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A White Paper of conference proceedings from the St. Louis OHRP National Research Forum and Community-Engaged Research Conference, held at Washington University in St. Louis in September 2011

Sarah Fowler-Dixon

*Washington University School of Medicine in St. Louis*

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# **COMMUNITY-ENGAGED RESEARCH: Exploring the Unique Community-Academic Relationship**

**A White Paper of conference proceedings from the St. Louis OHRP National Research Forum and Community-Engaged Research Conference, held at Washington University in St. Louis in September 2011**

**Compiled and Edited by:** Sarah Fowler-Dixon, PhD, CIP

## **Contributors** (in alphabetical order by department):

- Washington University Human Research Protection Office: Caryn Alper, MA; Tina Barrale; Jenny Berla, CIP; Diane Bohner, CIP; Jennifer Gartland, CIP; Abby Keeley, MS, CIP; Michael Leary, MA, CIP; Lisa Lawrence, MSW; Caitlin Plein, MA; Amanda Unanue; Linda VanZandt, MA, CIP; Jen Weinman, MA; and Erin Wingermuehle, CIP.
- Washington University Institute of Clinical and Translational Science Clinical Research Training Center: David Bundy; Carling Butler; Jackie Castillo; Neil Das; Amelia Drace; Julie Gary; Stephen Gradwohl; Elaine Khoong; James Krings; Iris Lee; Megan Lee; Mohammad Madani; Alex Malone; Camille Noel; Dan Peterson; Chris Sorensen; Sumeeta Varma; April Williams; and Hannah Xu.
- Washington University Becker Medical Library: Will J. Olmstadt, MSLS, MPH, AHIP



# COMMUNITY-ENGAGED RESEARCH: Exploring the Unique Community-Academic Relationship

## 2011 CONFERENCE PLANNING COMMITTEE, PRESENTERS & FACILITATORS

Brenda Battle, MBA  
Director, Center for Diversity and Cultural Competence  
Barnes-Jewish Hospital Diversity and Cultural Competence

Lori Behrens, MSW, LCSW  
Executive Director, SIDS Resources

Lisa Buchanan, MAOM, CIP  
Compliance Oversight Coordinator, Office for Human Research Protections (OHRP)

Mario Castro, MD, MPH  
Professor of Medicine and Pediatrics, Washington University School of Medicine  
Adjunct Associate Professor of Community Health at St. Louis University School of Public Health

Don Clayton  
Medical Public Relations, Washington University

Graham Colditz, MD, DrPH  
Niess-Gain Professor of Surgery Professor of Medicine  
Chief, Division of Public Health Sciences, Department of Surgery  
Associate Director, Prevention and Control, Alvin J. Siteman Cancer Center  
Deputy Director, Institute for Public Health, Washington University in St. Louis  
Member, Institute of Medicine

Barbara Council  
Community Expert Consultant  
Community Based Participatory Research Charrette Process, University of North Carolina

Brad Evanoff, MD, MPH  
Dr. Richard A. and Elizabeth Henby Professor of Occupational, Industrial and Environmental Science, Washington University School of Medicine  
Director, Institute of Clinical and Translational Science

Sarah Fowler-Dixon, PhD  
Education Specialist, Human Research Protection Office, Washington University



## **COMMUNITY-ENGAGED RESEARCH: Exploring the Unique Community-Academic Relationship**

Jane Garbutt, MB CHB

Research Associate Professor of Medicine and Pediatrics, Washington University  
School of Medicine

Co-Director, Center for Community-Engaged Research in the Institute of Clinical and  
Translational Science

Director, WU PAARC

Sarah Gehlert, PhD

E. Desmond Lee Professor of Racial and Ethnic Diversity, Washington University  
Director, Center for Community-Engaged Research in the Institute of Clinical and  
Translational Science

Jonathan Green, MD

Executive Chair, Human Research Protection Office, Washington University

Tiffany Israel, MSSW

Community Navigator, Institute for Medicine and Public Health, Vanderbilt University

Loretta Jones, MA

Founder and CEO of Healthy African American Families, Phase II, Healthy African-  
American Families (HAAF)

Assistant Professor at Charles R. Drew University of Medicine and Science (CDU)

Martha F. Jones, MA

Executive Director, Human Research Protection Office, Washington University

Yvonne Joosten, MPH

Assistant Professor of Medical Education and Administration, Vanderbilt University  
Coordinator, Meharry-Vanderbilt Community Engaged Core

Rick Kittles, PhD

Scientific Director and Co-founder of African Ancestry, Inc.,

Associate Professor of Medicine and Epidemiology and Biostatistics, University of  
Illinois at Chicago

Aziza Lucas-Wright, MEd

Clinical Instructor, Charles Drew University of Medicine and Science

Velma McBride Murray, PhD

Endowed Chair, Education and Human Development, Professor, Human and  
Organizational Development

Director, Center for Research on Rural Families and Communities

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## **COMMUNITY-ENGAGED RESEARCH: Exploring the Unique Community-Academic Relationship**

Co-Director, CTSA Community Engagement Research Core, Vanderbilt University

Charles P. Mouton, M.D., M.S.  
Senior Vice President for Health Affairs  
Dean, School of Medicine, Meharry Medical College

Kelley Mullen  
Senior Director Faculty Practice Plan (CME/CNE), Washington University

Joan Packerham, PhD  
Director, Office of Human Research Compliance at the National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH)

Russell Poland, PhD  
Vice President for Research and Professor of Psychiatry and Behavioral Sciences, Meharry Medical College

Ivor A. Pritchard, PhD  
Senior Advisor to the Director, Office for Human Research Protections (OHRP)

Susan Racette, PhD  
Associate Professor, Physical Therapy, Department of Medicine – Division of Geriatrics and Nutritional Science and Department of Medicine – Division of Endocrinology, Metabolism & Lipid Research, Washington University

Hannah Reinhart, MS  
Community Development Coordinator, Gateway Greening

Wayne J. Riley, MD, MPH, MBA, MACP  
President and Chief Executive Officer, Meharry Medical College

Darlene Ross  
OHRP Education/Quality Improvement, Division of Education and Development

Russell Rothman, MD, MPP  
Director, Vanderbilt Center for Health Services Research  
Co-Director Meharry-Vanderbilt Community Engaged Research Core, Vanderbilt University



## **COMMUNITY-ENGAGED RESEARCH: Exploring the Unique Community-Academic Relationship**

Larry J. Shapiro, MD  
Executive Vice Chancellor for Medical Affairs  
Dean, Washington University School of Medicine

Samantha Smith, PhD  
Public Health Analyst, Division of Education and Development, Office for Human Research Protections (OHRP)

Lauren Solberg, JD, MTS  
Assistant Vice President of Human Subjects Protection and Research Integrity,  
Meharry Medical College

Mitch Sommers, PhD  
Professor of Psychology  
Chair, behavioral IRB subcommittee, Washington University

Elyse I. Summers, JD  
Director, Division of Education and Development, Office for Human Research Protections (OHRP)

Jeanne Velders, JD  
Associate Director, Human Research Protection Office, Washington University

Caroline Vemulapalli  
Research Patient Coordinator, Washington University  
St. Louis Community/University Health Research Partnership Award Recipients

Consuelo Wilkins, MD, MSCI  
Associate Professor, Department of Medicine, Geriatrics and Psychiatry,  
Washington University  
Co-Director, Center for Community-Engaged Research in the Institute of Clinical and Translational Science  
Director, Community Outreach Program in the Nutrition Obesity Research Center  
Director, "Our Community, Our Health"

Monique Williams, MD, MSCI  
Director, African American Outreach Satellite for the Knight Alzheimer's Disease Research Center  
Director, Community Outreach and Recruitment Core for the Bioethics Infrastructure Initiative Assistant Professor of Medicine, Division of Geriatrics and Nutritional Science, Washington University



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Christina Yongue Hardy  
Community Research Fellow/Program Manager  
University of North Carolina, Chapel Hill

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## BACKGROUND

In 2007, Washington University (WU) was already experiencing an increase in Community Engaged Research specifically in school-based research, research in private physician offices, and research with community based organizations. To begin to address the needs of WU researchers and those they were partnering with, the Human Research Protection Office (HRPO) formed a task force composed of researchers and administrators to devise alternates for educating community partners. In looking at comparable educational alternates, issues of engagement, assurances, and a website to house materials were also discussed and considered by this task force. The first step, however, was to produce the Community Education Manual which was successfully piloted with 10 studies.

