BUILDING COMMUNITY PARTNERSHIP IN RESEARCH

Recommendations and Strategies

Centers for Disease Control and Prevention

National Institutes of Health

Food and Drug Administration

Human Resources and Services Administration

Substance Abuse and Mental Health Services Administration

Indian Health Service

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BUILDING COMMUNITY PARTNERSHIPS IN RESEARCH

EXECUTIVE SUMMARY

This report is in response to the President's request to the Secretary of Health and Human Services (HHS) to identify strategies to improve the participation of communities, especially minority communities, in research and to build trust between researchers and communities. It provides a framework through which Federal health agencies can establish an ethical basis for community-based research, enhance scientific and public credibility, and provide mechanisms to help build public trust in health research.

Minority and poor communities lag behind the overall U.S. population on virtually all health status indicators, underscoring the need for continued focus on health research to identify solutions to improve health status in these communities. Through commitment to a participatory approach, communities and researchers have the opportunity to build trust through true partnership. By working in partnership, communities, researchers, and funding agencies can further maximize the benefits of research by translating research findings into comprehensive health programs.

Basic issues of involving the community in research must be acknowledged and addressed. Inclusion is the core issue for building community partnerships in research, and it requires "grassroots" involvement. Researchers must reach out broadly so that all pertinent experience is represented. By bringing together the knowledge and experience of communities and researchers, excellence in science is enhanced. True collaboration and partnership entails sharing risks and responsibilities as well as resources and rewards. Commitment of adequate time and resources is essential--building a research relationship generally takes from two to five years, and resources must be available to support the activities and infrastructure necessary to build and sustain such partnerships. Building an effective partnership requires acknowledgment of the impacts of history, culture, and society on many of our most challenging health issues.

Trust must be built on the actions of researchers, not just faith in the benefits of research, and decision-making power must be shared throughout the research process. History demonstrates that people have been harmed when medical and public health research is planned and conducted without consideration of the human context of such work or regard for human rights. Individuals who participate in such research are directly affected in a variety of adverse ways; however, as members of a demographic or geographic group, the individuals' entire group or "community" is also indirectly affected and unintended, negative outcomes are often the result. Therefore, ethics must be addressed at the community level as well as at the individual level. Policies must be developed that facilitate participatory research through appropriate funding mechanisms. Education and training mechanisms must be developed to provide both communities and researchers with the necessary skills for a balanced partnership. Accountability and oversight mechanisms are necessary to ensure that mutual commitments are kept and that a system for corrective action is implemented when errors in judgment or overt abuses occur.

The goal of HHS is to promote awareness of and appropriate community participation in health research. Dialogue must continue among HHS agencies, researchers, and communities to provide ongoing development and guidance for building meaningful health research partnerships with communities. HHS will undertake the following action steps to attain this goal:

- **Establishment of a federally mandated Task Force on Participatory Research.** The Task Force will be composed of representatives from diverse communities, research institutions, and HHS agencies.
    - The Task Force will conduct regional hearings to gain grassroots community input on mechanisms and actions needed to build partnerships in research.
    - The Task Force will develop guidance on participatory research based on these hearings and other appropriate processes.
    - The Task Force will develop a plan to increase community participation in government-funded research.
- **Development and implementation of an HHS-wide evaluation plan to assess the impact of current health research processes, procedures, and funding mechanisms on community participation in health research and implementation of changes as needed to facilitate the use of participatory research models.**

INTRODUCTION

Although most research over the years has been conducted ethically and yielded great benefits to many individuals, history demonstrates that people have been harmed when medical and public health research is planned and conducted without consideration of the human context of its work or regard for human rights. As a result, laws and regulations have been passed to protect people who participate in research. However, there has been little or no consideration of the role of communities in influencing and guiding research that involves and affects its members. Inclusion of communities has great potential for reducing the likelihood of harm and for engendering trust in research.

