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Community-Based
Translational Research
in Arizona:

Enhancing
Partnerships with
Hispanic/Latino
Communities

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PREFACE

Underserved populations in the U.S. including members of minority populations and the elderly have not benefited from the investments made in advances in the nation’s healthcare system brought about by basic and clinical research. As a result, it has become a national initiative to engage underserved populations more effectively in translational research and clinical trials as one component of improving the health and well being of underserved populations.

In the fall of 2004, the Arizona Biomedical Research Commission and the Flinn Foundation convened a working group of representatives of leading healthcare and research organizations in Arizona to identify key issues that hinder or discourage members of underserved populations from engaging in translational research programs.

This working group identified Community-Based Participatory Research (CBPR) as the foundation for developing collaborative, team based engagements among their organizations and communities in Arizona. Native Americans and Hispanic/Latino communities were chosen as the initial focus for this initiative. This document is the culmination of one of the goals of this initiative—the creation of a handbook to familiarize and guide investigators in the principles and applications of Community-Based Participatory Research. This document is focused on the issues related to the Hispanic/Latino communities.

The handbook is the product of the efforts of many individuals, both local and national. One on one interviews, conferences, focus groups engaging community leaders and examination of publicly available information were used to inform the development of the handbook. Implementation of CBPR projects requires both consistency and flexibility. Key guiding principles and processes can be standardized to guide researchers and community members in the development of community based research agenda.

The information presented in this handbook is intended to provide guidance for productive dialogue(s) among parties and should not be construed as the “final word.”

The handbook is, and will continue to be, a living document—flexible and dynamic in its organization and content in response to the evolution of partnerships and activities.

The existing document is a working draft developed as the initial best effort. We recognize that input from tribal and community leaders is essential prior to distribution in order to ensure that the document reflects the views and needs of the community. For this reason, we request your assistance as reviewers by providing your comments and suggestions for improving the current version.

SUMMARY OF RECOMMENDATIONS FOR ENHANCING COMMUNITY-BASED TRANSLATIONAL RESEARCH IN ARIZONA

BEST PRACTICES

- Establish a long-term commitment by all partners.
- Recognize and acknowledge the community as a valuable and contributing partner, and create the means for the community to participate in the research activities, and work to build capacity within the community for the mutual benefit of all partners.
- Facilitate collaborative, equitable involvement of all partners in all phases of the research and in decision-making regarding the research activities.
- Integrate knowledge and intervention for the mutual benefit of all partners.

KEY LESSONS FOR ARIZONA FOR THE ENHANCEMENT OF COMMUNITY-BASED PARTNERSHIPS WITH MEMBERS OF THE HISPANIC/LATINO COMMUNITIES

- Develop structures and processes that facilitate the trust and the sharing of influence and control among partners.
- Build the capacity of all partners for continued involvement in translational research
- Plan ahead for sustainability.
- Be inclusive on all decisions regarding the communication of project results.

INTRODUCTION

There is a health crisis facing Hispanic/Latino communities. The disparities in health status are staggering.

Hispanics/Latinos are almost twice as likely to have diabetes as non-Hispanic whites¹, may exhibit symptoms of Alzheimer’s years earlier than other populations,² are hospitalized more frequently for heart attacks than non-Hispanic whites³ and require different effective doses of some medications.⁴

Causes of such high levels of health disparities are complex—reflecting differences in lifestyle as well as a lack of access to quality and timely healthcare services for Hispanics/Latinos. In March 2002, The Institute of Medicine (IOM) published a report on healthcare disparities that made suggestions for reducing and eliminating these disparities.^{5,6} Based on this report, the U.S. Department of Health and Human Services (HHS) issued its report on National Healthcare Disparities in 2003 that, while minimizing some of the conclusions of the IOM report⁷, does discuss the complexity involved in solving the problem of health care disparity. “There are differences in the care-seeking behavior of patients, which vary due to differing cultural beliefs, linguistic barriers, degree of trust of health care providers, or variations in the predisposition to seek timely care. In addition, the availability of care is dependent upon such factors as the ability to

pay for care (directly or through insurance coverage), the location, management and delivery of health care services, clinical uncertainty, and health care practitioner beliefs, among others.”⁶

But addressing health care access alone will not fully address the problem of health disparities for underserved populations. As the HHS report further explains, there are “different underlying rates of illness due to genetic predisposition, local environmental conditions, or lifestyle choices.” In fact, there is a growing body of research on the complex interplay of environmental and genetic factors contributing to the health disparities for Hispanics/Latinos. For example, there is evidence of a genetic basis for the susceptibility to Type 2 diabetes for both Mexican Americans and Pima Indians.⁸ The existing evidence raises the possibility of finding populations-specific molecular targets (enzymes, receptors, substrates for new drug development).⁹

Similarly, differences are found in the causes of cardiovascular disease in Hispanics/Latinos vs. non-Hispanic whites.^{10,11} As a result, many Hispanic/Latino patients, in all likelihood, do not receive an appropriate cholesterol-lowering “statin” drug adequate for their needs.¹²

Even more revealing on the challenges to treating diseases found among Hispanics/Latinos is the different responses these population groups may have to standard drug treatments than whites.¹³ Hispanic/Latino

groups have different genetic profiles for drug metabolizing enzymes¹⁴ that can be affected by environmental factors and diet.¹⁵

This growing body of evidence linking environmental and genetic factors to differences in health outcomes suggests the significant value that translational research targeted to these underserved population groups can have in improving the detection, prevention and treatment of specific diseases that disproportionately affect Hispanics/Latinos. Application of lab based scientific breakthroughs to improved healthcare of individuals requires additional investigations that link the discovery to possible effects in humans. These iterative, progressive investigations are usually referred to as translational research. Translational research links the discoveries of the research bench to the development of better diagnostic methods, therapeutic products and preventive processes that improve healthcare outcomes. More specifically, translational research programs can help in understanding the contributions of the various factors to health disparities by addressing the following issues:

- Identification of genetic vs. environmental effects on disease etiology;
- Use of genetic and metabolic profiles to better the design and delivery of drugs and other treatment modalities for specific population groups; and

- Development of preventive medicine strategies and interventions to help minimize healthcare disparities.