In 2009, with the development of *St. Louis Community/University Health Research Partnerships (CUHRP)* awards, the time was right to further develop services for Community Engaged researchers and their partners. A second task force was recruited to assist with the development of a website that includes overview information, information for community partners and information for WU researchers. Information on the website consists of:

### Overview section of the website

- General information on the Community Engaged Research (CEnR) Program.
- A step by step flow chart to take one through Planning, Funding, Assurances, and Approvals.
- A CEnR process overview that visually guides the user through the maze of planning, funding, IRB submission and assurances to the point of study approval.
- Information on “Our Community, Our Health.”
- A place for anyone visiting the site to ask a question.

### Community Partner section of the website

- Checklist for community partners that outlines what needs to be thought of from the time of planning through IRB approval. Areas addressed are: Setting up the collaboration, study design and funding, IRB submission, assurance needs, necessary guidance forms, human subjects education, confirmations and IRB approvals.
- Human subjects community partner education policy. Outlined are the requirements for those governed under this policy.



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- Training options for community partners that briefly outlines alternatives to on-line human subjects education. Alternatives consist of face-to-face sessions, options for sending materials electronically and having the exchange occur over e-mail. Face-to-face sessions are conducted by individuals that have been approved as trainers with materials that have been reviewed and approved by the Human Research Protection Office's Education Specialist certifying that the training is appropriate for the level of engagement required of the community individual as part of his/her research responsibilities.
- Information on how to obtain an assurance, whether it is a Federal Wide Assurance (FWA) or Individual Investigator Agreement (IIA). An explanation of the FWA and IIA is provided as well as a link to the OHRP website for on-line or paper submission. As part of the CEnR program, assistance is provided to the community partner in completing these documents.

### WU Researchers section of the website

- A more in-depth checklist of activities needed to accomplish IRB approval and to begin a research study.
- Additional areas addressed that are the responsibility of the WU researcher.
  - Funding documents (Letters of Intent, Memorandum of Understanding, Subawards & Subcontracts), HIPAA training, and a flow chart to help researchers determine the level of training that will be required of their community partners.
- A link to the WU Institute of Clinical and Translational Sciences (ICTS) website.
- Information on how to request WU as the IRB of Record
- The complete Community Partner Manual.

Development of a website was not the only goal of this second task force. It was determined that there needed to be a program that would help sustain community engaged research as this area expands in the St. Louis area. With this determination, the CEnR program was implemented.

To expand on these efforts, Washington University Human Research Protection Office (HRPO) hosted a Community-Engaged Research Conference in conjunction with Meharry Medical College (MMC), the Office for Human Research Protections (OHRP) and the Washington University Institute of Clinical and Translational Sciences (ICTS). The theme for this conference was "Community-Engaged Research: Exploring the Unique Academic-Community Relationship."



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The conference was held at Washington University on Monday, September 26 and Tuesday, September 27, 2011. The conference brought together representatives from the St. Louis community along with others from 25 states and 37 community organizations to present, speak, and participate in discussion groups with academic investigators from Washington University (WU), Meharry Medical College (MMC), Vanderbilt University (VU), University of North Carolina (UNC) and the Office for Human Research Protections (OHRP). On hand were representatives from Saint Louis University, St. Luke's Hospital, Mercy St. Louis, Missouri Baptist Medical Center and SSM Healthcare. In all, 306 individuals participated in the two day event. Day one of this conference focused on regulatory aspects while day two focused on challenges in community engaged research and the strategies to overcome them.

### INTRODUCTION

What does community-engaged mean? Community based participatory research was defined by Minkler and Wallerstein, 2003 as a "...collaborative approach to research [that] equitably involves all parties in the research process..." Community-engaged research focuses on incorporating community knowledge and participation into research and collaboration between the community and academia.

Ideally it means an equal partnership between an academic investigator and a community organization or individual. Through this partnership ideas for research studies relevant to the community served are generated, funded, and then conducted. As the research conducted is of importance to the community, information is sent back to the community from which it came.

There are four principles of community based participatory research:

- The process has to be bilateral and be based on co-learning opportunities; it has to be a genuine partnership.
- It must include capacity building in training the community.
- It must involve equitability.
- It should involve solving health and research disparities.

The conference began with a keynote address from Dr. Wayne Riley, President and Chief Executive Officer, Meharry Medical College. His message consisted of 3 key questions: "How can we engage the community in research? What events have affected the current lack of community engaged research? What are some basic practical principles that can help us move forward?"

*Question 1: "How can we engage the community in research?"* was answered in part by agencies that illustrated the types of research studies they are conducting in the

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community and abroad. Amongst the research projects described were those that depicted global aging issues, nutrition and gardening programs, mammography screenings for breast cancer, contraceptive choices and uses, diabetes self-management, and programs for preventing frailty and excess disability in older adults living in their homes. These types of studies are relevant to individuals living in the “community.”

So, “*What is a community?*” In Principles of Community Engagement: second edition published by the National Institutes of Health (NIH), “community” is thought of in four ways. The first is a systems perspective with a community likened to a living creature that has specialized parts that work together to serve the whole. A community can be looked at as a series of functions or services that work together: transportation, business, education, etc. The second is a social perspective linking a community through social and political networks. The third is a virtual perspective defining a community by a geographic area. And, the fourth is an individual perspective where community is defined by the memberships and relationships one holds and has. As wide-ranging as the definition of “community” can be so can the research that meets the needs of that community.

Question 2: “*What events have affected the current lack of community engaged research?*” This question can best be answered once the “community” for a given project is defined. Are there historical events that affect that community’s willingness to participate or are there more current issues that affect participation such as language or access to healthcare?

These constitute some of the “challenges” addressed by keynote speaker, Dr. Rick Kittles, a health disparities researcher from the University of Illinois at Chicago. Other “challenges” that were shared by Dr. Kittles and other conference speakers and participants were issues of mistrust, communication, unwillingness to accept another perspective, and power differentiation.

These “challenges” bring us to Question 3: “*What are some basic practical principles that can help us move forward?*” Fortunately, those who participated had many ideas on how to overcome the challenges in community-engaged research and how to move forward. Education was paramount for both the academic investigators and the communities in which they served. Establishing open lines of communication that allowed for bilateral information flow was high on the list as it leads to shared decision-making, trust building, and respect for another’s point of view. Another key is to establish long-term relationships that go well beyond a specific research project. This can be achieved by using advisory boards and community mentors to determine what is needed and what is of relevance in a given community. Transparency about the process, payments, and federal requirements when conducting a study that involves individuals also helps build trust and long-lasting relationships.

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Why community engaged research and why do we need new models for community engagement? Traditional approaches to population research have often:

- ignored community perspectives on how research should be carried out,
- been unclear about the relevance of the research,
- failed to share results and interpretation of the research with the community, and/or,
- created an environment of mistrust.

Although general health in the United States has improved significantly, health disparities persist and are frequently associated with worse outcomes and increased mortality. There are inequities that tend to be greater for all older adults especially for minority elders. Adverse outcomes also exist due to inequities; therefore it should be the goal of providers to decrease the amount of morbidity and mortality which are associated with inequities, especially in older and minority populations. Community-engaged research provides potential opportunities for greater impact on disparities and development of effective solutions.

However, in the conduct of community engaged research one might encounter a number of challenges. Addressed in this white paper are the challenges identified at the Community Engaged Conference held at Washington University in St. Louis in September 2011 along with strategies to overcome them. Included are practical examples and suggestions to help community engaged researchers overcome issues related to academic demands, communication, dissemination of results, compensation and division of assets, expectations, empowerment, health literacy and consent, recruitment, regulations, sustainability, training and education, and trust.

### **ACADEMIC DEMANDS**

Most academic researchers interested in community based research are young and have many time commitments. This does not allow them the time to form relationships needed to conduct this type of research. As these researchers tend to be early in their academic careers, promotion is a factor. Although community- engaged research may yield good results and outcomes, community engaged research may not lead to a large number of publications or funding as it is often difficult to obtain enough data to make significant findings in these population based studies. Both academic publications and funding are important when seeking tenure, further dissuading new researchers from entering this field of study. In an academic setting, funding is needed not only to fund the study but also to cover salaries. Thus, attracting more tenured and established faculty to this field of research would not only provide resources but also time needed to build effective relationships. Fortunately, interest in community based research is growing amongst experienced researchers. One such reason is the established of the



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Clinical and Translational Science Awards (CTSA) that have community based studies as one of their key elements.

