Informed Consent: Participants in medical research must give researchers their documented consent to participate. For this consent to be “informed,” it must be proven that all the implications of participating in the study were explained to participants; they understood the explanation; and they agreed to participate with a full understanding of what they were agreeing to, without being coerced in any way. For a project to proceed, researchers must demonstrate to their potential funding sources their plans for obtaining informed consent from participants. Institutional Review Boards are expected to review a study’s informed consent plans before approving it.

In-Kind: An in-kind participant in a project is someone who does not expect reimbursement for his or her role. This is sometimes referred to as “cost-sharing.”

Institutional Review Board (IRB): A committee that reviews research involving human subjects. The IRB is responsible for protecting the safety, rights, and welfare of human subjects, as well as ensuring compliance with regulations and policies for human subjects research. The federal government sets standards for the composition and function of review boards through the Food and Drug Administration and the Department of Health and Human Services. Information about Tufts IRB can be found at http://viceprovost.tufts.edu/HSCIRB/.

Letter of Support: This is a document submitted by an institution or supporter (but written cooperatively by the collaborators) and submitted with a grant application. It demonstrates that the collaborator who is not the primary grant submitter is on the same
page, knows his or her role, and is pledging his or her support to the project.

Memorandum of Understanding (MOU) or Memorandum of Agreement: This is an external document drafted by collaborators on a project that specifically defines the roles of each collaborator and what is expected of each of them. This is an important step in collaborating, since it prevents later disagreements over responsibilities. MOUs are usually defined in the subcontract packages. A guide to writing a memorandum of understanding from the U.S. Department of Health and Human Services can be found at http://aspe.hhs.gov/daltcp/reports/mouguide.htm.

Office for Human Research Protections (OHRP): The branch of the U.S. Department of Health and Human Services (HHS) that oversees ethical standards for human subjects research. OHRP approves IRBs and grants federalwide assurances (FWAs) to institutions conducting human subjects research supported by HHS. OHRP’s tools for investigators can be found at http://www.hhs.gov/ohrp/policy/investigators/index.html. A brochure for potential research participants can be found at http://www.hhs.gov/ohrp/education/brochures/3panelfinal.pdf.

Prime Institution: When multiple institutions or organizations are involved in a grant application, one institution must be designated as the prime institution, and funding for the other institution(s) must be requested via a subcontract to be administered by the prime institution. The prime institution is typically the organization by which the primary investigator is employed.

Subcontract/Subaward: When the prime institution wants to collaborate with researchers at another institution, a subcontract, or subaward, must be arranged so that funding can go to both institutions. An important requirement is that the roles of all parties are clearly defined. The differences between contracts and awards (discussed above) apply to subcontracts and subawards as well.
Helpful Acronyms

Research projects may involve a lot of research jargon, which can be a challenge when community groups and researchers collaborate. We compiled a list of acronyms that are commonly used in research projects, which may be helpful for you.

**ACRP:** Association of Clinical Research Professionals  
**AHRQ:** Agency for Healthcare Research and Quality  
**Biosketch:** Biographical Sketch  
**CBO:** Community-Based Organization  
**CBPR:** Community-Based Participatory Research  
**CEnR:** Community-Engaged Research  
**COI:** Conflict of Interest  
**CTSA:** Clinical and Translational Science Award  
**DUNS:** Data Universal Numbering System  
**eRA Commons:** Electronic Research Administration Commons  
**IAA:** Institutional Authorization Agreement  
**IIA:** Individual Investigator Agreement  
**LOI:** Letter of Intent  
**F&A:** Facilities and Administrative Costs  
**FDA:** Food and Drug Administration  
**FWA:** Federalwide Assurance  
**HHS:** Department of Health and Human Services  
**HIPAA:** Health Insurance Portability and Accountability Act  
**IRB:** Institutional Review Board  
**NIH:** National Institutes of Health  
**OHRP:** Office for Human Research Protections  
**PI:** Principal Investigator  
**RFA:** Request for Applications  
**FOA:** Funding Opportunity Announcement  
**RFP:** Request for Proposals  
**MOU:** Memorandum of Understanding
What Is Community-Engaged Research?

Community-engaged research (CEnR) is defined as research that engages in “the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the well-being of those people” (Centers for Disease Control definition, 1997).

In this broad definition, “community” can include a variety of stakeholders, including:

- Community leaders and staff in community-based organizations
- Providers, support staff, and administrators in locations like clinics, hospitals, mental health systems, long-term care facilities, schools, and home-based programs
- Patients and their families
- Individuals and groups paying for, purchasing, or setting policy about well-being and health.

CEnR is increasingly seen as an essential strategy for advancing innovative, high-quality research. Communities, researchers, and federal government funding agencies recognize the advantages of CEnR, which include research that:

- Is feasible to conduct in real-world settings
- Is relevant to community needs
- Can be disseminated and implemented in real-world settings
- Balances science and action.
One key principle of CEnR is an **assets-based approach**. CEnR acknowledges there are synergistic assets, or strengths, that communities and researchers collaboratively bring to the table. This asset-based approach relies on respectful, open communication and shared decision-making.

A second key principle is that CEnR is **action-oriented**. CEnR seeks to link research to changes in practices, systems, or policies. Often, CEnR includes community leaders, staff in community-based organizations, patients, advocacy groups, and community members as well as academic researchers from colleges/universities doing research together to improve health of underserved populations, geographical communities, or patient groups.

A third key principle is **capacity-building**. Inherent in the establishment and maintenance of community-academic research partnerships is the need to build the capacity for both community and academic partners to work synergistically with each other.

Community members vary in their roles in CEnR. They may

- Identify the need for research on a particular topic
- Bring that topic to the attention of funders like the federal government or foundations, or researchers at universities
- Commission research
- Serve as co-investigators on research projects with academic researchers
- Serve on steering committees or advisory panels, providing their perspectives on the research being conducted and helping to interpret any findings
- Recruit community members to participate in research
- Collect data for research (conducting needs assessments, surveys, focus groups, and interviews)
- Disseminate research findings to their constituency
- Advocate for systems, policy, and practice changes that are supported by research findings.

**Models of Community-Engaged Research**

CEnR lies on a continuum and may vary by who owns, operates, and conducts the research. It acknowledges that there
are multiple approaches for community members to engage with academic researchers: The approach chosen will depend on the identified goal of the collaboration, the expertise of each collaborator, and available resources (see Figure 1).