Recent events have set the stage for an open dialogue among government, communities, and researchers that considers the inclusion of communities in the planning, conduct, and application of health research. Most notable among these events was the Presidential apology for the wrongful conduct of the government-sponsored Tuskegee Study of Untreated Syphilis in the Negro Male. On May 16, 1997, President Clinton apologized to the Study's survivors and families, the African-American community, and to the American people as a whole, stating, "What was done cannot be undone. But we can end the silence. We can stop turning our heads away. We can look at you in the eye and finally say on behalf of the American people, what the United States government did was shameful, and I am sorry. The American people are sorry-- for the loss, for the years of hurt." The President further stated that the study at Tuskegee served to sow distrust of our medical institutions, especially where research is involved, and that this distrust impedes efforts to conduct promising research and to provide the best health care for all Americans.

This report is in response to the President's request to the Secretary of the Department of Health and Human Services (HHS) to identify strategies to improve the participation of communities, especially minority communities, in health research, and to build trust between researchers and communities.

Much of the input for this report was provided by community, researcher, and Federal agency participants at an interagency workshop on *Enhancing Community Participation to Restore Trust and Improve Science in Health Research* held at the Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia, on October 16-17, 1997. A list of participants is included at the end of this report. Insights and lessons learned were also garnered from an inhouse symposium held at CDC in May 1997 on *Community Partners for Prevention Research: Implications for the Science and Practice of Public Health.* Literature reviews, agency reports, and compilations of previously implemented strategies to enhance partnership were also consulted in the development of this report.

BACKGROUND

Health research is a set of investigative activities undertaken to improve the health of all people and communities by seeking to understand the causes of disease, illness, and death and the circumstances that promote well-being. Some aspects of health research can be conducted in laboratories or with computers; however, the laboratory specimens and data must be collected from people. Health research is, therefore, a fundamentally social activity, dependent on collaborative human interaction. To achieve our goal of improved health, we must value and cultivate the fundamental skills necessary for collaboration.

Health research is also a privileged and empowered activity in that the researchers have special access to resources and sensitive information about people and, through the analysis and presentation of research findings, are able to influence the way people think and have considerable influence on decisions regarding the allocation of resources. With the privilege and power given to researchers comes the potential for abuse. Guarding against such abuse is the personal and professional responsibility of every researcher and the collective responsibility of every institution that sponsors research. History has shown that we as a Nation must establish and enforce protections against abuse perpetrated in the name of research. We must commit to basic moral values such as respect for all persons, the preservation of their dignity, and the upholding of social justice in order to avoid harm.

While it is not possible to document all harms that have occurred in research in this report, it is nonetheless important to describe some of the harms and their social, historical, and cultural contexts. The recommendations and strategies described later in this report have been developed in response to the complexities of the real world that give rise to harm.

The Tuskegee Syphilis Study

In 1932, the Public Health Service, working with the Tuskegee Institute and other agencies, began a study in Macon County, Alabama, called the *Tuskegee Study of Untreated Syphilis in the Negro Male*. The study involved 600 black men--399 with syphilis and 201 who did not have the disease. Researchers told the men they were being treated for "bad blood," a local term used to describe several ailments, including syphilis, anemia, and fatigue. In truth, they did not receive the proper treatment needed to cure their illness. Although originally projected to last six months, the study actually went on for 40 years. In July 1972, a front-page *New York Times* story about the Tuskegee Study caused a public outcry that led the Assistant Secretary for Health and Scientific Affairs to appoint an Ad Hoc Advisory Panel to review the Study. The panel found that the subjects had agreed freely to participate in the Study based on various incentives, but there was no evidence that the researchers had informed them of the Study's purpose. In fact, the men had been misled and had not been given the necessary information about the study or the opportunity to provide informed consent.

In the summer of 1973, a class action lawsuit ended in a settlement that awarded more than $9 million to the study participants and their families. As part of the settlement, the U.S. government promised to give free medical and burial services to all living participants. The Tuskegee Health Benefit Program was established to provide these services. It also gave health services for wives, widows, and children who had been infected because of the study. The Centers for Disease Control and Prevention (CDC) was given responsibility for the program, where it remains today within the National Center for HIV, STD, and TB Prevention.