### COMMUNICATION

Communication is paramount. Communication between community and researcher benefits both sides. It is essential that the researcher go to the community and interview at least 5 people to learn about the community with which he/she wishes to work. Better yet, ask each individual for 5 more names, networking through the community until you have enough information to identify the specific community you wish to work with; learn the culture of the community, the needs and desires of the community and identify a partner(s) to help develop a study that is relevant to this community. Use a recorder to accurately document the information received and to help you, the researcher, better know the community. This process will help frame your project adequately.

#### Set Up Partnerships

In setting up partnerships, selecting the right partner is key and it is helpful to be mindful of the power differential. Often, both sides assume that the other side knows what to expect and that is often not the case. Both sides should have an agenda and the two sides should work together to build common goals. If the community's goals are unreasonable, the investigator should address this honestly as this builds trust.

It is useful to build and expand on existing networks when looking for a partnership. Tell your family, friends, and colleagues what your areas of research are. Do not allow individuals to use your name in the community unless you have sent that person out on your behalf. Your name and reputation can make or break a potential partnership. Plan on establishing a long-term partnership thus plan from the beginning to have a significant time investment not only in establishing but also in maintaining the partnership. Start with honest discussion about time lines. Explain the funding process, letting the community partner know that no funding does not equate to a bad research idea and discuss possibilities for implementation if the project is not funded.

In developing and maintaining a partnership, there are key components. Keep partners engaged throughout the process as delays can happen at all points. Methods for doing this include:

- Be upfront and honest about the process.
  - Be upfront and honest and educate all sides about the process (e.g. funding) and be open about what reasonable expectations for results would be;
  - Develop and continue communication lines and relationships;

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- Have activities and goals that don't require funding and perhaps aren't related directly to the project such as social networking;
  - Ensure the goals and objectives of the researchers are well aligned with the goals and objectives of the community group;
  - Everyone should have their agenda and it should all be out on the table;
  - The agendas/goals/aims need to be able to grow and change over time;
  - Carefully select your partners;
  - Use the network you've developed and keep in mind that the trust and equity that you've built needs and deserves protection.
- 
- Develop shared ownership.
    - Communicate and value the partner's perspective.
    - Honor intellectual property that includes papers and anything developed that can be of monetary value.
    - Design the study together, starting at the grassroots. This not only enhances trust and communication, it promotes ownership and sense of pride.
  
  - Use a Memoranda of Understanding (MOU) that sets the stage for the relationship and can help address the community's fear of litigation as these can be reviewed by general counsel. This can also address issues of ownership, authorship, and tasks to be performed by each side. Ask community members what they are willing to do. The MOU should be constructed by and agreed to by both sides.
  - Match costs with services rendered.
  - Treat conflicts as opportunities to learn about the other partner. Be open to hearing grievances.
  - Make a conflict resolution plan.
  - Meet with absolutely everyone involved as each will have a different perspective and different information that will be useful.
  - Use appropriate language for the context.
  - Do not make false promises.
  - Plan for growth, acknowledging that growth requires time commitments which can be difficult for both sides so you need to be reasonable with goals and expectations. Identify and cultivate 1 to 3 community individuals who will keep

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the interest, energy, and project going. Moving the project forward builds trust, confidence in the project, relationships, and sustainability.

- Return results to the community. Therefore, data collection and evaluation are necessary. Data collected can help drive subsequent research so that additional funding may be reached. Data collected can also be used to further, change or expand existing community services. Use Town Hall Meetings, reports, or coalitions to share results. Allow for suggestions from the community based on your results and ask for community perspective on what the next steps should be.
- Believe in the partnership and the idea.

**Farmer's Market example:** A primary and secondary concern centered on nutrition. The community was tired of the lack of good quality healthy food so a weekly farmer's market was established along with cooking classes as researchers found that individuals did not know how to clean and cook raw vegetables. These activities strengthened community ties and provided a social outlet. From these activities, cancer forums were started giving participants the opportunity to discuss diet and nutrition. College Bowls centered on nutrition were introduced to engage the young people.

**Breast Cancer example:** Researchers found that women living in North County in the St. Louis, MO area were not getting screened for breast cancer. Funding was obtained through the American Recovery and Reinvestment Act (ARRA) of 2009 to look at barriers to screening and to remove barriers by paying for mammograms. As a result 600 women were screened and mammographs were incorporated into normal services provided by a local free clinic. To collect data and not burden clinic staff, researchers helped prepare a direct access database. This gave both the community and researchers information on who received a mammography and who did not. In the end, both the community and the research study benefited from the services and information provided.

Communication is key to working out challenges posed in community engaged research. Establish the groundwork and then use these avenues for further communications. Set meetings with community experts at times and locations convenient for them. Listening is important in these communications. It's also important

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to “explain” rather than “tell.” When communicating, humility is important. Keep these words in mind when communicating:

- *improvisation* – must be able to change and adapt.
- *resiliency* – must keep trying in the face of failure or stagnancy.
- *connectedness to others* – sense of mutual benefice.
- *spirituality* – there is something out there greater than you.
- *emotional vitality* – emotional strength and awareness.
- *gallows humor* – optimism in the face of failure.
- *healthy suspicion of the message and messenger* – it’s only wise to question in a world of constantly changing messages.

What areas should be addressed during a meeting or communication session?

### Financial Issues

Communication is needed to determine costs for the academic institution and the community. How will these funds be dispersed? Will there be subcontracts, overtime payments, payments to research participants, or money sent directly to the community organization? Options for financial disbursements can be numerous. To determine what is best for a given community, communication is essential.

### Fear of Litigation

Community members may have a fear of litigation, especially when presented with regulatory documents containing information that may look like legalize. Communication about the regulatory process and any indemnifications afforded to research team members can be explained. Information pertaining to the legal process and providing statistics on how often an individual is actually sued when conducting research procedures can be presented. How often does a breach of confidentiality occur and how is that handled? A explanation of such could alleviate fear. Through communication confidentiality and security procedures can be emphasized. An explanation of the assurance agreement that the community member or organization is being asked to sign, what each bullet means in a practical sense, and why this document is required also goes a long way in building understanding and dissipating fears.

### Shared Ownership and Decision-Making

Show the community that their approach, perspective, and contributions are important. Share the ownership; have a Co-PI in the community. Put funds back in the community. Intellectual property should also be shared (anything of any intellectual or monetary value) such as co-authorship for example. Consider if data collected could shed an unfavorable light on the community and what if the community does not want it published? Should the community have power to prohibit publication? In a true

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partnership, either may determine that the results cannot be published assuming the methodology is appropriate; but, this should be discussed up front, potentially with a mediator. Everyone should understand that the outcome is unknown and that you may be uncovering a need in the community that was unknown to that community. Change the conversation so that is about the timing of dissemination rather than whether or not findings will be published. This gives the community the opportunity to share information and prepare for the publications to come.

### *Financial issues*

Provide exact monetary breakdowns. Define project roles for both academic and community partners. Educate the community partner about the financial aspect of the research and how resources are allocated. Discuss payment distribution to the community partners. Realize that the disbursement cycle from an academic institution's grants and contracts department may be very different than the payment needs for a community partner. To assist with this, identify community partners with shared goals. Create an exit strategy upon completion of grant funding. Clearly communicate with your community partner when funding ends and create a plan of action for how the community partner can self-sustain benefits and knowledge gained through partnership upon completion of the study. Consider that a loss or discontinuance of a large grant translates to a large financial loss to the community partner. Prepare your community partner upon research completion.

### **DISSEMINATION of RESULTS**

Framing the project means developing a plan for the study that includes a deliverable product or service, an evaluation component, and timeframe for the study. It is important to give results back to the community as this further solidifies lines of communication. Give results in plain language not in medical jargon. If you can find journals that appeal more broadly to the community, consider publishing in those journals as well as academic journals. Remember, the community has the right to ask their congressman, deans of the university, and other public figures where the results of the research can be found as National Institutes of Health (NIH) funds come from tax payers, in essence, the community taking part in the research. Dissemination of results is another form of empowerment for the community partners.

Ideally, the community should co-author the research. A good community advocate will not allow anything else. If the community does not co-author publications, then the researcher can be seen as conducting "helicopter research", using rather than involving the community. This type of research creates mistrust making it more difficult to recruit, consent, and partner with the community.