Often, an academic researcher may lead a project with a community group serving in more of an advisory or consultancy capac-

**Figure 1: Continuum of Community-Engaged Research**

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Shared Leadership</strong></td>
<td>• Strong bidirectional relationship &lt;br&gt; • Final decision making is at community level &lt;br&gt; • Entities have formed strong partnership structures</td>
<td><strong>Outcomes:</strong> Broader health outcomes affecting broader community. Strong bidirectional trust built</td>
</tr>
<tr>
<td><strong>Collaborate</strong></td>
<td>• Community involvement &lt;br&gt; • Communication flow is bidirectional &lt;br&gt; • Forms partnerships with community on each aspect of project from development to solution &lt;br&gt; • Entities form bidirectional communication channels</td>
<td><strong>Outcomes:</strong> Partnership building, trust building</td>
</tr>
<tr>
<td><strong>Involve</strong></td>
<td>• Better community involvement &lt;br&gt; • Communication flows both ways, participatory form of communication &lt;br&gt; • Involves more participation with community on issues &lt;br&gt; • Entities cooperate with each other</td>
<td><strong>Outcomes:</strong> Visibility of partnership established with increased cooperation</td>
</tr>
<tr>
<td><strong>Consult</strong></td>
<td>• More community involvement &lt;br&gt; • Communication flows to the community and then back, answer seeking &lt;br&gt; • Gets information or feedback from the community &lt;br&gt; • Entities share information</td>
<td><strong>Outcomes:</strong> Develops connections</td>
</tr>
<tr>
<td><strong>Outreach</strong></td>
<td>• Some community involvement &lt;br&gt; • Communication flows from one to the other, to inform &lt;br&gt; • Provides community with information &lt;br&gt; • Entities coexist</td>
<td><strong>Outcomes:</strong> Optimally, establishes communication channels and channels for outreach</td>
</tr>
</tbody>
</table>

Reference: Modified by the authors from the “Principles of Community Engagement, Second Edition.”
ity. Over the last several decades, community-based participatory research (CBPR) has increasingly gained international recognition as a means of creating social change. In CBPR, the entire process is jointly owned among researchers and community groups. Other names for this type of research include community-based participatory action research and participatory action research. A third model of CEnR also occurs when community groups conduct research at their organization with one or more academic researchers serving as consultants or advisors.

Examples of Community-Engaged Research

CEnR topic areas may be identified by community groups (e.g., the public, community agencies, patients, patients’ families, providers, etc.), academic researchers, or community-academic partnerships. Below are examples of CEnR research projects that are community initiated, researcher initiated, or jointly developed. The principles of engagement discussed above are also demonstrated through these examples.

**Example 1:** You have identified a growing need in your community. You want to understand its causes and develop potential interventions. You may want to collaborate with academic researchers to conduct research that will help meet the needs of your community. You and your organization are excited to engage in an in-depth research project.

Helena runs an after-school program and is committed to preventing gang violence in her community. She would like to apply for large federal grants or foundation grants to pursue her efforts. She is looking for a collaborative research partnership with an academic researcher at the local university. Helena will initiate conversations with an academic about her research ideas. She may want to be a leader of the research project or use a CBPR approach.

**Example 2:** You are asked by a researcher to help with a research study. Your tasks may include running focus groups, finding people to participate in the study, or participating in an interview as a key stakeholder.

Fred works for a housing initiative and is asked by researchers to find people to participate in a study on asthma triggers in low-income housing. Because Fred is central to the daily operations of his organization, his time is mostly spent on front-line services. Fred is also very interested in the impact of moldy carpets
on people living in the public housing in his area. He may choose to serve more of an advisory role on the research project and be less hands-on for the day-to-day activities of the project. Alternatively, he may feel this project is synergistic with his organization’s mission, there are sufficient resources to cover his shifting workload, and he wants more involvement with the research team. Fred can decide his level of involvement in the project.

**Example 3:** You would like to consult with a researcher about available data regarding needs in your community or methods to study an intervention in your organization.

Mai is interested in peer support groups for Asian women with breast cancer and has an idea for her organization. She would like to find out what has been published on peer support programs with Asian women and methods for possibly setting up and evaluating an intervention. Mai was not originally looking for a partnership to do research; however, she realizes how little is known about caring for Asian women with breast cancer and decides to jointly submit a grant proposal with the researcher.

**Example 4:** An academic researcher is exploring risk factors related to socioeconomic status and parenting practices. The researcher seeks help in disseminating information to the community.

Juan is the director of a community mental health center. A researcher is completing a study regarding parenting practices among socioeconomically disadvantaged families. In addition to producing academic manuscripts, the researcher is producing a series of fact sheets to share with the community. The researcher seeks Juan’s support to disseminate the information to the community. Juan invites the researcher to talk with his community mental health center staff about the content and tone of the fact sheet, and possibilities for distributing the fact sheets at community events.
How to Build Community-Academic Research Partnerships

Collaborating on research can be an exciting experience and a powerful tool for furthering the goals of your organization and community. It is critical to acknowledge that building an effective partnership between your organization and academic partners takes hard work, time, and resources from both parties. Community organizations and academic institutions have different cultures and missions. Developing a community-academic research partnership requires close attention to both of them.

Aspects of Community-Academic Partnership Development

Before enlisting in a research partnership, it is important to consider four aspects of community-academic partnership development:

- Learn about the possibilities for community-academic partnership
- Establish guidelines and strategies that will guide interactions with academic researchers
- Build and maintain relationships
- Establish a clear community-academic research partnership.

We discuss each of these four aspects of community-academic partnership development in more detail below.
Learning about the Possibilities of Community-Academic Research Partnership

The first aspect is aimed at better understanding the possibilities of community-academic research partnerships. As a community-based organization, the aim is to evaluate your goals in partnering with an academic researcher and determine if there are possible synergies with an academic researcher’s goals. You will need to know whether research fits with your organization’s overarching mission, strategic plan, and goals. Here are some questions you might ask yourself as a community-based organization, and questions you might discuss with your potential academic partners:

<table>
<thead>
<tr>
<th>Mission &amp; Goals</th>
<th>Community-Based Organization</th>
<th>Academic Partner</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mission &amp; Goals</td>
<td>• How would research help my organization achieve its goals and objectives?</td>
<td>• What are our goals for doing research together?</td>
</tr>
<tr>
<td></td>
<td>• How can I guide the research project to be consistent with my organization’s mission?</td>
<td>• What are the goals and objectives of our partnership?</td>
</tr>
<tr>
<td></td>
<td>• Do our organizational vision, mission, and values align with the academic researchers’ vision, mission, and values?</td>
<td>• How might our partnership help us each better achieve our own goals and objectives?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Benefits &amp; Risks</th>
<th>Community-Based Organization</th>
<th>Academic Partner</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benefits &amp; Risks</td>
<td>• How might my organization benefit from a research project?</td>
<td>• Who are the key stakeholders in our partnership?</td>
</tr>
<tr>
<td></td>
<td>• What are some of the benefits and drawbacks of research?</td>
<td>• How can these key stakeholders take part in the research process?</td>
</tr>
<tr>
<td></td>
<td>• Do the academic researchers understand our community’s challenges/needs? If not, are they open to learning? How can we help them to better understand our challenges/needs?</td>
<td>• How can we guide the research project to be consistent with the mission of our respective organizations?</td>
</tr>
</tbody>
</table>