Other Examples of Research Abuse That Have Led to Distrust in Research

- The history of research among American Indians and Alaska Natives has often been one of disregard for tribal sovereignty and basic human rights. From 1987 to the present, approximately 3,000 articles have been published in which American Indians or Alaska Natives were cited as research participants. Some American Indians and Alaska Natives have suggested that this volume of research indicates that their communities are used to evaluate therapies and preventive strategies that are intended to benefit other, particularly majority, communities. They believe that there has been little or no concern for how or when the results would directly benefit American Indian and Alaska Native populations, or how ongoing research could be used to improve the health of their communities. To address these concerns, many tribes have taken steps to ensure that all research is now undertaken with explicit concern for and involvement of their people. Model agreements between tribes and researchers have been developed by the Navajo Nation, the American Indian Law Center, and others.

- Some populations have suffered harm as a result of geographical location. The U.S. government actively developed and tested nuclear weapons for approximately 50 years. As a result of classified intentional releases such as the 1949 "green run" release of radioactive iodine from the Hanford Nuclear Facility in eastern Washington State, many communities believe they unknowingly were part of experiments conducted by the government that may have adversely affected their health [Jensen 1996]. Hundreds of such releases took place in secret and remained secret for decades. Also, from 1944 to 1974, the U.S. government sponsored classified human subjects research that was the focus of investigation by a 1994 Presidential Advisory Committee on Human Radiation Experiments. The Committee found significant lapses in ethical conduct. Many of the communities affected by the operations of the U.S. nuclear weapons complex are poor and require a specific environmental justice activity to address their needs and concerns [Environmental Health Perspectives 1995].

- Similarly, the U.S. nuclear weapons testing program at the Nevada Test Site and in the Republic of the Marshall Islands is being investigated to determine the possible influence of weapons testing on the health of the U.S. population and Marshall Islanders. Between 1946 and 1956, 67 atmospheric and above-ground nuclear tests were conducted in the Marshall Islands, equivalent to the power and radiation of 7,000 Hiroshima atomic bombs. During the hydrogen bomb detonation in 1954 (Castle BRAVO test), radiation fell directly on 253 Marshall Islanders. The now unclassified documents about the BRAVO test show that the Chief of Mission knew that wind changes would result in fallout over this population. In addition, other Marshall Islanders were moved back into radioactively contaminated areas, then were relocated months to years later after it was found out that these areas were still contaminated. At no time was there any community participation in the process, or informed consent, and the Marshall Islanders were told that this was for the "good of mankind." The truth was hidden from the public and the Marshall Islanders for many years in classified documents. The Marshallese people continue to suffer from the effects of the testing and have great mistrust of the U.S. government.

- Research conducted at Willowbrook State Hospital in Staten Island, New York, for over 15 years highlights the vulnerability of institutionalized populations and their families. In this instance, mentally retarded children were deliberately infected with hepatitis A and B viruses so that researchers could assess the natural history of the disease and its response to treatment. Parents were induced to consent to the research because hospital admittance for their child was at least implicitly contingent upon enrollment in the study at a time when hospital bed space was limited.

- In the mainland United States, the illegality of abortion in many States posed a challenge for human trials of the prototype contraceptive pill in the 1960s. Large trials were needed to find the optimal estrogen-to-progesterone ratio and to evaluate potential side effects. Researchers believed that they needed to be able to provide women participating in the trials with the option for abortion if the pill failed to prevent pregnancy. To simplify follow-up, they also wanted a large field population that was geographically contained and relatively stable. Abortion was legal in Puerto Rico at this time, and residents of a housing project in the San Juan metropolitan area were targeted for recruitment. Most of the women had low incomes and several children. They were approached by researchers who offered them the contraceptive pill as an option for having fewer children while continuing to have sexual relations. Other U.S. locales where abortion was legal were not targeted, and the burden of untoward side effects of the medications was experienced by mainly one group. Because this research targeted one socially disadvantaged group, it violated the principle of social justice and was unethical.