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**Suggestion:** Lay out the project to the community letting them know “I’m here for you.” The community must have something to assure them that the researcher is moving to do something to help them. An example is a mixed method project that had both a qualitative and a quantitative arm. The researcher asked different questions to get participants feelings about different aspects of the study. Participants vehemently refused to partake in certain parts of what was being asked of them (such as keeping their menstrual cycle on the refrigerator). Researchers were majority male and had not considered this being an issue. This experience changed these researchers forever.

To further dissemination efforts relevant to the community, translate findings into real life applications and avoid dissemination mistakes such as:

- Assuming that evidence matters.
- Substituting researcher perceptions for those of potential adopters.
- Using intervention creators as intervention communicators.
- Introducing interventions before they are ready.
- Assuming that information will influence decision making.
- Confusing authority with influence.
  - a. Authority can be an individual cited or appealed to as an expert.
  - b. Influence can be the act or power of producing an effect without apparent exertion of force or direct exercise of command.
- Self-selecting who information will be disseminated to.
- Failing to distinguish between change agents, authority figures, opinion leaders, and innovation champions.
  - a. Change agents are individuals who help members of an organization adapt to organizational change or create organizational change.
  - b. Authority figures are individuals who are regarded as an authority by someone else.
  - c. Opinion leaders are agents who are active media users and who interpret the meaning of media messages or content for lower-end media users. This concept arises out of the theory of two-step flow of communication propounded by Paul Lazarsfeld and Elihu Katz.
  - d. Innovation champions are individuals who support or encourage change or new ideas.
- Selecting demonstration sites on criteria of motivation and capacity alone, and
- Advocating single interventions as the solution to a problem.

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### **COMPENSATION and DIVISION OF ASSETS**

There are number of financial issues that arise when conducting community engaged research. Due to past experiences with funding and ability to sustain a project once the grant funding has ended, community members may be distrustful of the process and those approaching them. Therefore, transparency is paramount in helping to answer questions raised around compensation of the individuals in the community as well as any agencies involved. Transparency in a practical sense means build the budget together, researcher and community partner, so that each side can discuss and see where funds are going.

As the budget is developed, discussion around timelines for payment and participant compensation should take place. Explain the division of assets and any mandated overhead costs that may need to be included. Be realistic about the budget and the types of funding available for the research in question.

When addressing issues of participant compensation consider any overtime expenses that may be incurred by not only the participant but by any community personnel. Payments need to be fair for the given tasks and time involved in study participation whether it be for the research participant or the community personnel assisting with the study.

Determine how funding will be disseminated to the community organization or personnel. Will there be subcontracts or fee for service payments? For the research participants, what is the best method for payment: cash, gift cards, or check? Are there payment limits set by the institution or funding source that the researcher must abide by? Is the payment sufficient for the risks and discomforts that may be incurred by the research participants?

To answer these questions, begin with a dialogue about the budget. Identify the regulatory and ethical considerations for compensating subjects as a basis for this conversation. Discuss the importance of compensation in community engaged research and explain the different ways that may be used to determine compensation levels and amounts. Discuss the different types of compensation possible for the student participants and identify any special considerations when compensating participants in community engaged research.

Compensation is addressed indirectly in the federal regulations. The Belmont Report states that “the element of informed consent requires conditions free of coercion and undue influence. Coercion occurs when an overt threat or harm is intentionally presented by one person to another in order to obtain compliance. “Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or



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improper reward or other overture in order to obtain compliance.” (Grant and Sugarman, 2004) Therefore any compensation offered cannot in be so excessive that individuals who would not normally wish to participate would do so just to receive the compensation.

Remember, compensation is not a benefit and should not be presented as such during the consent process. Compensation is not necessary for a research study to take place. Compensation is normally used to off-set any inconvenience created by the study such as time off from work, travel costs, and meals that must be eaten at the research site. If overnight stays are required, there is the inconvenience of being out of one’s own home as well.

Compensation is sometimes used to encourage enrollment in a study when no direct benefit to the participant exists. Other times, compensation for the participant comes in the form of medical services that he/she might not normally receive such as free health screenings (e.g. physical exam, mammogram, EKG).

Compensation for time and inconvenience caused by a research study is important in a community engaged study because it shows respect for participants, encourages people to participate, and removes barriers that assist with retention. Compensation motivates participation.

In Guyll et al., 2003, the question was would \$100 affect parents’ decision to participate in a community based intervention for sexually active adolescents? What was learned is that payment for participation influences decisions to participate. Payment is more likely to influence people, with less formal education, to decide to participate (who may not otherwise participate), and also influenced people already considering participating. Runnels et al., 2009 conducted a study with homeless participants and found that this population agreed to participate more than once in a study involving interviews. Researchers attributed this to compensation offered (\$10 for 90 minute interview, \$20 for 90 minute interview in a 2 year study). Thus, it is important that compensation is not so high that attempts to repeatedly participate will be foreseeable.

When children are the subjects of the research, it may be appropriate to compensate them directly for their participation. It may also be appropriate to compensate the parents/families. Some institutions have policies/procedures for the compensation of children in research. When compensating children, ethical considerations apply as well. Parents make decisions about children’s participation in research if children are less than 18 years of age, therefore there are concerns that the payment may influence the parents’ decision to have a child participate. To help alleviate this concern, select compensation limits that would not be unduly influential for the given population and have adequate assent processes in place.



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So, how do you go about determining the appropriate level of compensation? There are some general principles for determining the level of compensation. The amount and type of compensation must be fair and reasonable in relation to the subject population, duration of study, nature of study, any potential risk or discomfort to participants, and any potential benefits of research to subjects.

In determining how to compensate participants, you may wish to consider the following Models of Payment for research participants (Dickert and Grady, 1999).

- Market model where compensation is based on supply and demand considerations. A completion bonus may be provided at the end of the study to incentivize study completion. (Please note that this model is sometimes considered coercive or unduly influential by institutional review boards (IRBs) and may not be allowed.)
- Wage payment model compensates participants based on amount of time one will spend in a study, amount of effort required by the participant, and possible discomfort that will be experienced. Standard, unskilled wage payment can be used as the allotment, with extra compensation for extra discomfort (Bentley and Thacker, 2004). The problem with this model is that lost wages lead to inequity, as different participants may have different wage levels (e.g. hourly workers vs. salary workers).
- Reimbursement model is intended to reimburse participants for any monetary loss associated with their participation in the research as participation in a research study should not cost the participant anything at all. In the reimbursement model expenses such as parking, gas, bus fare, taxi, and food are covered in addition to lost wages because of time taken off from work. Reimbursing these types of expenses in community engaged research is less likely to result in inequity as a flat completion rate can be estimated and applied across the board.

Other methods used for compensation include

- Variable compensation. Varying compensation may involve different amounts of compensation for different procedures within a study as these may differ with regards to time, procedures, level of discomfort for experimental, and control groups. Varying compensation may also involve



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using a formula for payment based on distance of home from research site or parking reimbursement for those who drive to/park at the research site.

- Compensation for referrals. This method is tricky because it can be seen as finder's fees which are not allowable by many IRBs because finder's fees can unduly influence the research staff to include participants who do not meet the inclusion/exclusion criteria for the study. However, compensation for referrals could involve reimbursing a community organization or site for time and effort in identifying potential participants whether or not those individuals are enrolled in the study.

Example: It may be appropriate in community engaged research to pay \$5 to anyone screened for the study who referred another person to the study. Note: the small amount of the "referral fee" that is paid for the referral only; enrollment of the person referred is not required.

Methods for reimbursement can consist of cash, parking vouchers, gift cards, gifts, entry into a raffle, or check. Participants may prefer cash rather than gifts or gift cards as demonstrated in Ejiogu et al., 2011 where community residents suggested they preferred money, not gifts, and Festinger et al., 2005 where cash was preferred to gift cards.

Even though there is a preference for cash payments, the research must consider if some populations will use cash payments to buy drugs or alcohol. Will carrying around cash for payments create undue risks to the researcher or research team? Is it unethical to restrict compensation due to concern about how the money is used?

Example: In a study to determine if cash payments to drug users in treatment research would affect drug use, only 1 out of 76 participants who received cash reported using it for drugs. Participants who were given cash instead of gift cards reported only slightly higher levels of coercion and these were minimal perceptions of coercion overall.