But translational research targeted to Hispanics/Latinos can only be effective if performed within a research framework that considers the real world differences in culture, broader community needs, socioeconomic status, and structure of health care delivery for these communities. Defining this framework and putting it into practice is at the heart of developing a “community-based participatory research model” for Arizona.

DEVELOPMENT OF HANDBOOK

This handbook is a first step in helping to develop guidelines to inform the advancement of translational research within the framework of a community-based participatory research model in Arizona for Hispanic/Latino Communities.

The handbook is organized in five sections:

- **Section One** considers the Arizona situation in collaborations with Hispanic/Latino populations and the state of preparedness of the research community.
- **Section Two** provides an overview into the concept of Community-Based Participatory Research

- **Section Three** examines several of the best practices models and key lessons relevant to the Arizona situation.
- **Section Four** advances a framework for implementing Community-Based Participatory Research (CBPR) with model research codes and templates developed by other organizations (included in the appendices) to provide guides for further discussions and development of Arizona specific approaches.
- **Section Five** sets out recommendations for statewide activities to support the development of CBPR in Arizona.
- Be culturally sensitive and responsive to the needs of special populations that can be addressed by research as opposed to those projects that provide value only to the investigator.
- Create mechanisms that will enable researchers to develop and work in true partnership with special populations. Key mechanisms will include cultural sensitivity training, academic tenure policies, capacity building and revenue sharing policies.
- Increase both federal (and state) funding that is more responsive to specific goals of Community-Based Participatory Research.

The development of this handbook is an outgrowth of the Arizona Translational Research Pathway project sponsored by the Arizona Biomedical Research Commission and Flinn Foundation. A Work Group of translational research leaders engaged with underserved populations was organized to determine how Arizona could go about building a stronger foundation for collaborating with underserved population groups.

The Work Group began with a focus on determining the best ways to:

- Link the knowledge gained from research on environmental and genetic contributions to the development of more effective treatments for diseases based on gender, ethnicity and/or age.

The Work Group agreed that these goals were best accomplished within the framework of advancing “community-based participatory research” (CBPR) in Arizona on a statewide basis. This, in turn, requires that community representatives be actively involved in shaping the requirements and implementation of a tailored approach to community-based participatory research for Arizona. Although many institutions have made efforts to engage in CBPR, the first major initiative to engage community leaders in a coordinated, ongoing statewide program that would build a sustainable process for CBPR in Arizona is The Southwest American Indian Collaborative Network. This NIH funded project links the Intertribal Council of Arizona, The Arizona Cancer Center and the Phoenix Indian Medical Center with researchers from Arizona Universities and healthcare organizations to

address cancer health disparities among American Indians in the Southwest. This handbook is part of the process to assist the establishment of additional CBPR efforts.

Valuable guidance in the shaping and development of this handbook has been provided by community leaders in the Hispanic/Latino communities of Tucson and Maricopa County.

**SECTION ONE:
THE ARIZONA SITUATION**

To help set the stage for tailoring an approach to community-based participatory research for Arizona, it is critical to be guided by an understanding of the situation on-the-ground facing the research community and the Hispanic/Latino community. On the positive side, there is experience in researchers working with Hispanic/Latino communities to advance together disease-focused research that will develop more effective healthcare for members of the community. But the unique challenges of conducting translational research

for all parties involved emphasizes the need for a new compact to make community-based participatory research a reality in Arizona.

The following discussion summarizes the challenges involved in CBPR translational research and the views of each of the major participants.

Figure 1: Representative Efforts of Arizona Institutions to Engage in Translational Research with Hispanic/Latino Communities

Many institutions in Arizona have ongoing programs Hispanic/Latino communities. Active efforts include those summarized below:

Institution	Selected Initiatives/Projects Underway*	Approach to Improving Engagement
Sun Health Research Institute	Member of Alzheimer’s Consortium,	Designated liaison for community interactions Development of educational materials to assist community in providing healthcare for elderly members
TGen	Member of Alzheimer’s Consortium, work with Avondale to promote community health in Hispanics/Latinos, emerging partnership with University of Mexico/NIH	Leadership, financial commitment, on-the-ground community commitment, educational programs for community
Mayo Clinic Cancer Center	Works with Central Phoenix Health Organization (Hispanics/Latinos)	Leadership, financial commitment, dedicated liaison to link community with appropriate investigator
Barrow’s Neurological Institute	Works with Alzheimer’s Latino Medical Organization, member of Alzheimer’s Consortium,	Leadership, financial commitment, bilingual staff, works with caregivers, gives talks in community
Southern Arizona VA Healthcare System	Home Buddies for home based primary care Hispanics(/Latinos), Alzheimer’s and Diabetes programs (/Latinos)	Strong community involvement and volunteerism; home-based care intervention
Northern Arizona University	Numerous educational and training programs, economic development programs, environmentally linked research,	Institutional commitment; coordinating center for ease of access
University of Arizona	Center for Health Disparities, Diabetes Prevention and Control, Arizona Hispanic Center of Excellence, Promotoras program for community health workers	Coalition building; established community health workers organization; centralized assistance to faculty; shared services across projects; bilingual staff.

RESEARCH COMMUNITY SITUATION

Many Arizona biomedical research institutions are actively involved in translational research programs with Hispanic/Latino communities. Figure 1 (page 7) summarizes a few of the many activities ongoing in Arizona today. Many of these initiatives are promoting exciting innovations to improve the ways of engaging researchers and the underserved communities.

Problems and Barriers to Address

Researchers and their institutions continue to face significant complications to working with Hispanic/Latino communities.

From the perspective of the individual researcher, community-based participatory research is a time-intensive effort fraught with delays. In many cases, each researcher needs to establish their own relationship with the community. This often means learning as they go what it means to be culturally sensitive and responsive to the needs of the community. Typically it can be more than 18 to 24 months to project launch.