continued on next page

• What will we each gain through this partnership (e.g., opportunities for staff development, learning how to best answer research questions, connections to key stakeholders, etc.)?  
• Do we each have significant time and energy to devote to a new research project and partnership?
<table>
<thead>
<tr>
<th>Benefits &amp; Risks continued</th>
<th>Community-Based Organization</th>
<th>Academic Partner</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• What are some of the challenges/needs of traditional academic research that I may come across as I work with an academic researcher? Am I open to learning? How can they better help us to understand their challenges/needs (e.g., funding timelines and limits, producing scientific results, publishing in professional journals, etc.)?</td>
<td>• What are some of the benefits and drawbacks of community-academic collaborative research? How might we address the drawbacks in order to make this partnership successful?</td>
</tr>
<tr>
<td></td>
<td>• Is there a process in place that is sensitive to both of our challenges/needs?</td>
<td></td>
</tr>
<tr>
<td>Ability &amp; Resources</td>
<td>• How will participating in a research partnership impact our day-to-day operations? Will this project mean adding staff or reorganizing our resources? If so, what are the consequences (positive and negative) of participating? Is it worth our efforts?</td>
<td>• In what ways are our respective organizations prepared and ready to engage in a new research project and partnership?</td>
</tr>
<tr>
<td></td>
<td>• How will the study’s budget address our specific need for extra training, staffing, and/or administrative resources necessary to conduct the research?</td>
<td>• What human, financial, and technical resources are needed for a good and healthy research partnership?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• How will the study’s budget address the potential need for extra training, staffing, and/or administrative resources necessary for both the community and the research members to conduct the research project?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• How will the resources we have or will receive be shared fairly between us?</td>
</tr>
<tr>
<td></td>
<td>• In what ways are our respective organizations prepared and ready to engage in a new research project and partnership?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• What are some of the benefits and drawbacks of community-academic collaborative research? How might we address the drawbacks in order to make this partnership successful?</td>
<td></td>
</tr>
</tbody>
</table>


### Establish Guidelines and Strategies to Guide Interactions with Academic Researchers

Community agencies or organizations are often asked to assist with research endeavors (e.g., they may be asked by graduate students who need study participants in order to complete their dissertations, or they may be asked by academic researchers who want to collaboratively address some research question). Community agencies or organizations need to establish guidelines and/or strategies for how they will manage requests and how they can effectively build relationships with their research partners. Build-
ing a relationship with an academic researcher often goes more smoothly if both groups

- Take the time to learn about each other’s work before proposing projects
- Come to the table without assumptions about each other’s priorities or interests
- Move forward at an appropriate pace, without rushing, and ask lots of questions throughout the process
- Propose projects that have a range of possible ideas and allow for flexibility.

Some institutions have published documents with guidelines for how they will do research with academic researchers. These may help with negotiating how you will work together. For samples, please go to http://www.tuftsctsi.org/Services-and-Consultation/Community-Engagement/Community-Engagement-Tools-and-Resources.aspx#SampleDocs.

Build and Maintain Relationships

A community organization's relationship with researchers will likely begin with one-on-one conversations, either scheduled out of mutual interest or perhaps resulting from events in the community attended by individuals from both parties. One challenge in moving an idea forward is scaling up a relationship that is person-to-person to one that is organization-to-organization. When two people form a mutually beneficial relationship and are excited about working together, it helps for community-based organizations and academic researchers to

- Meet one-on-one to share ideas about collaboration.
- Ask to get respective organizations on board. Are they likely to share our enthusiasm and vision?
- Consider what steps need to be taken to get the project approved by each respective organization. What is the structure of the organization, and how are decisions made? Is it necessary to meet with a governance committee, fundraising/development committee, or program evaluation committee?

Establishing organizational support, or buy-in, and establishing clear research goals can take considerable time. During this process it is helpful to keep formal and informal conversations
going with your academic partners to assist with strengthening your relationship. Once you have established organizational support, you are ready to begin discussing specific community-academic research partnerships.

Establish a Clear Community-Academic Research Partnership

Once you have built a relationship with an academic researcher and have committed to a collaborative research goal, you may be ready to establish a partnership around a specific project. However, establishing a clear understanding of your partnership is critical to a successful research relationship. The engagement process must be honest, and expectations must be clear, as efforts have floundered in the past due to the absence of transparency and reciprocity. You will want to clearly delineate roles and a decision-making process. Below are some questions that will help you throughout this process:

- Are the roles, responsibilities, and expectations within our partnership clearly defined and understood by everyone? Are these explained in writing (e.g., Who will do what? Who will ultimately be responsible? When we have conflicts about roles and responsibilities, how will those be handled?)?

- What kind of decision-making process will be used throughout our partnership (e.g., led by community organization members, led by academic researchers, jointly led by both community organization and academic researchers)?

- How will funding be shared across partners? If the funding agency proposes cuts to the budget, how will decisions be made about those cuts?

- How will the many parts of the research project (e.g., defining study questions, writing proposals, designing methods, analyzing results, distributing findings) be divided between the community organization and the academic partners?

- Who will have ownership of the data collected through the research project, intellectual rights of the research produced, and authorship of research papers?
What is the extent of the community-academic research partnership (i.e., Is this a long-term partnership? Is this a test case where we are learning about each other? Are we interested in the partnership only for a specific grant application?)?

Fundamental to all of these questions is trust. Do you have a relationship in which you can trust each other to negotiate decisions together that are as synergistic as possible, within the constraints of your different organizations, over the course of the community-academic research relationship? Once these partnership issues are addressed, community-academic partners can move toward addressing concrete research questions. We recommend partners consult the “Working Together for Research That Matters: Steps to Building Successful Research Partnerships” model developed by the city of Lawrence, Massachusetts, and schematically portrayed on the following page.

*Note:* The Working Together Model was created by Lawrence leaders and can be found at [http://www.tuftsctsi.org/Services-and-Consultation/Community-Engagement/Community-Engagement-Tools-and-Resources.aspx#SampleDocs](http://www.tuftsctsi.org/Services-and-Consultation/Community-Engagement/Community-Engagement-Tools-and-Resources.aspx#SampleDocs).
### Working Together for Research That Matters: Steps to Building Successful Research Partnerships