Gift cards have both positives and negatives. The positives are that some can be registered in event of loss. This may relieve concerns about how cash is spent and issues related to the researchers/staff carrying cash. Gift card negatives are that they cannot be used to pay bus fare; gift cards are only good at chosen retailers that may not be accessible to all participants, and some have hidden fees that diminish the value of the gift card. Other types of compensation that can be considered are pre-paid debit

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cards, books, pens, electronics, journals, iPods, child care, and raffle entries dependent on the amount of cash that would be given and what is allowable by your governing IRB.

Once the type of compensation is determined, develop a payment plan. The schedule of payments must not be coercive, meaning that each participant should be paid only for his/her time and effort on the study. A one-time payment at study completion is not normally acceptable because it penalizes those that are unable to perform all study activities for whatever reason. Therefore, payments are often pro-rated per visit or procedure. However, it may be acceptable to pay a reasonable bonus to participants who complete a study.

Example: If multiple study visits are required, consider paying per visit instead of at the end of study. If half an interview is completed, pay for the entire interview. If 2 out of 4 visits are done, pay for 2 visits.

Mentioning compensation in advertising is permissible as part of the text. Compensation should not be listed as a benefit nor should it be the most prominent text in any advertising material.

When thinking about compensation, it is okay to incentivize but not to coerce. The difference between incentivizing and coercing is that incentivizing motivates or encourages someone to do something they normally would not do but if the compensation is too great it can become unduly influential in that the potential participant will agree to be in the study against his/her better judgment.

### **EXPECTATIONS**

Both sides have expectations and those expectations may not be the same. Community organizations have their missions within the community and researchers have their research agendas. When these two interests coincide, synergy ensues but when the two sides have very different expectations in mind, problems may arise. Talking about issues from both sides is essential to not only improve communications but to also ensure that expectations on both sides are compatible. That is why it is important to understand the community's needs.

When speaking with community organizations, it is important to learn why research is important to the community organizations. This fundamental question helps: increase understanding and helps the researcher stay current, improve programs, and identify funding. As a researcher, think about what you can do for the community organization. How are you going to present yourself? Keep in mind that the community may not be interested in the research itself but may be interested in the results and services it can

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provide. Asking the community what it sees as its needs and looking for possible solutions that could be provided through research promotes a “win-win” situation.

Example: A goal of the research may be to promote better health. This is an area of interest to both a researcher and a community member. This would display knowledge of the community and its interests as well as provide a way to improve the given situation. A community based organization may have the same goal but approach it differently, as it provides a service to those who want it. Because of this, the community based organization has a “built-in-trust” with its clients that can be applied to any researcher working alongside it.

Important in understanding the community’s needs are understanding some fundamental differences between the community and the academic environment. For instance:

<b>Community</b>	<b>Academia</b>
Driven by community improvement	Driven by money
Multiple missions and priorities	Specific grants and projects
12 month calendar	8, 9, or 12 month calendar depending on the campus
Not much vacation time	May have long vacation breaks depending on the campus

The community will also perceive a power differential because academic members have formal training and privileges which community members may not have. Differing calendars, schedules, and priorities means that each side must be upfront and honest about their expectations and flexible in working out solutions and compromises.

A successful tool to use to better understand the community, gain their trust and keep lines of communication solvent are Community Review Boards.

### Community Review Boards

Community Review Boards (CRB) were created by Vanderbilt University as part of the Clinical and Translational Science Award (CTSA) to simplify and encourage the process of obtaining vital community insight into the design and implementation of

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translational research. This investigator-initiated forum has been used to strengthen protocol design, recruitment activities and materials, the consenting process, retention efforts, and implementation activities for research projects on the translational research (T1-T4) continuum which makes the results of research applicable to a population being studied. Drawing from a pool of 50 community members, each CRB consists of a panel of 8-10 experts representative of the investigator's population of interest.

The Community Review Board (CBR) expert pool is comprised of a diverse group of formal and informal leaders and advocates who have extensive knowledge about their communities. The Community Experts may be recognized or non-traditional leaders or advocates, have good verbal communication skills, good listening skills and a desire to learn about research. Community Experts represent many walks of life, including ministers, neighborhood association leaders, community organizers, caregivers, ministers, private sector employees, and others.

From the investigator's perspective, the benefits of a CRB include 1) access to community experts from different settings without the complexity of scheduling multiple meetings; 2) immediate feedback at different stages of project development and implementation; 3) an opportunity to build a relationship with community partners and deepen their understanding of the population that is the focus of their work, and; 4) assessment of the feasibility and appropriateness of the project for that population. For investigators unfamiliar with community engagement, the CRB may open the door to a more community-engaged approach to their work.

Community Review Boards assist with issues related to:

- Trust building,
- Addressing barriers to participation,
- Community-based interventions
- Recruitment materials,
- Consent (document and process),
- Compensation, and
- Retention initiatives.

Community Review Boards (CRBs) also address practical concerns that investigators often do not consider when planning a project such as, transportation (to and from "lab"), impact of time taken off work, and location and convenience of research procedures.

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Below is a description of how the Community Review Boards (CBR) are designed to function.

### *The Process*

Expert panels are selected from the pool of community experts based on their experience/expertise and whether they might meet the inclusion criteria for the proposed study. They are not, however, expected to enroll in the study. Meetings are scheduled at the convenience of the experts (nights, weekends, in their neighborhood instead of at the university). A facilitator leads and moderates the discussion. The facilitator:

- i. Sets the ground rules at the beginning.
- ii. Helps each group “speak each other’s language.”
- iii. Collects feedback from experts (anonymous unless expert chooses to self-reveal) which is aggregated by a note taker for the researcher.

A Community Navigator manages the logistics of the Community Review Board. Her role is to recruit and orient community experts; explain the process to the researcher or research team and help them prepare their presentation; schedule the event and secure a community location; takes notes during the session; and provides a summary to the researcher.

At the beginning of the session, the researcher makes a brief presentation without jargon or acronyms and poses 2-3 specific questions related to the research project to the community experts. An experienced facilitator manages the meeting while remaining content neutral, maintaining a balance of power between the academic and community representatives in the room, encouraging full participation on the part of the community experts, and helping to bridge the academic and community worlds. The facilitator sets the tone for the session, explains the ground rules, keeps the discussion on track and on time, and summarizes the main points made by the experts.

*Follow-up:* The researcher receives a detailed summary from the CRB prepared by the Community Navigator. The community experts are informed of any resulting changes in the project (e.g. whether or not recruitment materials were modified, if money was added to the protocol for participants, etc.).

Longer-term: The investigator is encouraged to share study findings with community experts as they want to know! The facilitator then follows up with experts after the CBR meeting and lets them know what changes were made as a result of their input. The

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facilitator also shares research results and community impact. The facilitator then asks those involved if the CRB was worthwhile and if the community benefited.

*Evaluation:* On-going evaluation of the Community Review Board is done to assess the effectiveness of the model and improve it. Every participant (researchers and community experts) completes a post-session survey, and focus groups are conducted within 1 year of the session. While there are some differences in how researchers and community experts perceived the impact of Community Review Boards (CRB) surveys to date indicate a very favorable assessment from both. Researchers strongly believed that their sensitivity to the community was increased and that they gained insight on community outreach and recruitment.

### EMPOWERMENT

The definition of empowerment is to equip or supply with ability. When empowerment is used to give someone else the power, the implication is that power can be taken away. This creates an unequal partnership.

One of the challenges in community engaged research is to empower the other side without setting up a power differential. Often it is perceived that the academic researcher is more powerful than the community partner. However, this depends on the situation. It could be that the community partner has valuable information and knowledge needed by the academic researcher.

Example: A researcher went to the IRB to conduct a community project with gang members. A community member assisted this researcher by recruiting 15 gang members. All the gang members recruited stated that purple was their favorite color when asked. The researcher assumed that the community member was allowing the gang members to talk to each other. But, in reality, the gang color was purple.

In this example, knowing the community would have avoided undue delay and accusations. The question could have been reframed to ask “Other than purple, what is your favorite color?”

Knowledge is power. As information can be shared between parties, spending time learning about the community not only empowers the community and its members, it empowers the researcher. Ways to empower a community member include:

- Building on the resiliency of the individual instead of making accusations.
- Getting the community partner involved in the decision making.
- Asking for opinions.



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- Creating an environment where everyone can be involved and motivated. Everyone must think about the project, the research. Once you understand this then you can understand the added value of partnerships.
- Spending time in planning and learning about the community before engaging that community in a research study.