From the perspective of the research institution, Arizona's efforts in collaborating with underserved Hispanic/Latino populations are currently highly fragmented. No mechanism(s) exists to support the scale up of efforts or to learn from best practices. Newer entities trying to establish programs find that they are often less than successful due in part

to a lack of understanding of the complex issues involved.

Currently, Arizona institutions need to overcome:

- Disjointed efforts both among and within institutions. There is no system or infrastructure to help researchers and institutions in Arizona work together.
- A level of distrust in many Hispanic/Latino communities due in part to a lack of cultural sensitivity and true partnership on the part of investigators.
- Poor communication and dissemination of knowledge gained as a result of the research to the community.

The missing element in many efforts is a predictable, community-led effort to engage with the research community as partners in developing the research agenda.

TRANSLATIONAL RESEARCH WITH THE HISPANIC/LATINO COMMUNITIES OF ARIZONA

The term “Hispanic/Latino” refers to a highly diverse population.

Distinctions are found in national origin, immigration status, acculturation, socioeconomic status, educational level, English and Spanish language proficiency, dialect, skin color and other physical attributes,

political beliefs, geographic location (urban and rural) and cultural traditions. Not only can this diversity result in different dietary practices and preferences, research has demonstrated an altered genetic predisposition to some diseases.¹⁶

This diversity is mirrored in Arizona. The Hispanic/Latino community is not a single entity—communities that border Mexico have different issues than urban communities such as Tucson and Phoenix, which in turn vary among themselves including socioeconomic standing, educational attainment and cultural beliefs.

While many members of Arizona’s Hispanic/Latino population share strong ties with Mexico, other members of the community have ties to Latin America. In addition, there are significant differences between those members of the community who have been here for generations vs. recent immigrants, between rural, border communities and urban communities.

What Hispanic/Latinos share is a strong sense of community, strong work ethic, preservation of their cultural heritage, patriotism, political affiliation, religious faith, and shared experiences of prejudice and discrimination.¹⁷

Issues in Advancing Translational Research with Hispanic/Latino Communities

As one considers translational research in the context of the Hispanic/Latino community, the challenge of having a diverse community raises the key need to develop mechanisms to identify health care needs and address ways to engage the community as partners in their healthcare. While there are efforts underway to put in place these types of mechanisms, they are few and just emerging. Examples of such efforts include:

- The Healthy Avondale 2010 project is using a community-based “saturation” approach to improve health in the Hispanic/Latino community including an emphasis on cardiovascular disease.
- Use of Promotoras, or community health workers. These healthcare providers have no formal health training but are leaders among their peers in working with border communities. Promotoras have advanced community coalitions that truly listen and respond to community needs. They engage community leaders to direct programming and set priorities, including clinical trials to meet the needs of the community.

Initiatives to engage the Hispanic/Latino community must also consider language and cultural differences. Language is not simply the use of words, but how words are interpreted. Non-verbal communication (use of the hands for example) is very important in the Hispanic/Latino community. In addition, Hispanic/Latinos are non-confrontational and

are not likely to question or disagree with the doctor or investigator.¹⁸ Special care is needed to ensure that the concepts of community-based participatory research and use of healthcare resources are adequately translated, including an understandable explanation of complicated procedures and medication regimens. There also must be respect for and sensitivity to the specific culture of each Hispanic/Latino community. They are not all the same.

Many Hispanic/Latino communities have poor access to healthcare. Seeking to advance research without improving other aspects of healthcare provision will be resisted.

Initial discussions with Hispanic/Latino leaders in Tucson suggest that **community outreach must be central to any efforts to advance translational research among Hispanic/Latino communities**. This outreach should be comprehensive in nature, including:

- Involve front line providers, such as physicians, nurses, and clinics;
 - Connect with community groups, and organizing and/or contributing to events such as health fairs;
 - Provide explanations, in Spanish, of the clinical trials process and contributions to improved healthcare;
 - Develop specific support groups for caregivers, patients;
- Address special needs such as transportation that are barriers to participation in clinical trials and other aspects of healthcare participation;
 - Develop training programs and acknowledge participation. Provide encouragement and incentives for ongoing participation; and make a focused effort to include community representatives as reviewing and voting members of Internal Review Board committees. **IRB policies will need to respect cultural norms.**

SECTION TWO: OVERVIEW OF COMMUNITY- BASED PARTICIPATORY RESEARCH (CBPR)

The ABRC/Flinn Foundation Special Populations Work Group on Translational Research and Special Populations recognizes Community-based Participatory Research (CBPR) as the foundation for enhancing partnerships with Hispanic/Latino communities. This approach is used by several institutions in the U.S. to support programs with underserved, minority groups.

WHAT ARE THE GUIDING PRINCIPLES OF CBPR?

From discussions with and publications by national leaders in the field of CBPR, four key principles emerge as providing the basis of successful CBPR.^{19,20}

- **Long term commitment** to developing and maintaining trusting relationships of value to the communities.
- **Ongoing communication and support** for capacity building within the community is essential.
- **Cultural sensitivity** ensuring that the beliefs, customs, laws and other aspects unique to special populations and communities are respected and incorporated into any project on an ongoing basis.

- **A true partnership** involving the community in all phases of the project, including setting the research agenda, with an active, ongoing dialogue as the project is implemented. Community input into project design, implementation, data analysis and communication of results is essential to successful research projects.
- **Sufficient funding** for completion of the project and with focus appropriate to the needs of the community.
- **Continuation of successful care outcomes** with continued access to healthcare for participants in research projects.

Ultimately, the litmus test of CBPR is ensuring that the rights of community participants are respected and effectively embedded in the process. These rights include:

- Certain rights that are determined by law (for example—privacy rights through HIPPA; human subject protection; and state laws on healthcare guardianship, safeguards on personal/medical information).
- Projects/programs that provide benefit to the community.
- Institutional Review Boards that include community members and evaluate human subjects research in light of cultural norms.