<table>
<thead>
<tr>
<th>Pre-Research Stage: Find Common Ground &amp; Take Steps to Work Together</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>COMMUNICATION</strong></td>
</tr>
<tr>
<td>Either party (community or researchers) contacts the other about emerging community problems or research question</td>
</tr>
<tr>
<td>Both Community &amp; Researchers make clear ways they hope to use the research results to understand where goals match</td>
</tr>
<tr>
<td><strong>EDUCATION</strong></td>
</tr>
<tr>
<td>Community and researchers educate each other from their own perspectives</td>
</tr>
<tr>
<td>- Community shares concerns that could be helped through research</td>
</tr>
<tr>
<td>- Researchers share recent research findings or practices</td>
</tr>
<tr>
<td><strong>PROCESS</strong></td>
</tr>
<tr>
<td>Community &amp; Researchers decide</td>
</tr>
<tr>
<td>- Who should be at table</td>
</tr>
<tr>
<td>- How funding will be shared</td>
</tr>
<tr>
<td>- Whether to proceed or not</td>
</tr>
<tr>
<td><strong>PRODUCT</strong></td>
</tr>
<tr>
<td>Community &amp; Researchers arrive at</td>
</tr>
<tr>
<td>- Initial agreement to work together on a community problem that needs research</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Research Design Stage:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>COMMUNICATION</strong></td>
</tr>
<tr>
<td>Community &amp; Researchers discuss what they hope will take place at application &amp; sharing stage (decisions and products)</td>
</tr>
<tr>
<td><strong>EDUCATION</strong></td>
</tr>
<tr>
<td>As the design progresses, Community &amp; Researchers look at their respective emerging community dynamics, research design learning needs</td>
</tr>
<tr>
<td>- Community shares concerns that could be helped through research</td>
</tr>
<tr>
<td>- Researchers share recent research findings or practices</td>
</tr>
<tr>
<td><strong>PROCESS</strong></td>
</tr>
<tr>
<td>Community &amp; Researchers decide</td>
</tr>
<tr>
<td>- On research question or problem to be addressed</td>
</tr>
<tr>
<td>- On research design</td>
</tr>
<tr>
<td>- On process for recruiting participants</td>
</tr>
<tr>
<td><strong>PRODUCT</strong></td>
</tr>
<tr>
<td>Community &amp; Researchers arrive at</td>
</tr>
<tr>
<td>- Research question and hypotheses</td>
</tr>
<tr>
<td>- Research plan</td>
</tr>
<tr>
<td>- Instruments</td>
</tr>
<tr>
<td>- Institutional Review Board applications</td>
</tr>
<tr>
<td>- Plan for Sharing and Disseminating results</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Research Conduct Stage: Intervention(s) and Data Collection</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>COMMUNICATION</strong></td>
</tr>
<tr>
<td>Community &amp; Researchers jointly identify unexpected problems (e.g., too few participants) and develop plan to address</td>
</tr>
<tr>
<td><strong>EDUCATION</strong></td>
</tr>
<tr>
<td>Researchers educate the Community regarding monitoring procedures as research progresses</td>
</tr>
<tr>
<td><strong>PROCESS</strong></td>
</tr>
<tr>
<td>Community &amp; Researchers note potential changes needed regarding negative outcomes or other issues to protect participants</td>
</tr>
<tr>
<td><strong>PRODUCT</strong></td>
</tr>
<tr>
<td>Community &amp; Researchers oversee</td>
</tr>
<tr>
<td>- Research modification</td>
</tr>
<tr>
<td>- To proceed or not</td>
</tr>
<tr>
<td>- On plan for sharing research</td>
</tr>
<tr>
<td>- How data generated will be stored &amp;/or shared</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Application &amp; Sharing Stage: Sharing Results and Using for Change</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>COMMUNICATION</strong></td>
</tr>
<tr>
<td>Coordination of plans for sharing results</td>
</tr>
<tr>
<td><strong>EDUCATION</strong></td>
</tr>
<tr>
<td>Reviews of content of various products</td>
</tr>
<tr>
<td><strong>PROCESS</strong></td>
</tr>
<tr>
<td>Community &amp; Researchers discuss ways this work will continue in the community after researchers leave</td>
</tr>
<tr>
<td><strong>PRODUCT</strong></td>
</tr>
<tr>
<td>Community may need to help researchers understand which channels and messages work for community &amp; have clear application potential for community</td>
</tr>
<tr>
<td>Researchers may need to assist community in understanding how results might enable other researchers to learn from previous partnerships</td>
</tr>
<tr>
<td>Press releases, community meetings, conferences, academic journal articles in ways that satisfy need of community &amp; researchers</td>
</tr>
</tbody>
</table>

---

Source: City of Lawrence Mayor’s Health Task Force Research Initiative. Used with permission.
Administrative Logistics

Writing a grant application can be a challenging process. In addition to developing research questions that are competitive for grant funding, community-academic partners need to manage logistical issues. Many of these logistics will need to be addressed concurrently, which results in numerous, simultaneously moving parts. Below is a grant application checklist to help guide you through the process:

Application Process Checklist

Pre-application Process

- I have established linkages with researchers.
- My organization’s mission aligns with the goals of this research.
- My organization is on board for the project and has the resources to commit to the project.
- My organization has tax-exempt status (e.g., 501(c)(3) or other).
- My organization has a Data Universal Numbering System (DUNS) number.
- My organization has an eRA Commons identification number.
- My organization has an established facilities and administration (F&A) rate (also known as indirect cost rate [IDC]).
Application Process

- I am aware of potential funding opportunities.
- I have identified a potential funding source and sent a letter of intent.
- I know the titles, roles, and expected pay of all collaborators in the project.
- I have discussed human subject research ethics requirements and informed consent with my collaborators.
- I have co-written and signed a memorandum of understanding with my collaborators.
- I have discussed potential conflicts of interest with my collaborators and completed conflict of interest forms.
- I have developed a budget, taking into consideration direct and indirect costs, inflation, and allocation of funds among collaborators.
- All collaborators have appropriate biosketches ready.
- I have completed a letter of support if I am not the principal investigator (PI).
- I have written the grant text that I am responsible for.

Several of the above items were discussed in earlier sections of this guide (e.g., how to build community-academic partnerships). This section includes information to help guide you through additional aspects of the grant application process.

Pre-Application Process

Tax Exemption

Most community-based organizations already have established tax exemption because of their non-profit status. If your organization does not yet have tax exemption, you will need to obtain 501(c)(3) or other tax-exempt status through the Internal Revenue Service (IRS). Please see IRS publication “Tax Exempt Status for Your Organization” at http://www.irs.gov/pub/irs-pdf/p557.pdf.

Data Universal Numbering System (DUNS)

A Data Universal Numbering System (DUNS) number is a unique, nine-digit identification number. It is free for all organizations
required to register with the U.S. federal government for contracts or grants and is necessary for your organization to receive grant funding. You may request a DUNS number via the web by visiting http://fedgov.dnb.com/webform/index.jsp.

**eRA Commons Identification Number**

Principal Investigators (PI) and signing officials (SO) from applicant organizations need to have an eRA Commons account, as do other people who may be assisting in the process of grant application submission. To register an institution within eRA Commons,


2. Read the instructions and click the Register Now button.

3. Complete the information fields for the Institution Information and Accounts Information sections, noting the following:
   - All fields followed by a red asterisk (*) are required.
   - A minimum of one address line (Street 1) is required.
   - The Institution Name may contain a maximum of 100 characters.
   - An Official’s Title may contain a maximum of 240 characters.
   - The User Name must have a minimum of six characters (numbers and letters can be combined but no spaces can be used). User names may not exceed the maximum of 20 characters.
   - The Accounts Administrator (AA) position and information is optional. When completing information for the AA, fill in the required account information fields and submit.
   - The DUNS Number is a unique, nine-digit identification for single business entities.