### HEALTH LITERACY and CONSENT

Literacy is defined as the ability to read and write. Literacy can also mean being knowledgeable in a particular subject or field. Health literacy is defined as the ability to process health information and obtain health services. The components of Health literacy are:

- Conceptual ,
- Oral (listening, speaking),
- Print literacy (writing, reading), and
- Numeracy (basic math skills - understanding numbers). In daily life, math is used to calculate medication doses. In research, numeracy is used to calculate the probability and risk.

There has been an increase in concerns about literacy skills and the challenges that low health literacy create when engaging a member of the community in research or services that may be of benefit to him/her.

Who has literacy issues? In its research, Vanderbilt University found that in 1992 and 2003 there were an estimated 90 million Americans with poor literacy. Greater than 50% of Americans struggled with basic math skills, that is they could not appropriately complete a bank deposit and had difficulty understanding a bus schedule. Many of those who struggle with day to day literacy are completely illiterate when it comes to health care. Individuals with low health literacy have difficulty understanding consent documents, written prescriptions, medical instructions such as dosing and timing for medications, and nutritional information. In order to participate in research both high literacy and math skills are needed. Ultimately, low literacy results in poorer healthcare outcomes such as disease knowledge, clinical outcomes, and increased risk of hospitalization.

Positive outcomes are linked with literacy. Health literacy helps us understand our own health better enabling us to change behaviors.

***Literacy with Food Labels Example:*** Vanderbilt University did a study where they recruited a wide range of subjects and tested them for literacy with food labels. What they found was that less than 24% of those tested had an 8<sup>th</sup> grade literacy level. And, less than 63% had 8th grade math literacy. Only 1 person

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scored 100% when reading food labels for content. Vanderbilt researchers also found that the participants were easily overwhelmed when given complex information. The average readability of a research consent form is 10<sup>th</sup> grade.

***Diabetes and Numeracy Example:*** This study involved diabetes and numeracy studies. 398 patients took a quiz. Researchers found huge deficits in performing tasks being asked of them. Errors were made in interpreting serving sizes. Individuals had difficulty using fractions and decimals. Thus, most people got the serving information wrong despite diabetes education.

These two examples illustrate why it is not surprising that individuals with low literacy who are diagnosed with diabetes are at an increase risk of complications because they are more likely to not understand food labels.

### *Literacy & the consent process*

Often the consent document is perceived as a contract with the goals surrounding its use unclear to the members of the community. There tends to be general distrust when the word research is brought up.

We must also remember that consent is both a written process and an oral process. In looking at the online consent processes, the median time for a participant to consent was 53 seconds. Participants need to understand both the oral and written process to be fully informed. However, the oral process is often not done well. It is often rushed and one sided. Information is often thrown at the participant rather than having a dialogue where both sides engage in a conversation about the study. It is not uncommon for a participant to sign a consent document without fully understanding the study, what is involved, or the risks of the study.

How information is framed can help understanding. There is often a disconnect between what we think participants can do and what participants actually understand. It is difficult to identify participants with low literacy as they often do not ask questions, and will say that they understand. Therefore, verbal assessment is difficult. Depending on the population, it may be best to assume that there is low health literacy and use strategies to help overcome this challenge. By assuming low illiteracy you improve information to all individuals and more people will understand.

Use plain language. Redesign the consent forms to avoid jargon and use concrete terminology. Avoid over explaining an issue. This can create more confusion. Explain key concepts one at a time. Use figures and pictures. Simplify the text and include lots of white space to increase readability of the document. There are a variety of readability indexes that can be used to help guide you in simplifying the consent document.



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Use language appropriate to the population in the consent document, handouts, and recruitment materials. In describing the study, use shared goal setting, making the participant an active part of study requirements. Historically, IRBs have asked for consent forms to be written at a 6<sup>th</sup> to 8<sup>th</sup> grade level. But, with low health literacy, we must set a lower target of 5<sup>th</sup> to 7<sup>th</sup> grade. Ideally, consent forms would be written at a 4<sup>th</sup> to 6<sup>th</sup> grade level. Unfortunately, most consent forms exceed this target.

Be aware of any cultural issues or challenges such as limited proficiency, multi caregivers, language barriers, family structure, or health beliefs that differ from Western culture. When using an interpreter, address the potential research participant, not the interpreter when speaking about the study. Use an objective interpreter, familiar with the terminology used in your study in both English and the other language, not a family member translator who may be influenced by family structure or cultural views.

Utilize open ended questions to determine if the potential participant understands what he/she is being asked to do and the risk involved in the study. If the participant does not understand, the researcher can re-evaluate how the study is being described, re-explain and re-test using “teach back” or an “assessment of understanding.” When these techniques are used, participants not only have better recall they have a better understanding of the study. This is particularly useful with children.

Remember that decreased literacy does not mean that one is less intelligent. Be careful not to talk down to participants. Those with high literacy can also struggle with complicated consent documents and informed consent processes. What benefits those with low literacy benefits all, leading to improved health outcomes.

### **RECRUITMENT**

Recruitment in community populations requires cultural sensitivity, working with issues related to health literacy or low literacy, remaining transparent, and considering the risks and benefits to the community as well as the individual. Effective recruitment is a consistent concern in any study. As studies become increasingly complex and demanding, achieving recruitment goals can be more challenging. Active recruitment methods include:

- One-on-one interactions with targeted audiences,
- Classroom presentations,
- Telephone screening,
- Person to person invitations, and
- Inpatient referrals.

Active recruitment methods provide opportunities to determine if interventions can be effectively implemented in the real world setting because there is interaction with the potential research participant who can provide feedback and information useful in



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modifying a recruitment approach. Passive recruitment methods such as broad distribution of materials not issued to specific individuals, flyers, brochures, posters at facilities and medical clinics, newspaper, TV and radio ads, press releases and announcements are not as effective because the one-on-one interaction is missing so the researcher never really gets good feedback or information about the community he/she is targeting.

When planning your recruitment and consent strategies, consider these points:

- How are you defining recruitment vs. outreach? Will your institution allow “recruitment?” Recruitment is defined as enrolling or seeking to enroll new members. Outreach is defined as the process of reaching out, extending or lengthening one’s reach.
- It may be difficult to establish trust in populations that were possibly misused in the past. One way to address this may be to shorten the time from when consent is obtained to when activities begin to demonstrate that you are trustworthy and reliable.
- It may be that you are exploring a topic that is not well received as it does not meet the current needs of the community. It is possible that this topic may become popular or a hot topic years down the road. But, you may need to take a step back in developing your research study to first meet the current needs of the community and build a relationship before delving into the original topic you were considering.
- You must develop trust with potential participants and groups (organizations) from which you wish to recruit.
- Consider the larger group, not just the subset with which you wish to work. Dissemination of information and results will keep all informed and may be useful to the larger group as well.
- Consider intergenerational differences when thinking about appropriate times to call, recruit, or consent an individual. Consider rural vs. urban cultural differences. Does your population like “to visit” or are they “in a hurry?” Do they wake early or stay up late? Are they likely to be home during the day?
- Is the consent document long and likely to overwhelm your population? What can you do to improve this situation?
- In what setting will recruitment take place? Is it private? Does your setting lend itself to an unhurried conversation? The recruitment setting can affect quality control for the consent process.





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- When working with individuals from other countries, ethnicities, or religions consider cultural differences that may exist. In order to accomplish this you must first determine what “the community” is for your study and who is consenting the community as well as the participants. This may lengthen the consent process especially when language barriers exist.
- When obtaining consent from a family, individuals within the family may not want other family members to know whether they decided to participate in the study or not. The family is another dimension of the community you may be working within.

**Example:** When conducting genetic research, participation in the study can easily extend beyond the person you have consented and can have implications for the family so you need to consider whether to tell the family or not. Keep in mind that if family members did not consent, they do not know genetic testing is taking place and those family members did not give permission to have their information shared. Should the family be consented as well? By not telling the family, will you be withholding possible future treatments or limiting study data collected that could be valuable not only to the study but to the family? On the other hand, if the study tests reveal new information for which there is no known treatment, would/should the family know the results?

- Participants have a right in terms of clinical information but research data is often not shared with individual participants unless clinically relevant. Some participants do not understand this disparity and wish to know why they will not receive research data. It may take a bit more time and effort to explain that although research data may help lead to important information for the community at some point, individual results may not be relevant to the current care of the individual. You may also need to explain who makes the decision regarding when and if individual results are shared with the participant as well as the protections put in place to protect that data from any misuse. In these instances re-consenting may be appropriate.