- Respect as full partners in the research including input into design, evaluation and information prior to dissemination to external sources.
- Data collection and evaluation processes that accurately reflect the unique characteristics of the community.
- Agreement as to and acceptance of said agreements related to ownership of data and disposal of data and other contributions such as tissue and DNA. Some communities will not allow publication under certain circumstances and such research must be performed as a service to this community.
- Allocation of financial resources that recognize community contributions including indirect cost funds, Intellectual Property royalties, workforce/training funds.
- Hiring policies that support community participation in programs.
- Commitment to and sustainability of programs in order to provide benefit to the community.

DEFINING CBPR FOR ARIZONA?

While there is a national movement towards Community-Based Participatory Research, there is no single definition that fits all situations. National leaders in the field of CBPR have found that it is important to understand the historical

context and barriers facing a community in order to set out an appropriate definition for that particular situation.

To define CBPR for Arizona, the concept was discussed with Arizona research and community leaders using published definitions as a starting point.

For Arizona stakeholders, an effective working definition of CBPR is:

A collaborative partnership approach to research that involves community members, organizational representatives, academic institutions, state and local public health agencies, health care institutions, funding agencies and researchers in all aspects of the research process. The partners contribute their expertise and share responsibilities and ownership to enhance understanding of a given problem, “foster community and institutional capacity for participatory research at national and local levels” and “facilitate approaches for effectively translating community-based interventions in public health and prevention into widespread practice at the community level.”²¹

**SECTION THREE:
BEST PRACTICES: EXAMPLES
AND LESSONS LEARNED**

There are a number of examples of leading CBPR programs from across the nation. The focus of these efforts range from disease

oriented programs, preventive care programs, and more comprehensive research to health care programs.

Given the focus on translational research, the involvement of university partners is a central attribute, along with the many different funding partners involved.

Table 1 (below) sets out an overview of several of the leading programs found across the nation.

Table 1: Examples of Leading CBPR Programs Across the U.S.

	Partnership Characteristics	Project Orientation	Best Practices
Mature Programs	Extensive integration of research and community		
The Healthy African American Families Project, Los Angeles, CA	Integrates funding agency, community, university participants into a strong partnership with joint decisions and commitment on part of funding agency to be closely involved	Holistic approach to health care needs of community—prevention, intervention, extended care and social support	Hired from community Project was housed in community
Community Action Against Asthma, Detroit, MI	University and community united in addressing asthma in community	Project focused on positive interventions	Community members involved in leadership positions and hired as staff; community hired researcher
Johns Hopkins University, Baltimore, MD	Operates community health stations on reservations	Began by addressing healthcare problems/needs of the community (ex., newborn diarrhea)	Summer training program for youths from community. Hires and trains staff from community as outreach workers
The Midwest Latino Health Research, Training and Policy Center; University of Illinois at Chicago, Jane Addams College of Social Work	Established in 1993 by Aida L. Giachello, Ph.D., to improve the health state and the quality of health care delivery, including increased participation in clinical trials, to Hispanics/Latinos in Chicago and the Midwest	Has developed infrastructure to focus on areas that have received limited attention in Hispanic/Latino communities including chronic illness, injury, and maternal and child health	Implementation of capacity building, in the community; focus on targeted action; system and policy changes; coalition building with community, training of practitioners, researchers; development of cultural sensitivity guide
Emerging Programs	Early development invested significant time and effort in establishing relationships		
University of New Mexico	Community involved in all stages of planning including initiated contact with university in order to solve community-based problem of dental care	Expanded programs with specific support groups (ex., breast cancer)	University made commitment by convening partnership conference with representatives of underserved populations and the university to extend interactions
University of Washington	University wide initiatives rather than a focus on any specific population		University commitment to CBPR signaled with published guidelines for CBPR that have been endorsed by Dean and University president. University has centralized advisory committee to interact with community and coordinate communications. Have some funds flow through community organizations to signal partnership relationship

BEST PRACTICE LESSONS

Among the best practice lessons that emerge from these successful examples of CBPR are:

- **Establish a long-term commitment by all partners.** This is seen in the ongoing programs by Johns Hopkins University which began in the 1970's and continue to address specific healthcare problems that result in healthcare disparities among American Indian Tribes. Active demonstration of an interest in the needs and concerns of the community over a period of time is merely the first step in establishing a partnership. Developing a community-institutional partnership is inevitably a non-linear process involving many “starts” and “restarts.” Interaction with and participation in the life of the community must occur on an ongoing basis.

Community-based partnerships can not be rushed. Time plays a significant role in developing community partnerships and success may be defined differently for each stage of the process. Providing benefits to the community on multiple levels on an ongoing basis should be the prime definition of success. Early stages will be successful if the community begins to trust researchers and has the opportunity to communicate their needs and concerns. Later stage successes will include research projects that address the healthcare needs of the community and involve the

community in the process of meeting these needs.

Long term commitments must include funding resources sufficient to support initiatives and projects. It is highly important, therefore, to maintain close involvement of funding institutions/agencies. Funding agencies need ongoing participation in order to understand the progress and alterations that may be requested. Inclusion of the funding agency as a member of the team permits timely and necessary revision of protocols, timelines, and funding needs. This is shown in the Healthy African American Families Project that integrated the funding agency with other participants to ensure alignment of goals and expectations and in the work of Johns Hopkins University which provides institutional support in addition to external funding agencies.

- **Recognize and acknowledge the community as a valuable contributor, create the means for the community to participate in the activities, and work to build capacity within the community for the mutual benefit of all partners.** This is demonstrated in the Healthy African American Families project which identified key healthcare issues and possible causes, designed preventive measures and provided ongoing support to enhance the overall health of the

community. Social and cultural contributions are essential to the successful identification of health issues and implementation of preventive behaviors as well as therapeutic interventions. Without community participation and feedback, long term benefits will diminish over time. Hiring and training community members is found in all best practice institutions and embeds knowledge gained from the project into the fabric of the community to ensure ongoing application and interpretation of research findings.