4. Verify that all entered information is correct before selecting Save, which generates a completed registration form with signature and date lines.

5. Print, sign, and date the registration form.

6. Fax the completed registration form to NIH at 301-451-5675.
NIH will send an email to the designated SO that contains a hyperlink to verify the SO’s email address.

7. Click the email hyperlink to verify the SO email address.

The email verification screen confirms that the email address provided for the SO is valid. NIH then reviews the registration, which is now pending approval.

8. Once the SO’s email address is confirmed and the registration request is reviewed by the NIH, a second email is sent stating the status of the application (either approved or rejected) and, if applicable, providing a hyperlink to confirm and complete the registration process. If approved, select the hyperlink in the message to finalize the registration process. Once the institution information is confirmed, the last two registration emails are sent with the Commons user name in one and a temporary password for logging into the Commons system in another. After successfully logging into Commons using the temporary password provided in the final email, the user is prompted to change the password in accordance with the NIH password policy.

Facilities and Administration (F&A) Rates

It is important to establish a facilities and administration (F&A) rate before you submit a grant application, as it is a major component of your budget. Please refer to the Research Budget & Budget Justification section of this guide for additional information.

Application Process

Knowing the Landscape of Potential Funding Opportunities

Now that you have established a community-academic research partnership and you understand the logistics of grant writing, it is time to look for funding opportunities to support your research projects. Funding opportunity announcements (FOA) and requests for proposals (RFP) frequently become available; however, these announcements can be unpredictable. It is essential that community-academic research partners share the responsibility of searching for funding opportunities. Federal FOAs can be found at [http://www.grants.gov/web/grants/search-grants.html](http://www.grants.gov/web/grants/search-grants.html), a website that
organizes funding opportunities from 26 federal agencies. Within the public health sector, community-academic partners might be most interested in FOAs from the U.S. Department of Health and Human Services (HHS) (see Figure 2).

Once you have identified a funding opportunity, there are a few details that will require special attention:

**Unique rules, requirements, culture, and language.** Each funder, whether a foundation or an agency within the local, state, or federal government, has its own rules, requirements, culture, and language. It is essential to find someone with expertise who can help you.

**Short timelines.** With shifting markets and budget challenges, recent calls for research have been issued with very short turnaround times. Being able to efficiently respond to requests for applications is critical, but it can stress organizations and relationships among community groups and academic researchers.

**Limited infrastructure support for community members to participate in the grant application process.** There is an expectation that academic researchers have fiscal and/or administrative help with developing and submitting grant applications. Many community-based organizations do not have this fiscal or administrative support in place. Academic universities also may lack the resources to provide infrastructure support to community stakeholders to participate in the grant application process.

**Letter of Intent (LOI)**

A letter of intent (LOI) proposes the research project your team will be conducting and your plans to apply for funding. Some funding agencies will request that you submit an LOI, and others may not.
It is critical that you read carefully all requests for proposals (RFPs) to determine whether an LOI is necessary. For more information on how to write an LOI, visit [http://www.nimh.nih.gov/funding/grant-writing-and-application-process/letter-of-intent.shtml](http://www.nimh.nih.gov/funding/grant-writing-and-application-process/letter-of-intent.shtml).

**Negotiating Roles**

Health research is usually conducted by teams. Common terms used by foundations, governmental agencies, and universities to identify different team members are listed and defined below. In community-academic collaborations, the research teams are divided into strategic positions that are assigned appropriately so that roles and tasks are suitable for each team member’s skill set. It will be helpful to talk about each person’s role within your proposed research project because this information will need to be clearly outlined in your grant text.

<table>
<thead>
<tr>
<th>UNIVERSITY</th>
<th>COMMUNITY</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Principal Investigator (PI):</strong> This is the leader of a research team. The PI is ultimately responsible to the funding sources for the completion of projects. Sometimes funding opportunities permit two equivalent PIs, called “Dual PIs.” In a community-based participatory research (CBPR) grant, there may be an academician and a community member serving as Dual PIs.</td>
<td></td>
</tr>
<tr>
<td><strong>Co-Investigator:</strong> An investigator who is involved in the scientific research in addition to the PI. Co-investigators cannot allocate use of funds in the project without written approval of the PI. They may be community members or research scientists.</td>
<td></td>
</tr>
<tr>
<td><strong>Research Scientist:</strong> A university faculty member who works on or directs research, often full-time. Depending on the institution, a research scientist may also be called an Assistant, Associate, or Full Professor. Research scientists may have their salaries covered by their universities. Alternatively, some research scientists are on “soft money,” which means their salaries are usually covered by research grants.</td>
<td></td>
</tr>
<tr>
<td><strong>Research Assistant/Associate/Coordinator:</strong> These individuals work on research projects under the supervision of a more senior faculty member. Assistants usually have some experience; associates and coordinators may have an advanced degree (e.g., MPH, Master’s).</td>
<td></td>
</tr>
<tr>
<td><strong>Community Outreach/Coordinator/Surveyor:</strong> This position is usually in the “field” and serves as front line staff on the project (assists with recruitment; conducting surveys, focus groups, etc.).</td>
<td></td>
</tr>
<tr>
<td><strong>Consultant:</strong> Consultants provide unique insight into the community that will help facilitate the research project. This role can provide a variety of services from language translations to exploring cultural sensitivities.</td>
<td></td>
</tr>
<tr>
<td><strong>Advisory Panel/Member of the Board:</strong> People serving in this role provide their perspectives on the research being conducted and help to interpret any findings.</td>
<td></td>
</tr>
</tbody>
</table>
Human Subjects Research Ethics Requirements

It is essential that community-based organizations discuss human subjects research ethics requirements and informed consent with their collaborators before submitting a grant application. The funding agency will want to know how you will protect health information and your participants. Please refer to the Ethics & Best Practice in Research section (page 33) of this guide for more information.

Memorandum of Understanding

A memorandum of understanding (MOU) is an external document drafted by collaborators on a project that specifically defines the roles of each collaborator and what is expected of them. This is an important step in collaborating since it prevents later disagreements over responsibilities. MOUs are usually defined in the subcontract packages. When developing an MOU, it is helpful to consider the following questions:

- Are the roles, responsibilities, and expectations within your collaboration clearly defined and understood by everyone? Are these explained in writing?
- What kind of decision-making process will be used throughout your collaboration (e.g., led by community organization members, led by academic researchers, jointly led by both community organization members and academic researchers)?
- How will you handle conflict?
- How will the many parts of the research project (e.g., defining study questions, writing proposals, designing methods, analyzing results, distributing findings) be divided among the collaborators?
- Who will have ownership of the data collected through your research project, intellectual rights of the research produced, and authorship of research papers?
- How will you distribute products, share results (e.g., published papers, topic papers, presentations), and communicate messages to relevant target audiences (including other researchers, funders, government agencies and representatives, stakeholders, and the community)?
When the project ends, how will you make sure that resources are available from internal and/or external sources to continue your research project and collaboration?