**National Children’s Study Example:** The National Children’s study is a large database study that has been conducted over many years in many locations. This particular study has raised and still raises a lot of questions. As a longitudinal study, it is common for participants to ask “What am I really consenting for?” Most participants really have no idea what the data and samples they donate will be used for in the future. In a

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study such as this, it is also common for the researcher to not really know all the future potential uses of the data and samples collected. Therefore, it is important the consent process be ongoing and should share study findings with the participants on an on-going basis. It is also important to have built-in safeguards that protect the data and samples collected as well as their use.

***Health disparities in Alzheimer's Dementia (AD) Example:*** Research at Washington University has shown that African Americans (AA) and Caribbean Hispanics experience a higher incidence of Alzheimer's Dementia (AD). However, racial and ethnic minorities remain underrepresented in Alzheimer's Dementia (AD) research. Mistrust was found to be the key factor in nonparticipation due to past wrongs, or recent adverse experiences in clinical care that was superimposed on research. It was found that there is also a feeling that there is a lack of information and lack of reciprocity in disseminating information. And, the informed consent looks like a legal document that is protecting the researcher. During the course of these AD studies, it was found that 1/3 of African-American women avoided clinical trials because they did not trust scientists, 37% wanted to be treated by an African-American doctor, and 28% of the African-Americans thought research was unethical. Additional barriers included:

- Fear of the unknown and adverse effects,
- Inconvenience,
- Reputation of the researcher and the research institution,
- Perceived level of experience, and
- Limited information.

To overcome these barriers, strategies employed included assessing barriers which resulted in increased numbers and frequency of programs as well as increased participation of community organizations in the development of content and format, providing education for physicians and other health providers which lead to modified healthcare provider programs, and collaborating to provide outreach, education, and support. As a result, new customized recruitment and outreach programs were put in place.

## REGULATIONS

The regulations pose another challenge. Knowing and working within the regulations can be a challenge when conducting research in a community setting as there are no regulations that specifically address community engaged research. Instead, a variety of regulations and federal guidance must be applied to the community setting. Often,

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these guidance documents are conflicting which can cause confusion and frustration when trying to conduct research.

Example: A study being conducting in a school setting that wishes to collect information using a survey, student records, and students' BMI (Body Mass Index) is receiving funds from a local grant. Although this appears to be a simple study, it actual involves Department of Education's Family Educational Rights and Privacy Act (FERPA), Department of Health and Human Services' 45 CFR 46 subpart D which protects children, and the U.S. Department of Health and Human Services' Health Insurance Portability and Accountability Act (HIPAA) which governs any individually identifiable information that is placed into or taken out of the medical record. Both FERPA and HIPAA require written signatures. The children are not considered legally capable of consent so a parent's signature would be necessary. The school is allowing access to its individually identifiable information and therefore is an engaged site in this study. The school would either have its own IRB or the researcher would need to request that her IRB become the IRB of Record for this study.

Often this is the case with community based research. What appears to be a simple, quick study is really a more involved study not only with respect to the community and the time it takes to build relationships but also with respect to the regulations governing human subjects research that need to be observed and adhered to.

### **SUSTAINABILITY**

Do the burdens and incentives match? Is there a burden on the community? If so, what are those? It is important to find the priorities and feasibility of a project in order to ensure sustainability of a project. For long term sustainability there must also be long term funding, a clear definition of who the partners are and a clear definition of how to redirect power. Resiliency within the community is also needed.

Sustainable partnerships are an important key to the puzzle. Sustainable partnerships should include respect, trust, communication, and the ability to see the other side's point of view. Egos tend to get in the way of constructive behaviors. In the end, constructive behaviors such as respect must pervade in order for a partnership to flourish.

Questions that should be asked by the community in developing a partnership are:

1. Why do you need my community as a partner?
2. What is needed from my community? What are the time commitments? Is money involved?
3. What are long and short term benefits to community?
4. What happens when the grant money goes away?
5. What are the roles and responsibilities of each side?

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6. What is the track record of the researcher in conducting community engaged research? Are there any references? What has the researcher done prior to this study?
7. Does the researcher really want to be here? Is the researcher using terms such as “we/us/our?”
8. Is your project in the right community? In determining this, the goals and mission of the community must align with the goals and mission of the research study. All healthcare issues will not be solved with one study so start with the needs of the community, understanding any historical information that may be pertinent and relevant to the central issue of the study.

Conversely, the researcher can ask the community the questions above.

### TRAINING and EDUCATION

Training often poses many challenges. The first step is to make researchers aware of the importance of training community partners. This seems to require a paradigm shift as the needs and wants of the public are just beginning to be recognized and understood.

**Example:** Pediatrician offices were involved in a study targeting community members and parents. Parents were surveyed to see whether their child had asthma or allergies and what types of concerns the parents had about their child’s health. Based on these surveys, researchers found areas of relevance and concern that needed to be studied. A research protocol to study these specific concerns was developed. Once the study was developed it was necessary to train the pediatricians involved in the study. In order to accomplish this goal, the researcher and her assistant, developed a manual that walked the pediatricians through the regulatory framework, explaining the various terms and necessary documents. Pediatricians were then asked to complete a human subjects training session lead by a qualified trainer.

Just as the community individuals involved in a study need to be trained, those reviewing the studies (IRB members) need to be trained as well. Training IRB members in community engaged research would mean that they could better understand the methodology and populations involved thus making it easier for them to understand not only which regulations and ethical guidelines apply but how those would apply as well. This would facilitate communication between the IRB and researchers and as well as encourage further research in the community as researchers would experience less struggles and frustration when submitting their studies for IRB review.



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Those holding the purse strings are another population to educate. Often this type of research is not seen as scientifically rigorous and therefore does not score well when submitted to national funding sources. Data collected may be considered “soft.” There may not be much preliminary data. Community concerns may not be seen as “scientifically significant.” Funds are required to initiate and sustain any type of activity. Through education and awareness of alternative data collection models as well as relevance and importance of community concerns, more funds may become available to community engaged researchers.

Regardless of the group, training must be an ongoing and continuous process. Often labor intensive and time consuming, training provides a foundation that encourages communication, sharing of knowledge, and awareness building through which change and progress are possible.

### **TRUST**

Trust is another key component. Trust the other person but also trust yourself enough to raise issues when there are questions or concerns. You must understand the reality of the community so that you do not end up feeling like an outsider. Ways to bridge gaps between the community and researcher are to:

- Find realistic community advisors.
- Encourage opportunities for open discussions in the community about health and other issues, even if they are painful.
- Develop community partnerships.
- Develop mentorship and training in the community.
- Be careful who you bring to the community.
- Expect and plan for engagement to be consistent and long term.

The community will be more willing to participate if you are totally honest. But, sometimes you can't be fully open with the research participants. In other cases, there are a lot of unknowns as with genetic studies. So, the key is to be as upfront and honest as possible; if you do not know that a technique or treatment will work, say so. If there are problems continuing a program due to funding or other factors, let the community know why you are or are not continuing the program. Be transparent, especially about financial issues, as transparency builds trust.

### **CONCLUSION**

Attitude and disillusionment with research can affect resources and willingness to participate. Resources can be skills, time, equipment, or people. Research is another resource in that it builds knowledge. Community engaged research not only builds knowledge but it empowers communities and builds networks. For those that have

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participated in a research study and have not experienced the satisfaction they expected, they may be reluctant to agree to participate in another study or partner with another researcher. A community partner that has not achieved hoped for gains, may also be reluctant to share any time or dedicate any resources to what may be seen as a fruitless endeavor. In summary, some practical steps to move all aspects of community engaged research forward are:

- Increase health care access by establishing community hospitals and community health initiatives such as the formation of the Homer G. Philips Hospital in Tennessee.
- Create a foundation for research partnerships.
- Use existing partnerships and elaborate on those such as partnerships that may already exist between primary care physicians and researchers.
- Look at what other institutions do successfully and replicate those efforts.
- Identify parts of your organization that may already be contributing to community engaged efforts and network within to expand resources and knowledge.
- Create new academic partnerships between neighboring institutions such as Meharry Medical College/Vanderbilt University and Washington University in St. Louis/Saint Louis University.
- Establish community based consortia.

Collecting information for the purposes of research on a community program alone means that the bar is raised when it comes to protecting those who have agreed to share that information. Knowing and working within the regulations can be a challenge when conducting research in a community setting, but education can be the road that paves the way to a better understanding and application of the regulations within a study. This knowledge makes it possible to conduct a study that not only meets the needs of the defined community but that also has the proper protections in place. Bi-directional dissemination should be the standard with communication as a central component.