- **Facilitate collaborative, equitable involvement of all partners in all phases of the research and in decision-making regarding the activities.** Recognizing the strengths and resources within the community enhances the caliber of the research project by incorporating community knowledge and expertise. This is shown in the emerging programs at the University of New Mexico that are based upon initial outreach from the community. Partnerships have been developed that jointly identify key issues and actions. Equitable involvement is also demonstrated by the Michigan project in which community members are an important part of the information dissemination process—often appearing as co-speakers at conferences and as co-authors on publications.
- **Integrate knowledge and intervention for the mutual benefit of all partners.** This

is shown in the work by Michigan University researchers and community leaders in Detroit, Michigan to enhance mechanisms for asthma intervention and ongoing support for patients. A second example is that of The Midwest Latino Health Research, Training and Policy Center of the University of Illinois – Chicago. This organization has focused on health issues for Hispanic/Latino communities that have received limited attention by healthcare organizations. Dissemination of key findings and knowledge to all partners provides a positive impact on the health of the community as seen in the prevention of newborn diarrhea in Native Americans resulting from a partnership between the tribal community and Johns Hopkins University.

WHAT IT TAKES TO ESTABLISH AND MAINTAIN COMMUNITY-BASED PARTICIPATORY RESEARCH EFFORTS

Existing CBPR programs can also provide guidance on what it takes to establish and maintain such programs. Based on a two year benchmarking project by The Centers for Disease Control (CDC),²² it was found that CBPR institutional partnerships differ by:

- Age and history.
- Type of research focus and mission.
- Levels and mechanisms of community participation.
- Staffing structures.
- Geography.

- Funding sources.
- Types of partners involved.

There is no one right way to address who should be invited to form or join a research partnership but it is very important that members have a prior history of positive working relationships. Newer members must be willing to abide by the rules and procedures of the ongoing partnership.

The CDC has recently produced a list of recommendations developed from surveying national leaders in the field of CBPR. These recommendations can serve as an outline for discussions by investigators and other participants to identify issues that could become barriers and potential methods of resolving them.

There are four key lessons of particular relevance for Arizona:

1. Develop Structures and Processes that Facilitate the Development of Trust and the Sharing of Influence and Control among Partners

Jointly create the mission, vision and priorities for the partnership and jointly develop partnership principles and operating procedures. As with any joint effort, there will be the inevitable conflict and tensions. Procedures and mechanisms based on mutual respect should be included in the initial plan to identify and resolve conflicts before they

become barriers to a successful community-institutional partnership.

Community involvement is critical, including participation in: the process of building a shared conceptual model of health and disease; the development of data collection instruments that are relevant, valid and culturally appropriate; data collection processes that enhance response rates and data quality; data analysis; the dissemination of findings and follow-up actions for incorporation of findings into community action.

These processes require researchers and community partners who are willing to approach problems from each other's perspective.

No one set of principles and procedures are applicable for all partnerships. While partnerships can build upon previous examples, all partnerships must engage in the process of developing, adopting and putting into practice their own principles and procedures that are tailored to the local culture and community context. Such principles and procedures should be reviewed periodically, changed as needed and "codified" for dissemination to new potential collaborators to ensure that any new projects affiliated with the partnership are in compliance.

2. Build the Capacity of All Partners

Develop and implement strategies for capacity building of all partners involved. Strategies should include striving to achieve and invest an equitable distribution of costs, benefits and resources among the partners. This can include the establishment and maintenance of on-site facilities; hiring of community members as staff; purchasing supplies; partnering with local businesses; and providing training, technical assistance, and continuing education to partners.

In addition, “capacity building and structural changes must occur at the institutional and funding levels so that funding agencies, ethics review boards, and university promotion and tenure committees are informed of and responsive to the necessity of the time needed for trust building, community entry, and the building of sustainable research relationships within an OCAP (ownership, control, access, and possession) era.”²³

3. Plan Ahead for Sustainability

Issues of sustainability need to be addressed at all phases of a partnership. Sustainability will require dedication and commitment on the part of both partners in terms of dedicated personnel, time and resources. A key contributing element of sustainability is the engagement of funding agencies to ensure ongoing financial resources. This can be approached by working with funding agencies to increase their understanding of and support for the benefits gained and the resources

required by this work. The partnership should routinely send partnership reports, papers, news clippings and other products to funding agency project officers and key organizational leaders.

4. Be Inclusive on All Decisions Regarding the Communication of Project Results.

Establish policies at the inception of the project concerning the communication of project results. The community must have significant input as to the use and communication of information resulting from the research project. A consensus among investigators and community must be established on many aspects of the communication process prior to any dissemination of results. Key decision points include: the interpretation and implication of project results, determination of which results are to be communicated to third parties, the identity of the third parties, and the extent of community participation in the communication of results and the choice of preferred medium of communication.

Successful community-institutional partnerships recognize the contributions of all members often including community members as authors and presenters of the information.

Long term benefits of the partnership can result from the dissemination and translation of research findings that lead to policy change(s).

Education of policy makers requires developing ongoing relationships with policy makers and their staff, developing a policy agenda for the partnership, and creating and disseminating policy briefs that reflect the key issues, findings and recommendations for action.

SECTION FOUR: FRAMEWORK FOR IMPLEMENTING CBPR IN ARIZONA

The objective of this handbook is to advance a framework in which Arizona can go forward in establishing statewide approaches to community-based participatory research with Hispanic/Latinos and other communities. As emphasized previously, the research agenda must be established with community involvement. Participatory research to fulfill this agenda requires attention to the procedural specifics that underpin translational research.

The key elements of the framework include how to address:

- Coordination
- Institutional Review Boards
- Patient Consent
- Data Ownership and Dissemination
- Biological Samples
- Intellectual Property
- Funds Flow

Below is a presentation of each of these specific elements based on discussions with Arizona-based organizations, a review of literature, and an assessment of best practice models.

We also set out key principles for the research community to embrace as they seek to work with special underserved communities.

A. COORDINATION

Why it is critical to implementation:

Coordination of research activities among institutions and with the communities involved is a critical differentiator in the success or failure of CBPR programs. Coordination in the CBPR is a cross-cutting need at all stages.

Key Issues Involved:

Members of the community are not interested in inter-institutional political battles.