In addition to these specific examples of wrongs by researchers, the simple conduct of research on certain health issues can result in negative stereotyping and stigmatization. Many health conditions are burdened with stigma, such as HIV, sexually transmitted diseases, tuberculosis, mental illness, substance abuse, and violent injury. Individuals with these conditions can suffer severe consequences including social avoidance, economic boycott, discrimination in housing or provision of other goods and services, and violent "bashing" from others. When research is conducted or research findings are reported in a way that is disrespectful or insensitive, the result is further negative stereotyping and stigmatization of the affected individuals and the communities in which they live. Minority communities are understandably concerned about the potential for harmful labeling and discrimination that may arise from research on stigmatizing diseases.

A New Beginning

When research causes harm, that research contributes to, rather than lessens, the stresses endured by communities. The harm endures through years of emotionally and often financially taxing attempts to effect redress. Communities who have been harmed by research believe that trust must be built, not rebuilt. Establishing a foundation for trust requires commitment and right action. The actions of researchers today must be clearly distinct from those that led to the wrongs of yesterday. This report provides individuals, institutions, and Federal health agencies engaged in research with a framework for establishing an ethical basis on which to build trust and partnerships with communities.

PARTICIPATORY HEALTH RESEARCH

Defining "Community"

While an understanding of the concept of "community" is integral to community participatory research, there is no consensus on a definition of "community" or its operationalization within health research. At its simplest, a community is a "group of individuals with a common interest and who identify themselves as a group" (Labonte 1997). While many people tend to think that a community requires geographic proximity--that is, people living and working in the same place--many modern communities are based primarily on shared interests or characteristics such as culture, ethnicity, occupation, or a sense of purpose or vision (Hatch et al. 1993, Royal Society Report, Jewkes and Murcott 1996, Labonte 1997, Minkler and Wallerstein 1997).

Communities are dynamic and emergent, with fluid, flexible boundaries (Walter 1997; CDC 1997), and are often characterized by diversity. The multiple constituencies and interests within a community must be acknowledged and appropriate strategies and processes developed for full partnership (Minkler and Wallerstein 1997). For these reasons, no single definition of community will be adequate to meet the needs of every situation.

> **From a participatory research perspective, "community" should ultimately be defined in terms of those whose participation is necessary for the implementation of the research and whose well-being is likely to be affected by the conduct of the research.**

The Importance of Health Research

Minority and poor communities lag behind the overall U.S. population on most health status indicators. The extent of this disparity and the consequent waste of human lives and productivity has been extensively chronicled. An estimated 60,000 excess deaths occur among African Americans, Hispanics, Asian and Pacific Islanders, and American Indians annually. (Excess deaths are defined as deaths that would not occur if mortality rates for minorities were the same as for nonminorities.) More than 80 percent of these excess deaths occur in six categories--cancer, heart disease and stroke, homicide and unintentional injuries, infant mortality, diabetes, and chemical abuse (primarily alcohol abuse)--all of which have contributing factors that can be controlled or prevented.

African Americans experience some of the greatest disparities in health in the United States. At birth, African Americans have consistently lower life expectancies: in 1993 their life expectancy was 69.2 compared to 76.2 years for whites and 75 years for Hispanics. Similarly, African-American babies are almost two and one-half times more likely than white babies to die in the first year of life. In 1993, the African American infant mortality rate was 16.8 per 1,000, while for whites it was 6.8 per 1,000. Elevated infant mortality rates have also been reported for American Indians and Puerto Ricans.

> **To improve the health status of the U.S. population as a whole, disparities in the health status of our subpopulations must be addressed.**

The Participatory Research Model

Community participatory research is not a methodology but rather an approach that combines systematic investigation, learning, and action (George et al. 1996). Researchers and community members each bring unique and important contributions to the research process. Researchers bring skills in research design and methods and knowledge of health. Community members bring knowledge about the community's culture, social norms, and networks. In the participatory approach, the community collaborates in the conduct of all aspects of the research process as an active, influential partner. Through such participation, community members and researchers work together to develop a set of priorities and identify research questions that can "satisfy the needs of both" (Hatch et al. 1993).