In conclusion, community engagement is vital. Establishing trust and collaboration will create better data and statistics to provide evidence-based translational healthcare allowing community based efforts to positively influence policy and disparity awareness.



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## REFERENCES and RESOURCES

### Compensation

Bentley, JP, Thacker PG, *The influence of risk and monetary payment on the research participation decision making process*, J Med Ethics 2004; 30:293-298.

Dickert, Neal, Grady, Christine, *What's the Price of a Research Subject? Approaches to Payment for Research Participation*, N Engl J Med 1999; 341:198-203.

Ejiogu N, Horbeck J, Mason MA, Cromwell BC, Zonderman AB, Evans MK., *Recruitment and Retention Strategies for Minority or Poor Clinical Research Participants: Lessons From the Healthy Aging in Neighborhoods of Diversity Across the Life Span Study*, The Gerontologist 2011; 51(S1): S33-S45.

Festinger DS, Marlowe DB, Croft JR, Dugosh KL, Mastro NK, Lee PA, DeMatteo DS, Patapis NS, *Do research payments precipitate drug use or coerce participation?* Elsevier Ireland Ltd. 2004, J Drug Alc Dep 2004

Grant, RW, Sugarman, J. *Ethics in Human Subjects Research: Do Incentives Matter?* Taylor & Francis inc., J Med Philos, 29(6): 717-738, 2004

Guyll M, Spoth R, Redmond C, *The Effects of Incentives and Research Requirements on Participation Rates for a Community-Based Prevention Intervention Research Study*, J of Primary Prevention 2003; 24 (1): 25-41.

Iltis, AS, DeVader S, Matsuo H, *Payments to Children and Adolescents Enrolled in Research: A Pilot Study*, Pediatrics 2006; 118 (4): 1546 – 1552.

### Health Literacy

Cavanaugh K, Huizinga M, Wallston K A, Gebretsadik T, Shintani Ai, Davis D, Gregory, RP, Fuchs L, Malone R, Cherrington A, Pignone M, DeWalt DA, Elasy TA, Rothmann R, *Association of Numeracy and Diabetes Control*, Ann Intern Med. 2008; 148: 737-746.

Desch K, Li J, Kim S, Laventhal N, Metzger K, Siemieniak, D, Ginsburg, D, *Analysis of Informed Consent Document Utilization in a Minimal-Risk Genetic Study*, Ann Intern Med. 2001; 155:316-322.

DeWalt, DA, Berkman ND, Sheridan S, Lohr KN, Pignone MP, *Literacy and Health Outcomes*, J Gen Intern Med 2004; 19:1228-1239.

Huizinga, MM, Carlisle, AJ, Cavanaugh, KL, Davis, DL, Gregory, RP, Schlundt, DG,

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## **COMMUNITY-ENGAGED RESEARCH: Exploring the Unique Community-Academic Relationship**

Rothman, RL, *Literacy, Numeracy, and Portion-Size Estimation Skills*, Am J Prev Med 2009; 36 (4): 324-328.

Huizinga, MM, Elasy, TA, Wallston KA, Cavanaugh, K, Davis, D, Gregory RP, Fuchs LS, Malone R, Cherrington A, DeWalt DA, Buse J, Pignone M, Rothman RL, *Development and validation of the Diabetes Numeracy Test (DNT)*, BMC Health Services Research 2008, 1 – 8.

Kumar D, Sanders L, Perrin EM, Lokker N, Patterson B, Gunn V, Finkle J, Franco V, Choi L, Rothman RL, *Parental Understanding of Infant Health Information: Health Literacy, Numeracy, and the Parental Health Literacy Activities Test (PHLAT)*, Academic Pediatrics 2012: 10(5): 309-316.

Paasche-Orlow, MK, Taylor HA, Brancati FL, *Readability Standards for Informed-Consent Forms as Compared with Actual Readability*, N Engl J Med 2003: 348 (8): 721-726.

Rothman RL, DeWalt DA, Malone R, Bryant B, Shintani A, Crigler B, Weinberger M, Pignone M, *Influence of Patient Literacy on the Effectiveness of a Primary Care-Based Diabetes Disease Management Program*, JAMA 2004; 292 (14): 1711-1716.

Schillinger D, Grumbach K, Piette J, Wang F, Osmond D, Daher C, Palacios J, Sullivan GD, Bindman AB, *Association of Health Literacy With Diabetes Outcomes*, JAMA 2002: 288 (4): 475-482.

Schillinger D, Piette J, Grumbach K, Wang F, Wilson C, Daher C, Leong-Grotz K, Castro C, Bindman AB, *Closing the Loop: Physician Communication With Diabetic Patients Who Have Low Health Literacy*, Arch Intern Med 2003; 163: 83-90.

Wolff K, Cavanaugh, K, Malone R, Hawk V, Gregory BP, Davis D, Wallston K, Rothman RL, *The Diabetes Literacy and Numeracy Education Toolkit (DLNET)*, The Diabetes Educator 2009; 35 (2): 233-245.

### **Understanding the Community**

Jordan, C, Lee P, Shapiro E, *Measuring developmental outcomes of lead exposure in an urban neighborhood: the challenges of community-based research*, J Exposure Analysis and Environmental Epidemiology 2000: 10: 732-742.





## **COMMUNITY-ENGAGED RESEARCH: Exploring the Unique Community-Academic Relationship**

Katz, E, *The Two-Step Flow of Communication: An Up-To-Date Report on an Hypothesis*, Public Opinion Q 1957; 21 (1): 61-78.

Runnels V, Hay E, Sevigny, E, O'Hara P, *The Ethics of Conducting Community-Engaged Homelessness Research*, J Acad Ethics 2009: 7: 57-68.

Rothman RL, Malone R, Bryant, B, Shintani AK, Crigler B, Dewalt DA, Dittus RS, Weinberger M, Pignone MP, *A randomized trial of a primary care-based disease management program to improve cardiovascular risk factors and glycosylated hemoglobin levels in patients with diabetes*, The American Journal of Medicine 2005; 118: 276-284.

Santoyo-Olsson J, Cabrera J, Freyre R, Grossman M, Alvarez N, Mathur D, Guerrero M, Delgadillo AT, Kanaya AM, Stewart AL, *An Innovative Multiphased Strategy to Recruit Underserved Adults into a Randomized Trial of a Community-Based Diabetes Risk Reduction Program*, The Gerontologist 2011: 51 (S1): S82-S93

### **Institutional Resources**

Meharry Community Outreach

<http://www.mmc.edu/research/centers/chd/community/community.html>

Merriam-Webster On-Line Dictionary, <http://www.merriam-webster.com/>

National Institutes for Health, Principles of Community Engagement, second edition  
[http://www.atsdr.cdc.gov/communityengagement/pdf/PCE\\_Report\\_508\\_FINAL.pdf](http://www.atsdr.cdc.gov/communityengagement/pdf/PCE_Report_508_FINAL.pdf)

University of Chicago Urban Health Initiative

<http://www.uchicago.edu/community/uhi.shtml>

US Department of Health and Human Resources, The Belmont Report

<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>

Vanderbilt-Meharry Community Engaged Research Core

<http://www.mc.vanderbilt.edu/victr/pub/community/>

Vanderbilt University Institute for Public Medicine & Public Health

<http://medicineandpublichealth.vanderbilt.edu/>

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Washington University Human Research Protection Office Community-Engaged Research Program, [http://hrpohome.wustl.edu/community\\_research/cbr.aspx](http://hrpohome.wustl.edu/community_research/cbr.aspx)

Washington University Institute of Clinical and Translational Sciences, <http://icts.wustl.edu/>

### **Institutional Literacy Resources**

Agency for Healthcare Research and Quality (AHRQ), <http://www.ahrq.gov>.

Harvard School of Public Health, Health Literacy Studies: Teaching Patients with Low Literacy Skills  
<http://www.hsph.harvard.edu/healthliteracy/resources/doak-book/>

Institute of Medicine (IOM), Health Literacy: A Prescription to End Confusion  
<http://www.iom.edu/Reports/2004/Health-Literacy-A-Prescription-to-End-Confusion.aspx>

National Center for Education Statistics, National Assessment of Adult Literacy (NAAL)  
<http://nces.ed.gov/naal/>

Vanderbilt Health Communication, <http://medicineandpublichealth.vanderbilt.edu>