A lack of coordination among institutions hinders 1) the development of more effective trusting community-based partnerships due to inconsistencies in the application of the principles of CBPR by various institutions and 2) the development of strategic long range planning efforts by research organizations and key state and community organizations.

Ongoing community outreach programs, on the other hand, do lead to a positive positioning of the institution within the community—a pre-requisite for successful CBPR projects.

Best Practice Guidelines:

- Establish advisory committees both at the institutional and statewide level to

formulate long term goals and plans for attaining them.

- Hire a dedicated community liaison to facilitate interactions between institutions and the community.
- Define (on a preliminary basis at minimum) roles, responsibilities, funds flow and communication plans among institutions prior to initiating dialogue with the community.
- Coordinate, communicate and educate all parties of the partnership via community outreach programs including attendance at healthcare fairs, presentations at schools, and use of community-based media.

B. INSTITUTIONAL REVIEW BOARD

Why it is critical to implementation:

Any research involving human subjects must ensure the safety of the individual. The federal government has adopted laws and procedures regulating federally-funded and federally-sponsored research to ensure that human subjects are protected. The trust necessary for successful CBPR projects is dependent upon an Institutional Review Board process that acknowledges the involvement of both the community and the individual in the research project.

Key Issues Involved:

IRB policies need to respect culture, language and other restrictions of the community. Hispanic/Latino communities have strong beliefs in community ties and benefits. IRB applications will need to discuss the benefit(s) of the research to the communities as well as to individual subjects. Data collection (biological and surveys) must respect the sensitivities of the community. As a result, guidelines related to storage, secondary use and disposal of

biological samples are likely to be more complex than many investigators are used to.

Best Practice Guidelines:

- Develop specific training programs for community members of IRB committees.
- Invest the time up-front to confer with community representatives in the preparation of an IRB application prior to submission.
- Include community as reviewing and voting members of IRB committees.

Include bi-lingual members of the research team to assist community IRB members in the proper evaluation of the application.

C. PATIENT CONSENT

Why it is critical to implementation:

Inadequate attention to obtaining truly informed patient consent is a major cause of distrust. In the case of research with tribal members, individual consent is only one step—tribal consent may also be needed. Attendant issues that are not discussed (time commitment, financial costs and compensation) may result in volunteers withdrawing from the study at a later date.

Key Issues Involved:

Language barriers can cause significant confusion –many concepts or disease conditions will not have a corresponding English/Hispanic/Latino term rendering the process of informed consent a difficult process. In addition, condescending behavior/attitudes on the part of the investigator can lead to reluctance on the part of the participant to ask questions resulting in a lack of consent or an uninformed consent.

Best Practice Guidelines:

- It is essential that this be a bi-lingual process that recognizes the difficulty of appropriate translation.
- Patient Consent materials must be developed with language appropriate to the target audience.
- Inclusion of family/community members in the process is important.
- Allow sufficient time for examination of the form and questions in order to increase the level of comprehension.

D. DATA OWNERSHIP AND DISSEMINATION

Why it is important to implementation:

The lack of inclusion of the community in data collection processes, analysis and communication is a major source of dissatisfaction with research projects and a violation of one of the key principles of CBPR.

Key issues involved:

Project design without involvement of the community often results in inappropriate instruments and incorrect data. Data evaluated out of cultural context has resulted in invalid and damaging conclusions that have not been communicated to the community and vetted prior to publication. In addition, project data has often been used for secondary, unapproved projects without permission of the community.

Best Practice Guidelines:

- Every case is different but it is *essential* to agree up front on issues related to data ownership, confidentiality and dissemination.
- Investigators need to take the time to obtain and include community feedback and revisions to ensure data interpretation includes cultural issues and subtleties.
- Investigators should also insure that the community understands the results of the research and its implications for their benefit. Provision of links to university, organization libraries will help knowledge transfer independent of specific individuals.

E. BIOLOGICAL SAMPLES— OWNERSHIP AND DISPOSAL

Why it is important to implementation:

Collection, use, and disposal of biological samples as dictated by the cultural beliefs of special populations is an area that is rarely addressed properly by investigators resulting in serious dissatisfaction (and worse) by research participants.

Key issues involved:

To members of many cultures, biological samples are not mere research reagents.

Storage and disposal of biological samples must respect the cultural beliefs of the community. In addition, secondary use of biological samples is viewed as a separate project and must be approved by the community in order to ensure cultural sensitivity.

Best Practice Guidelines:

- Biological samples include tissue samples, DNA, and other materials.
- The investigator needs to determine and negotiate ownership of these samples and the limitations and utilization in repositories, and secondary use and development of cell lines.
- The investigator also needs to understand cultural beliefs in the disposal of such samples.

F. INTELLECTUAL PROPERTY

Why it is important to implementation:

The creation of intellectual property (IP) from research activities is often considered a significant success of the project. While not all discoveries have commercial value, there is a significant level of effort required to identify, protect, manage and license intellectual property generated through research activities. In the context of translational research collaborations, the basic issues relating to intellectual property (disclosure, patenting, marketing/commercializing) are compounded by questions concerning the rights to share in IP generated among the collaborating parties. These rights to IP are closely linked with rights to data ownership and publication rights. The community has an ownership share in IP generated as a result of the CBPR research project.

Key issues involved:

Communities are interested in benefiting from research discoveries made through study of their populations. That interest in now extending to the commercialization of research discoveries. Community interests in controlling the release of information and the right to publish may at times conflict with the need to protect intellectual property. Policies dictated by funding source and the partner organization may result in barriers to some community-based research projects.

There is no short cut to negotiations related to intellectual property—an issue that is likely to become more and more complicated with increasing collaborative research projects. IP generated by research projects is usually owned or controlled by the funding agency. Research investigators and institutions may negotiate allocation of their shares (and their shares only) of the IP. The portion of Community-based ownership of IP is retained by the community.

While a coordinated effort among Arizona organizations to establish basic policies would be useful it is more reasonable to realize that negotiations will be needed on a case by case basis.