A major benefit of community participatory research is the sustainability of subsequent interventions or prevention programs (Altman 1996). Population-based prevention research is an ideal type of research for community participation. The importance of community-based programs for improving health is outlined in *Healthy People 2000;* community-based programs are increasingly comprehensive, taking a positive approach to health and well-being through planned, coordinated, ongoing efforts. By working in partnership, communities, researchers, and funding agencies can maximize the benefits of research by translating research findings into comprehensive programs for improving health.

Participatory research requires sufficient time for partners to become acquainted and build trust. However, as noted by the Royal Society of Canada, there may be times when "problems cry out for more urgent solutions and expedient ways of gathering knowledge and taking action" (p. 58). And, there may be types of research (e.g., multisite clinical trials) that are not easily adapted to a participatory approach.

> **Researchers should strive to work within a participatory model to the extent possible, always remembering that any research study must include the qualities of respect, honesty, and integrity. Participatory research should be the "gold standard" toward which all federally funded research aspires.**

HHS will conduct a department-wide evaluation of the impact of current health research processes, procedures, and funding mechanisms on community participation in health research and implement changes as needed to facilitate the use of participatory research models.

BASIC ISSUES IN COMMUNITY PARTICIPATION

Inclusion

Inclusion is the core issue for building community partnerships in research. Who should be included? How and when are they included? Do the decision-makers include the people who are affected by the consequences of the decisions, and how much weight do they carry when decisions are being made? Who will be held responsible for the consequences of decisions?

The research process is currently dominated by formally educated people who bring extensive information and expertise to the research situation, but who are often personally detached from that situation. Traditionally, these researchers or others who are articulate in the language of science have articulated the concerns of the research participants and consumers. But their voices often do not sound the same as or resonate with the voices of the people "in the trenches." As one community representative phrased it, "inclusion means that however 'broken' my language may sound to you, permit me to speak it as I see it; then we will work together to put the ideas together." Even those who doubt the most or have their own agendas must be heard. We must reach out broadly so that all experience is represented.

Inclusion means establishing deliberate and explicit mechanisms for enabling voice and vote in each step of the research process by research participants, beneficiaries, and other affected parties. Inclusion means "grassroots" involvement to the extent possible, of the people most affected, either directly or indirectly. It means making the effort to include individuals and various local organizations (like block clubs and local school councils) whose organizing methods include door-to-door contact, involvement of people beyond their own membership, provisions for "bottom up" planning and decision-making, and creation of indigenous leadership. Persons at the grassroots level, in this context, are people who do not work for organizations that conduct research and whose views are not influenced by research-oriented employment.

> **Obtaining grassroots input is an ongoing process that requires constant attention to the issue of inclusion and an understanding of the complexities of a participatory community partnership.**

Excellence in Science

The goal of inclusion should be to improve science by expanding effective research methodology, not replacing it or creating alternatives. Scientific rigor must be preserved while incorporating the skills, talents, knowledge, and strengths of the participants and beneficiaries of the research. Excellent science benefits everyone.

Scientific rigor is defined as "the scrupulously precise and scientifically exact application of research methods for gathering data and of analytic techniques used to treat and analyze the data" (Ratcliffe and Gonzalez-del-Vale 1988). Scientists are trained to strictly adhere to prescribed methods for data collection and analysis so as not to introduce bias into a study. Community involvement benefits scientific decision-making by requiring researchers to make their methods and assumptions explicit and understandable by all. Scientific credibility is strengthened when researchers are challenged to interpret study results in ways that reflect the realities experienced by those living in the community. Ethical research is enhanced when data collection methods are respectful of study participants.

> **Concerns that community involvement may interfere with the strict requirements of accurate measurement and with the process of conducting objective research are outweighed by the potential for improved and more effective research design and maximally beneficial results for the community.**

Collaboration and Partnership

Collaboration is not a consultative process where opinions are sought from one group, but decisions are made by another; nor is it negotiation where parties with unequal resources use win-lose strategies to protect their interests. True collaboration entails sharing risks, responsibilities, resources, and rewards and includes shared and balanced investment, responsibility, liability, goals, expectations, and benefits. Collaboration requires partnerships among policymakers, funders, researchers, evaluators, communities, families, and individuals.