A guide to writing an MOU from the U.S. Department of Health and Human Services can be found at http://aspe.hhs.gov/daltcp/reports/mouguide.htm.

Conflicts of Interest (COI)
A conflict of interest (COI) is a situation in which investigators in a research study have a relationship or interest that may conflict with the goals of the project. COIs should be avoided at all costs or accounted for in project proposals. COIs should be discussed with research collaborators, and all team members should complete a COI form. Most institutions have their own COI forms. Refer to the http://grants.nih.gov/grants/policy/coi/ website for additional information.

Budget & Budget Justification
A budget and budget justification are necessary to and critical components of each grant proposal. Please refer to the Research Budget & Budget Justification section (page 38) of this guide for more information. You may also refer to the http://grants.nih.gov/grants/funding/phs398/phs398.html website for updated, fillable forms.

Biosketches
A biosketch is a form that summarizes the education and experience of a research team member. This is short and should aim to highlight the experience that makes the researcher a strong applicant for the grant in question. The template for the National Institutes of Health (NIH) biosketch and a sample can be found here: http://grants.nih.gov/grants/funding/phs398/phs398.pdf.

Letter of Support (LOS)
If you are not the PI on a grant application, you may need to write a Letter of Support (LOS). This letter describes your commitment to the project and what you will specifically be doing. The goals of an LOS are to

- Specify what the consultant/collaborator will contribute to the research
Convince the reviewer that the consultant/collaborator will fulfill the request

Convey enthusiasm for the work

Lend credibility to your proposal.

As long as your letter demonstrates specifically what you will be contributing to the project, there is no right or wrong way to draft a strong LOS. Further guidance can be found at http://viceprovost.tufts.edu/grantwriting/resources/letter-of-support/.

Grant Text

You may be asked to contribute to the actual grant text. For example, you may be assigned to write a specific aim of the research project or to provide a description of your organization (e.g., mission, target population, activities, space, funding) as part of your role in the application process. Make sure you are aware of deadlines and whether you are able to meet them. Grant applications are a team effort, and all collaborators need to respond to requests responsibly.

In addition to the process of developing grant text, it is essential that writers follow the guidelines specified by the funding agency, such as the number of pages and the format for references. These guidelines should appear within the request for proposals and on the funder’s website.

Finally, before submitting any grant application, it is critical that several people proofread the document for typos and clarity. If a reader needs to pause and reread a particular section, it is likely confusing or poorly written. In this case it is worth investing the time to strengthen that particular section. As a general rule, you do not want to overly tax the grant reviewers. Instead of rereading your application, the reviewers are more likely to deduct points.

Conclusions for Administrative Logistics

Every grant application requires attention to many logistical details, and they can be difficult to prioritize. Community organizations should prepare themselves for grant opportunities by addressing all of the pre-application process items before a request for proposal is made public. This will allow you to focus on more important aspects of the grant proposal, rather than getting bogged down in the details (e.g., applying for tax exemption).
Additionally, these pre-application process items take time and may prevent you from submitting your grant proposal before the deadline. Although the process may seem daunting, once you have submitted one grant application, each one thereafter should be easier.
Why Is Research Ethics Important?

When people participate in research studies, that research is termed “human subjects research” to differentiate it from other research, such as research with bacteria or animals. Human subjects research raises critical ethical issues focused on how we protect research participants from harm. Several processes are in place to ensure ethical conduct of research that involves human subjects. The following items should be considered when research proposals are drafted and/or after proposals are funded:

- Institutional Review Board
- Conflicts of Interest (COI)
- Health Insurance Portability and Accountability Act (HIPAA).

Institutional Review Board (IRB) & Federalwide Assurance (FWA)

During the 20th century, a number of events occurred where ethical concerns were raised about the research conducted. Some examples include research conducted in concentration camps during World War II, research with African-Americans in the Tuskegee study, and research with hospitalized children with developmental disabilities. In response, the U.S. government published the Belmont Report in 1979, establishing the ethical framework for human subjects research in the U.S. The Belmont Report specifically called for research to conform to the principles of respect for persons, beneficence (i.e., concern for the welfare of research participants), and justice. In 1991, the Common Rule (officially termed 45 CFR part 46) was published, giving additional protections to
vulnerable populations including pregnant women, human fetuses, neonates, children, and prisoners. In accordance with these ethical mandates, academic institutions were required to set up Institutional Review Boards (IRBs) to oversee human subjects research studies and review these studies to make sure they are conducted in an ethical manner.

Every institution that conducts federally funded human subjects research is required to enter into an agreement called a Federalwide Assurance (FWA). An FWA provides an assurance of compliance, usually negotiated with the U.S. Department of Health and Human Services (HHS), that the organization will follow the ethical principles outlined in the Belmont Report and the Common Rule. The Office of Human Research Protections (OHRP) within HHS is responsible for overseeing FWAs, registering IRBs, and enforcing compliance with the Common Rule.

Community organizations participating in research are required to comply with these regulations. Some community organizations may need to obtain their own FWA and have their own IRBs; others may obtain an FWA, but rely on another organization’s IRB.

If a community organization is relying on another organization’s IRB, there are two types of agreements to keep in mind: Individual Investigator Agreement (IIA) and an IRB Authorization Agreement (IAA). These agreements are easily and often confused because of their similar acronyms.

An Individual Investigator Agreement (IIA) is a written agreement between a principal investigator at the FWA-assured institution, like a medical hospital or university, and organization/individuals outside of the assured institution (e.g., community agency or service organization). The principal investigator at the FWA-assured institution directs and supervises the research activities to be performed by the collaborating individual investigator(s) outside of the assured institution (e.g., a community agency). In essence, a community agency without FWA-assurance will be covered under the FWA of the assured institution through the IIA. An IIA is appropriate for small community agencies or organizations that are participating in research and have no intention of continuing their research beyond their current involvement (i.e., do not plan to apply for federal funds or to conduct a follow-up study) and are not named responsible for overseeing the research activities.

Through an IIA, the collaborating individual investigator(s) confirm the following:
The collaborating individual investigator is not working for an organization with an FWA.

The conduct of the research is permitted at that organization.

The collaborating individual investigator and his/her organization will abide by the decisions of the IRB and the policies of the assured institution.

The collaborating individual investigator and his/her staff will complete any ethical educational training required (e.g., many institutions require researchers to complete the Collaborative Institutional Training Initiative [CITI] for Human Subjects Research online training).

An **IRB Authorization Agreement (IAA)** is a written agreement between two organizations that are FWA-assured. In this agreement, one organization (Organization A) agrees to serve as the IRB of record for a human subjects research project for the second organization (Organization B), which cedes the responsibility of the IRB review to the first organization. Each organization retains responsibility for its own researchers’ conduct in the eyes of the government. This document must be kept on file by both parties and provided to OHRP upon request.

Organization A agrees to:

- Provide an IRB review that will meet the human subject protection requirements of Organization B’s FWA.
- Follow agreed-upon procedures for reporting its finding and actions to appropriate officials at Organization B.
- Make available relevant minutes of IRB meetings to Organization B upon request.