Best practice Guidelines:

Key issues for negotiation include:

- Inventor and institutional designation (a legal determination),
- Ownership and control of research data,
- The decision process for:

Utilization of intellectual property: assigning rights to third, not-for-profit entity, direct licensing to industry, and use as the basis for establishment of company.

Involvement in licensing negotiations, for example: distribution of royalties and/or equity.

Institutions may need to revise existing intellectual property policies in order to support CBPR projects.

G. FUNDS FLOW

Why it is important to implementation:

True CBPR partnerships are more likely to be successful with “open book” sharing of financial resources leading to some level of capacity building for the community. The ultimate goal of the research efforts must be kept in sight at all times to ensure that financial resources are utilized to the benefit of all participants in the project.

Key issues involved:

Projects will not be successful if the community believes that the research project has been developed only to acquire funding for and advance the career of the investigator.

Resentment from the community has resulted from projects where “the riches” were not shared. Control of funds by the research organization contributes to a perception of control and superiority by failing to communicate the use of research funds.

Best practice guidelines:

Investment of some funds to the community is an important component of CBPR as a sign of true partnership and a road to capacity

building. Administration of some awards through a community/tribal organization is one method of “sharing the wealth.”

Indirect Cost Determination and Distribution: any negotiation about the allocation of funds among partners may require alteration/revision of university policies.

Intellectual Property, Royalties and Other Revenues: allocation of revenues from intellectual property needs to be negotiated at the beginning of the project design; utilization of Intellectual Property may provide the opportunity to enhance business development by community members.

Procurement/Staffing: increased use of local business and employees may be a means of offsetting university-directed Indirect Costs.

SECTION FIVE: RECOMMENDATIONS FOR AN ARIZONA STATEWIDE APPROACH TO COMMUNITY- BASED PARTICIPATORY RESEARCH

Arizona can best advance a statewide approach to community-based participatory research by:

- Recognizing the rights of community members
- Addressing, statewide, the issues of coordination, funding, intellectual property, IRBs and patient consent, data ownership and distribution and biological samples.

RIGHTS OF COMMUNITY MEMBERS IN CBPR

Research investigators and participants in CBPR need to ensure that the community/participant is entitled to:

- Upfront negotiations and understanding by all partners on key issues related to the specific project;
- A valid project conducted by qualified investigators;
- Respectful treatment of samples and information;

- Periodic updates during and after completion of the project (if desired) on successes, failures and implications;
- Community involvement including the hiring of local members to be part of process when possible;
- Inclusion of community participants in presentations and meetings with funding agencies when possible; and
- Continued access to healthcare once the research period is over.

It is important for the investigator to remember that one of the returns for their investment in establishing true CBPR partnerships is the increased quality of their research as a result of community input into data acquisition and interpretation.

RECOMMENDATIONS FOR ARIZONA RESEARCH ORGANIZATIONS

In order to establish trust with Hispanic/Latino communities, Arizona research institutions would benefit from coordinated, consistent, standardized policies and procedures for a more reliable implementation of CBPR. With consistent base line procedures and policies, time and effort could be invested in more value added negotiations related to project specific issues. The following recommendations would contribute to the goal of statewide implementation of CBPR initiatives.

Coordination of statewide efforts

Establish a Statewide Advisory Committee to facilitate research/community partnerships

Each institution should consider designating a point person/office to facilitate team building and community interactions. When multiple departments/programs are involved with their own representatives—ongoing coordination and communication is essential to support community interactions.

Funding

Establish a pool of funding dedicated to CBPR projects for special populations

Research priorities are often set by funding agencies rather than community needs. Additionally, little funding is available for early stage projects in Community-Based Participatory Research yet it is the early stages that provide the basis for success or failure. A dedicated, ongoing statewide pool of funds that would require application of CBPR principles would provide the incentive and support and time to align research projects with community needs.

Institutional Review Board (IRB)

Develop a pool of Hispanic/Latino representatives that are available for consultations prior to submission of the IRB application.

The added complexity of IRB applications for projects involving Hispanic/Latino community members demonstrates the need to have a pool of committee members trained in both the technology and the cultural aspects of projects.

Development of a pool of representatives from Hispanic/Latino communities that would advise and serve on a statewide basis would be a valuable coordinating and communication resource. Overlapping terms for these representatives would provide consistency, aid knowledge transfer and accelerate the application process.

Intellectual Property

Historically, research subjects have not experienced immediate benefits from successful research projects. Therapies developed commercially from research projects may be inaccessible to members of special populations due to cost; the financial return on resulting intellectual property in the form of royalties does not find its way downstream. Consequently, members of special populations are revising their approach to ownership of intellectual property to more actively participate and benefit from commercialization.

Training for Research Community Working with Special Populations

Require that all researchers working with members of special populations utilizing

state funding support or conducting research at public universities take a training course.

Training of researchers in CBPR concepts is critical to achieve the required cultural mind set on the part of the research community. Training is an important element for building capacity and ensuring quality control. It may be useful to have such training provided by a third party, which can serve as a more neutral and honest broker of needs from both the researcher's and community's point of view. Identification of key qualifications for participation in CBPR projects would help identify those investigators best qualified to participate and lead sensitive research programs. In addition, *a dedicated residency program and/or qualified mentors* could provide relevant training to physicians and other primary care providers to better engage in research with special population groups.

Key elements of the training program are as follows:

1. Acquire a more holistic mind set

The investigator needs to recognize that communities are dealing with complex issues—many of which will not be solved by the investigator's research agenda. Within the broader social/healthcare context, the research project may not provide value to the community within the time frame expected (or at all). The investigator's funding/career is not the primary concern of the community and a research

interest does not automatically translate into value to the community. The balance between intellectual freedom and social responsibility with links between the research and healthcare policy is an important component of CBPR.

2. Gather the right team

Traditional research projects, not involving special populations, typically require only that the investigator research team be competitive for funding from federal and state agencies or foundations. This is not the case in working with special populations, where the community needs to be integrated into the research activity. As a result, investigators are not used to building teams with members from widely diverse areas of expertise. To participate successfully in CBPR, investigators will need to be more inclusive in their approach.