> **Collaboration is shared decision-making where all those affected participate in making decisions, and all parties are willing to contribute their resources to benefit the partnership.**

Commitment of Adequate Time and Resources

There is often tension between inclusion and efficiency--the more people involved in the research process, the more complex it becomes and the longer it takes. Researchers and community members who have conducted participatory research uniformly describe the need for a commitment of adequate time to the participatory process. Building a research relationship with a community can take from two to five years. Attempts to speed up the process are likely to backfire, adding to the historical accumulation of distrust and creating an even more challenging situation for the next researcher seeking to conduct research with the community.

The resources for partnership must be adequate to support the activities and infrastructure necessary to build and sustain the relationship. Researchers, and those funding them, must be sensitive to the actual costs of participation and the ability of communities to share those costs. Some communities, especially highly educated middle and upper class communities, can draw on significant, well-established, diverse resources that can facilitate their involvement in the research process or can help them mobilize and take effective action if they believe that they are being harmed. Conversely, in communities where basic resources are lacking, infrastructure is inadequate, information is unavailable or unreliable, and day-to-day survival consumes the limited resources that people have, community members must balance the demands of a research partnership against all the other demands in their lives. Poor communities are the most vulnerable to exploitation by researchers, and thus stand to benefit the most from inclusion as equal partners in the research process. But a community cannot be an equal partner if it is dependent on the researcher for the resources needed to act as a partner.

> **Resources must be available to the community to build its capacity for partnerships with researchers.**

History, Culture, and Society

There are many dimensions to understanding communities that need to be understood--and respected--by researchers, many of whom are unaware that their own cultural assumptions shape their interpretation of the responses and behavior of others. The particulars of history, especially perpetration of institutionalized racism, internalized oppression, legacies of slavery, and violated treaty rights, have led many communities to establish ground rules for interaction with outsiders; that too often are misunderstood or disregarded in the course of research. Economic factors and their impact on health disparities within their communities should be evaluated. The spiritual and religious beliefs of a community are intimately related to health, healing, and well-being, and should be appropriately respected and addressed. Finally, respect for and willingness to discuss the emotional content of issues related to health and research within communities is crucially important, but is often a very difficult subject for researchers trained to value intellectual attributions over emotional ones.

> **A grasp of history, culture, and society is critical to solving many of our most challenging health issues. To practice effective inclusion, researchers need to understand the affected communities. Understanding develops gradually through ongoing interaction with community members, often resulting in the reshaping of assumptions held by the researchers and the community members. With understanding, the researcher gains better insight into both the causes of health problems and their potential resolution, and community members are more likely to incorporate the research findings to improve their health status.**

Trust

To build trust, communities need to experience direct benefit from their relationships with researchers and to know that individuals and institutions are held accountable for their actions. These aspects are often complicated by legal and ethical issues such as confidentiality, contractual relationships, and proprietary interests. However complex, they need to be spelled out so that communities are assured that they have full access to information and that the research serves them.

> **Full disclosure throughout the research process is essential and includes many aspects such as financial status, informed consent, and changes in plans.**

Power

There are many forms of power, but the critical one for research is decision-making power. In the research process, researchers tend to have considerably more decision-making power than the people participating in the study. This is especially true for research conducted in poor communities or with vulnerable populations such as the homeless, institutionalized persons, and youth. Because they themselves are answerable to powerful institutions, researchers are not always fully aware of or sensitive to the discrepancies in power that communities clearly perceive. It is usually the researcher, and not the community, who decides that a particular study will be done, secures and controls the funds for studies, and controls the data that can describe the community's problems--and strengths--and apply study results to the solutions to the community's health problems. And it is the researcher, not the community, who determines how the research will be done, how the data will be analyzed, and how the results will be disseminated. Often, the one decision left to community members is whether to participate as subjects during the process of informed consent.

> **A prerequisite for building trust is a more equitable distribution of decision-making power with a commitment of resources to build capacity in communities.**

Ethics

A number of mechanisms are currently in place to promote the highest ethical standards in research. The Office for Protection from Research Risks (OPRR), National Institutes of Health, provides oversight, advice, and clarification of rules on involving people in federally-funded research. OPRR certifies Institutional Review Boards (IRBs) that are required by law comprise members from a variety of disciplines and include representatives from the community. IRBs review research plans to decide whether the proposed studies can be ethically conducted with humans. In October 1995, a National Bioethics Advisory Commission (NBAC) was also created to review current regulations, policies, and procedures to help ensure that all possible safeguards are in place to protect volunteers in research.