Organization B agrees to:

- Ensure compliance with the IRB’s determinations and with the terms of its OHRP-approved FWA.
- Ensure proper conduct of the research by its investigators.
- Report necessary information about the conduct of the study to the IRB at Organization A.
Specific questions should be directed to the respective IRBs of any organizations participating in the research proposal. Please note: the Indian Health Service (IHS) maintains its own processes for research conducted at HIS facilities or with IHS staff and resources (see link in sidebar at left).

Conflicts of Interest (COI)

The term “conflict of interest” (COI) in research refers to situations in which personal or financial considerations may compromise or cloud a researcher’s professional judgment in conducting or reporting research. COI is different from research misconduct (i.e., fabrication, falsification, and plagiarism). Even if researchers are conducting high-quality research, concerns have been raised about the potential biases that researchers may have in interpreting results. For example, a researcher who gives talks for a pharmaceutical company with regard to psychotropic medication use in adults may be inadvertently biased in terms of how he or she interprets research data.

As new challenges arise with human subjects research, new requirements are instituted, with the goal of making sure research is conducted in an ethical manner. Newer requirements include that all named investigators complete conflict of interest forms describing any possible financial or relational interests that may influence a study.

Health Insurance Portability and Accountability Act (HIPAA)

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule establishes the conditions under which protected health information (i.e., any personally identifiable information about a patient including name, address, social security number, and date of birth) may be used or disclosed by covered entities (e.g., health plans, hospitals, clinics) for research purposes. The Privacy Rule also defines the means by which individuals must be informed of uses and disclosures of their medical information for research purposes, and their rights to access information about them held by covered entities. Where research is concerned, the Privacy Rule protects the privacy of individually identifiable health information, while at the same time ensuring that researchers con-
continue to have access to medical information necessary to conduct vital research. To access health information, researchers must have IRB approval. To disclose protected health information, researchers must have both documented IRB approval and patient consent.
Developing a Research Budget & Justification

When preparing your organization for submitting a federal grant application, you will need to decide who will submit the application as the “lead” or “prime.” For federal grants, the lead is typically the academic researcher’s institution because of eligibility requirements, and because federal grants often have more administrative requirements than private and foundation funding. Most research institutions have administrative staff experienced in navigating these complex applications.

If the academic institution functions as the lead, it is important to develop your budget in tandem with that institution while maintaining consistency with the existing financial, administrative, and fundraising procedures of your organization. Developing a proposal without considering these items could yield a non-competitive proposal or cause an administrative burden and/or unwanted organizational challenges if the grant is funded. Close collaborative work on the initial proposal budget is important because community partners may be aware of additional costs that academic researchers may or may not know about.

One type of additional cost is translation. When working with non-English- or limited-English-speaking communities, the translation of consent forms (and then translation back into English) is necessary to ensure concepts are appropriately captured in another language, or a translator isn’t using a term particular to one area that isn’t used in another area. For example, the word “depression” has no comparable word in Chinese. As another example, some phrases used by Spanish-speaking natives in Mexico may not be used by Spanish-speaking natives in the Caribbean; alternative wording may need to be considered.
How to Develop a Budget

Developing a strong budget is critical to obtaining grant funding. On the one hand, it is important to be conservative in your budget. On the other hand, it is important that you request adequate dollars for the proposed project. With the recent economic downturn, some funded applications have had their budgets reduced. There are also instances of funding being reduced during the grant period because of federal budget reductions. This is almost impossible to plan for, but should be taken into account.

There are a few considerations to keep in mind when developing a budget, including:

- What resources do you already have to commit to the project?
- What resources does the proposed project need in terms of staffing, supplies, travel, and other materials?
- To what extent do you need to factor in facilities and administration (F&A) rates (i.e., indirect costs)?
- What is the organization’s role (i.e., prime, subcontract, or consultant) and what are the expectations?
- How will funds be shared across community-academic research partners?

We discuss each of these areas in the sections that follow.

Existing Resources
Community-academic research partners may already have a number of resources that provide support to a research project. For example, a community-mental health clinic may be receiving reimbursement for its clinical care through insurance billing. Therefore, one would caution against requesting funds to cover a clinician’s clinical time. Similarly, a researcher may have access to work-study students who may assist on a project but require a smaller stipend than research assistants.

Needed Resources
Although it is important to be conservative when creating a budget, it is critical that community-academic research team members account for all of the necessary money they will need to successfully carry out their proposed research. Inexperienced grant writers may forget miscellaneous details within their budgets, which can
later result in underfunded work, so it is helpful to have a mentor review your application materials before the submission deadline. Resources you may want to consider include

- Salary and fringe support for personnel (fringe includes insurance, disability, sick/vacation time, etc.)
- Consultants
- Equipment (e.g., software, iPads, etc.)
- Travel (related to the study if conducting site visits, reimbursing study participants’ travel costs, or related to presenting at conferences)
- Conference registrations
- Project costs (e.g., remuneration for participants, transcription services).

**Facilities and Administration (F&A) Rates**

Budgets also need to take into account Facilities and Administration (F&A) rates. F&A rates include indirect costs that cannot be allocated to a specific research project. These include the costs of rent, phones, internet, accounting, custodial services, building depreciation, and other utilities. With regard to F&A rates, some large not-for-profit organizations such as universities, hospitals, and larger social service agencies have an approved negotiated F&A rate with the federal government, which can be anywhere from 15% to 65% or higher. These organizations have successfully coordinated a rigorous proposal process between their administration, board of directors, and a federal agency.

Other not-for-profit organizations may need to establish their own F&A rate. This link offers more guidance: [http://www.fcadv.org/sites/default/files/Sample%20Indirect%20Cost%20Proposal%20Format.pdf](http://www.fcadv.org/sites/default/files/Sample%20Indirect%20Cost%20Proposal%20Format.pdf).

**Understanding Your Specific Role in the Grant Process**

When developing your budget, begin by understanding your role in the research project. A community organization can play any of a few different roles in submitting a federal grant, such as lead, or prime, organization or subcontract, or consultant (defined below):

**Applicant or Prime Institution:** When multiple institutions or organizations are involved in a grant application, one institution must
be designated as the prime institution, and funding for the other institutions must be requested via a subcontract or consultancy to be administered by the prime institution. The primary investigator is typically employed at the prime institution, which has the administrative capacity to meet federal funding requirements.

**Subcontract/Subaward:** When the Prime institution wants to collaborate with individuals at another institution, a subcontract or subaward must be arranged. An important requirement is that the roles of all parties be clearly defined. There is generally a key personnel section written into the subcontract that describes who from the organization will be providing what services, at what percent time, and for what duration. As a subcontract, the organization is required to submit several government-issued forms (discussed below) and a formal budget. Academic institutional grant administration departments have experience with these forms and can provide clarity and support for a community-based organization. Often there is specific language to be used (such as “Prime organization”) that a grants administration department will know well and can explain to organizations that may not have been exposed to this type of language before. It is worth noting that some of these forms and specific language may be new to the investigator as well, particularly if he or she is new to community-engaged research or has never before submitted a grant with a subcontract.