In order to understand the cultural, legal, social and regulatory issues, it will be necessary to perform a significant amount of due diligence prior to approaching the community. In addition, the complete institutional team is needed early in the process to a) facilitate this due diligence and b) assist in developing and negotiating the project plan. Team members could include research administrators, anthropologists, other social scientists, legal experts, and primary caregivers. Community representatives should also be included in early stages of project design and negotiations to ensure a successful project.

In all of this, investigators will need to recognize that *sharing of control and authority is a given*. Be prepared for iterative consent procedures for many aspects of the project—including such issues as manipulation of materials and secondary use of samples (viewed by many communities as a new study). Ongoing communication and management will also be significant time commitments in CBPR. When dealing with tribal governments, it may be necessary to renegotiate many issues when new members join the tribal council.

3. Use complete and clear language, not jargon

Experts in any area communicate with others in the field by jargon and technical terminology. Other team members and members of the community are not likely to be fluent in what is essentially another language. For example, “Standard procedures” does not provide sufficient information for the research participant to truly understand what is involved in the project. Use plain language and explain fully the concepts involved in the project.

4. Exercise cultural sensitivity

The beliefs and customs of each community must be respected in all aspects of the research project. Commit time to learn about the culture of the community and participate in community events in order to build a trusting, long term relationship.

Investigators need to take the time to obtain community feedback and revisions to ensure the project design and interpretation of results includes cultural issues and subtleties. One person’s “myth” is another’s deeply held belief. It is also important that the community understands the procedures and results of research and implications for their benefit. For example, significant educational efforts may be needed for some tests or procedures such as an autopsy.

Probe and clarify your assumptions. Members of the community are receiving their information from many sources. What you assume is common knowledge may not be so. Not everyone feels positively regarding the human genome project and other genetics research projects. Be willing to respect diverse opinions and question your own assumptions regarding the value of research to communities and healthcare.

IN SUMMARY

Translational research is the process by which basic science discoveries are advanced into new clinical operations leading to improved health care outcomes. It is increasingly recognized, however, that translational research is not a “one size fits all” endeavor and that certain populations are significantly underserved in the current approach to linking research and healthcare.

As an extension of the current Arizona initiative that seeks to enhance the contributions of translational research to healthcare, the Arizona Biomedical Research Commission and The Flinn Foundation convened a broadly representative group of major academic and research institutions and healthcare providers in Arizona to better understand how translational research can serve the needs of Arizona's Special Populations by improving and expanding the partnerships between their organizations and members of Arizona's special populations.

The group chose as their initial focus the advancement of collaboration mechanisms that establish community-based participatory research (CBPR) with initial concentrations on working with Native American and Hispanic/Latino populations.

The accomplishment of a key goal—development of this handbook to guide investigators in CBPR—is the result of work by and information from many individuals. The contents were developed by an investigation of national best practices as well as input from Hispanic/Latino community leaders.

This handbook is meant to serve as a living document and guide for developing a collaborative and productive dialogue with community members that will lead to interactions of benefit to both investigator and community.

ENDNOTES

¹ National Diabetes Information Clearing House, National Institute of Diabetes and Digestive and Kidney Diseases.

² National Alzheimer's Association, "Hispanic News" 2005.

³ Goff DC, Nichaman MZ, Chan W, et al. *Circulation* **18**: 1433–1440, 1997.

⁴ Reyes C, Van de Putte L, Falcon AP, Levy RA. Genes, Culture and Medicines: Bridging Gaps in Treatment for Hispanic Americans, The National Alliance for Hispanic Health. 2004.

⁵ *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*. Institute of Medicine, March, 2002.

⁶ National Healthcare Disparities Report. U.S. Department of Health and Human Services Agency for Healthcare Research and Quality. Rockville, MD, July 2003.

⁷ *A Case Study in Politics and Science. Changes to the National Healthcare Disparities Report*. United States House of Representatives Committee on Government Reform. January, 2004. Source: http://www.house.gov/reform/min/politicsandscience/pdfs/pdf_politics_and_science_disparities_rep.pdf

⁸ Genes, Culture and Medicines: Bridging Gaps in Treatment for Hispanic Americans, The National Alliance for Hispanic Health.

⁹ Sesti, G. *Pharmacogenomics J.* **2**: 25–29, 2002.

¹⁰ Haffner SM, Stern MP, Hazuda HP, et al. *Am J Epidemiol.* **123**: 830–839, 1986.

¹¹ Mitchell BD, Kammerer CM, Blangero J, et al. *Circulation* **94**: 2159–2170, 1996.

¹² See: Reyes C, Van de Putte L, Falcon AP, Levy RA. Genes, Culture and Medicines: Bridging Gaps in Treatment for Hispanic Americans, The National Alliance for Hispanic Health. 2004.

¹³ Bradford LD. *Pharmacogenomics* **3**: 229–243, 2002.

¹⁴ Lee CR, Goldstein JA, Pieper JA. *Pharmacogenomics* **12**: 251–263, 2002.

¹⁵ Mendoza R, Smith MW, Lin KM. In: *Cross Cultural Psychiatry*. New York: Wiley: pp3–16, 1999.

¹⁶ See: Reyes C, Van de Putte L, Falcon AP, Levy RA. Genes, Culture, and Medicines: Bridging Gaps in Treatment for Hispanic Americans. The National Alliance for Hispanic Health and the National Pharmaceutical Council, 2004.

¹⁷ See: Arizona Hispanics. The Evolution of Influence. 81st Arizona Town Hall, October 27–30, 2002.

¹⁸ Orlando Gonzalez, Presenter, Culturally and Linguistically Appropriate Healthcare Services for Latino Patients. (Webcast)

¹⁹ Examining Community-Institutional Partnerships for Prevention Research. Report of Findings and Recommendations. January 2004 CDC Prevention Research Center.

²⁰ *Community-Based Participatory Research for Health*. Minkler M, Wallerstein N. (eds). Jossey-Bass, 2003.

²¹ Examining Community-Institutional Partnerships for Prevention Research. Report of Findings and Recommendations. January 2004 CDC Prevention Research Center.

²² Ibid.