Despite these efforts, concerns are still raised about the adequacy of existing mechanisms to ensure the ethical conduct of research. The adequacy of community involvement on IRBs needs to be evaluated . There is debate over the appropriate balance of universal versus culturally specific guidelines, especially with regard to the weight given to individual autonomy. Informed consent at both the individual and community levels should be addressed in detail.

> **The possibility that research can do social harm in a community through stigmatization or diminishment of resources needs to be explicitly considered and guidelines developed on how to apply the concept of "do no harm" at a community or societal level.**

Policy

To arrive at legitimate, community-based solutions to local public health problems, we need to do more than improve the dialogue among communities, academia, and local, State, and Federal health agencies. Dialogue sets the stage for relevant public health research, but ultimately, research is shaped and implemented through funding mechanisms. The majority of public health research funding comes from Federal institutions and private foundations through short-term commitments (generally five years or less) that focus on a particular disease or condition. Rarely are policymakers and funders willing to provide resources to sustain the structures and relationships among communities, health agencies, and academia that identify and make possible relevant public health research.

> **Sustainability is necessary if successful research is to be translated into programs of lasting benefit to communities.**

Education and Training

With their years of specialized education and training, researchers tend to either take for granted that they have the necessary expertise to conduct research in diverse community settings, or they turn to their professional colleagues for guidance. Yet few universities require or provide formal education in ethics, cultural competency, collaboration, or communication skills beyond those needed within the confines of a particular academic discipline. It is assumed that the nobler intentions of the researcher will compensate for any deficiencies in these other skills. This emphasis on scientific over social skills and ethical discipline is often combined with a shallow regard for the importance of local history and culture and a devaluing of community-based knowledge and expertise. Whether intended or not, the end result is stereotypical "researcher arrogance" that undermines the trust of community members. It also robs the researcher of valuable information that could lead to important insights.

Similarly, in order to function as true partners in research, communities need education and training on pertinent health issues, research processes, and research options for identifying and resolving particular problems. Individuals want full disclosure of information related to health issues and research in their communities expressed in language that they can understand, and they want sufficient time and opportunity to review and understand complex information. They do not want information to be presented in a manner that implies that it has been selectively edited for a less intelligent (as opposed to a less educated) audience.

> **Through education targeted to the community, we can confront the issue of scientific literacy (or illiteracy) in the United States and ensure that more of our citizens are educated about the fundamentals of research and are able to benefit more fully from such activity. In addition, through education targeted to researchers, we can improve the competence of researchers to work with communities effectively by understanding community cultures, history, and needs.**

Accountability and Oversight

> **Many of the issues that underlie public distrust of research are issues of accountability. Researchers should be held accountable when charged with the responsibility of conducting ethical research. This means: (1) following relevant regulations and laws concerning research, (2) being knowledgeable and culturally competent about the community, (3) having the interpersonal skills necessary to work with the community, and (4) practicing proven participatory research techniques.**

Researchers often seek help from local stakeholders such as leaders and respected organizations to gain access to communities, especially minority communities, where distrust of research is very high. If such assistance is given, community stakeholders become accountable for the actions of the researchers. If the researchers lack sensitivity, make a mistake, or cause harm, the community leaders lose credibility within their communities and may lose their effectiveness, either temporarily or permanently, thereby creating a gap that may not easily be filled. The researchers may be oblivious to these consequences as they endeavor to meet their own data collection goals. Efforts should be made to protect the privacy of individuals especially of vulnerable populations and the confidentiality of information they provide. Accountability and oversight are needed to protect local stakeholders and their communities from the negative impacts of insensitivity and exploitation, as well as to reward researchers who invest the time and resources necessary to build sensitive, equitable relationships.