**Consultant:** In a grant application, a consultant is an independent individual or organization from outside the prime institution that will be paid hourly for services provided for the project. The consultant will need to provide a social security number (for an individual consultant) or a tax identification number (if the payment will be going to an organization) on the appropriate forms.

**Sharing Grant Funds**

It is essential that the community-based organization and academic partners have open and clear communication about the budget (e.g., both parties review and sign off on the budget proposal before it is submitted to a funding institution). Discussing how grant funds should be split or allocated can be uncomfortable. When grant funds are allocated to certain people (regardless of their organization), they need to be clear about what those funds are paying for them to do. Job descriptions should be clear and specify certain responsibilities (e.g., study recruitment, data col-
lection, data management, manuscript preparation, etc.) and/or deliverables (e.g., monthly progress report, publication of results, etc.). If a community-based organization is shouldering most of the research responsibilities, it makes sense that more research dollars are allocated to it; if more of the research responsibilities are assumed by the academic partners, more dollars may need to be allocated to them.

How to Develop a Budget Justification

A budget is a simple representation of what a specific and definable project will cost in order to be successful. Costs that are entered into a budget must be

**Allowable:** Allowable expenses are reasonable and necessary, allocable to sponsored projects, given consistent treatment and conform to any limitations or exclusions set forth in the relevant federal regulations (if applicable), the sponsored agreement, and the academic institution’s policy.

**Allocable:** An expense is allocable if it is incurred solely to advance the work under the agreement, or if it benefits both the sponsored agreement and other work of the institution, in proportions that can be approximated through use of reasonable methods.

**Reasonable:** A cost is reasonable if it is one that a prudent person would have incurred under the circumstances prevailing when the purchase was made.

**Consistently treated:** Costs incurred for the same purpose, in like circumstances, must be treated consistently as either direct or indirect (F&A) costs. This means that if an organization normally includes an expense as part of its F&A rate, then it should not include that same expense as a direct cost in a proposal. For example, if a business lists phones as part of its F&A rate, it cannot include phones as a direct cost in a grant proposal.

A budget justification is a written document that explains in detail each of the items included and explains why the project's success requires each item. Different federal agencies use different forms and have different budgeting guidelines. The U.S. Department of Health and Human Services (HHS) is a common supporter of academic and medical center research, so the examples below use a set of its forms. It is important to read through the notice of funding availability carefully and to learn the budget requirements...
for your specific grant submission. If your organization is acting as a consultant or a subcontract, it is essential to coordinate the budget development and form production with the prime institution.

The HHS grant application guidelines are called PHS 398 Guidelines. No matter what the organization’s role, the following forms will need to be completed by you or by the prime institution:

- Form Page 4
- Form Page 5

Once these forms are completed, the prime institution will list the sum of these costs listed in the Form Page 4s and Form Page 5s under “Consultant Costs” or “Consortium/Contractual Costs.” Your forms and justification will be included in the budget section of the final proposal.

**Form Page 4:**
To complete this page it is helpful to have the budget planned and broken out by year including staffing, salary allocation, and any other necessary costs.

A few things to note:

- Budgets to federal agencies often use an academic calendar to define a person’s percent effort on a project. This can be very confusing, but you can use a basic formula: every 10% of a full-time equivalent (e.g., four hours in a 40-hour work week) is equivalent to 1.2 months in the academic calendar.

- Increase in costs from year to year from inflation is not allowed.

- The prime institution may have a ceiling amount for your engagement.

- Be specific in the justification and have clear deliverables for the costs.

**Consultant:** If the organization is consulting on an application, the prime institution will fill in the total costs on Form Page 4 in the Consultant Costs section. It is important for the consultant to provide an hourly rate to the prime institution that can be substantiated with a clear formula. A consultant can also work with the prime to draft the scope of work at this stage to ensure the formula relates back to the required work.
Example Formula for Consultant Hourly Rate

An organization was asked by another organization to consult on a project. It is expected that the scope of services will take the organization 40 hours to complete and require both the director and program manager. The prime institution requested an hourly rate to use in the preparation of the budget. Below is a table that outlines how this is calculated:

<table>
<thead>
<tr>
<th>Budget Item</th>
<th>Note</th>
<th>Base Salary</th>
<th>Fringe @25%</th>
<th>Total</th>
<th>Monthly Rate</th>
<th>Hourly Rate @180 Hours/Month</th>
<th>Total # Hours</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cheryilyn Sarkisian</td>
<td>Director/Key Personnel</td>
<td>75,000</td>
<td>18,750</td>
<td>93,750</td>
<td>7,813</td>
<td>43</td>
<td>40</td>
<td>1,736</td>
</tr>
<tr>
<td>Demi Guynes</td>
<td>Program Manager</td>
<td>42,000</td>
<td>10,500</td>
<td>52,500</td>
<td>4,375</td>
<td>24</td>
<td>40</td>
<td>972</td>
</tr>
<tr>
<td>Research Supplies</td>
<td>Survey Printing, Participant Incentives</td>
<td></td>
<td></td>
<td>2,000</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Direct Costs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4,708</td>
</tr>
<tr>
<td>F&amp;A</td>
<td>Rate Used is 8%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>377</td>
</tr>
<tr>
<td>Total Cost</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>5,085</td>
</tr>
<tr>
<td>Hourly Cost for 40 Hours</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>127</td>
</tr>
</tbody>
</table>

The organization’s hourly rate is $127 per hour. Smaller community organizations, particularly those engaged in direct service or emergency response, often have a different and less structured approach to how time is counted. This topic should be discussed with the academic research partner so that all partners are clear about their respective commitments.

Subcontract: If the organization is a subcontract on an application then it will need to complete its own Form Page 4 for each of the years of funding. The same planning and methodology is used in creating these forms. However, instead of listing an hourly rate, the actual costs are put on the forms. Also, as a subcontract, an organization is allowed to include indirect costs on the forms.
Form Page 5:

Consultant: A consulting organization does not need to complete this form.

Subcontract: A subcontract organization needs to complete this summary page using the information entered in the separate Form Page 4 documents.

Successfully Collaborating: The Critical Role of Communication

Working in a community-academic research partnership can be a rich and mutually beneficial experience. Establishing open and complete communication during the proposal writing process is essential for a productive and collaborative research relationship over the course of the funded grant. If specifics are discussed, defined, and agreed upon at the beginning of the project, it will be easier to manage unexpected events and challenges encountered along the way.
Conclusion

This guide was developed for community-based researchers by academic and community partners. It provides a foundation for community-engaged research and how to successfully submit a community-academic research grant application. We hope this guide will be helpful in fostering mutually beneficial community-academic partnerships and research projects. For more information, please visit http://informatics.tuftsctsi.org/pims/request.htm to submit a request.

Citation for this publication