Mechanisms are needed that hold researchers and their institutions accountable when communities are adversely affected by research. These mechanisms may include public forums for the discussion and mutual resolution of unforeseen outcomes and human error, compensation mechanisms for avoidable costs incurred by communities, and criminal penalties for intentional, serious harm to the community.

ACTION STEPS

The goal of HHS is to promote awareness of and appropriate community participation in health research. Dialogue must continue among HHS agencies, researchers, and communities to provide ongoing development and guidance for building meaningful health research partnerships with communities. HHS will undertake the following action steps to attain this goal:

1. **Establishment of a federally mandated Task Force on Participatory Research.** The Task Force will be composed of representatives from diverse communities, research institutions, and HHS agencies.

    a. The Task Force will conduct regional hearings to gain grassroots community input on mechanisms and actions needed to build partnerships in research.

    b. The Task Force will develop guidance on participatory research based on these hearings and other appropriate processes.

    c. Task Force will develop a plan to increase community participation in government-funded research.

In formulating the plan, the following issues will be considered:

(1) The need to develop model programs that not only include health research goals, but also community capacity-building goals for conducting specific research activities such as community training on literacy skills, organizational development, and community mobilization skills and researches capacity building goals such as cultural competence, social skills, and communication skills.

(2) The need for basic research on a range of models for effective collaboration between researchers and communities, on factors that promote and deter effective collaboration, and on how people decide to be research participants.

(3) The need for social and historical analyses to document episodes of research injustice in a way that will inform monitoring groups and research sponsors of factors that indicate a high potential for exploitation, injustice, and harm in research and the impact of policies that contribute to participatory research in reducing injustice.

2. **Examination of HHS procedures and funding mechanisms to determine whether obstacles exist to community participation in health research and implementation of changes as needed to facilitate the use of participatory research models.** Strategies to enhance community participation in the research process must be implemented within larger societal and institutional frameworks that are supportive of participatory research. Current practices in research funding, dissemination of study findings, and scientific career advancement are based largely on nonparticipatory research models. Federal support for participatory research is the single most effective mechanism for change.

Several key issues that will be included in the evaluation are:

a. The length of time allowed in grants and cooperative agreements to facilitate community involvement. Currently, funding (project) periods for community research are limited to three to five years; however, the process of even building a research relationship with a community so that research can proceed can take up to five years. Funding agencies need to ensure that there is a logical coordination of funding and research start-up time, with provision of adequate funds prior to the initiation of actual research to support community and researcher efforts to build a trusting relationship. In addition, better intra- and interagency coordination are needed in funding and conducting research in order to avoid overlapping or competing research in communities and to support complementary research based on community-defined priorities.

b. The diversity of application review committees. Federal review committees need to include reviewers who can effectively evaluate the participatory aspects of research proposals, and represent diversity through the inclusion of individuals who can speak to the historical, social, and cultural subtleties that affect the conduct of health research.

c. The need for education and training opportunities for researchers and community members. Researchers could work with communities more effectively if they had knowledge in ethics, cultural competency, and participatory research techniques. Likewise, community members could be more effective with knowledge of research processes. Funding and technical support should be available for career development of students, especially minority students, in community participatory research, and for the development and implementation of training programs for community-based public health paraprofessionals. Communities should share appropriately in the infrastructure costs of conducting research, and funding should be available for communities to explore the use of their own cultural traditions as a basis for answering questions and finding solutions.

d. Accountability through the use of Federal regulations. Meaningful collaboration among communities, researchers, and HHS agencies should be defined and evaluated on the basis of actions such as the use of respectful and equalizing language; clear statements on the participatory roles of communities, researchers, and agencies; and data sharing plans that outline technical requirements, confidentiality protections, and publication constraints.

e. Access to information. Effective partnership requires that community members have access to information on research, including basic requirements for the ethical conduct of research, explanations of research terminology, factors to consider when weighing the risks and benefits of study participation, evaluating the credentials of the research team, descriptions of funding sources, and the options available if problems or concerns about the research arise. In addition, currently funded collaborative models should be documented and mechanisms developed to disseminate information on them to communities, funders, researchers, and policymakers to share lessons learned.

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