Universal Design Principles of
Community Based Participatory Research/Participatory Action Research
As applied to Bio-Medical and/or Genetics Research

BACKGROUND: WHY DON'T MINORITIES PARTICIPATE IN RESEARCH?

   Racial disparities in health outcomes and accessing health care have been documented extensively and for many years [1]. Similar evidence of racial disparities in accessing education and disability services and related outcomes has also been reported [2]. Corbie-Smith and colleagues point out that while federal agencies mandated that minorities be included in clinical research [3] they failed to listen to the researcher's ethical and scientific concerns over their ability to do this successfully [4, 5]. Furthermore, in a recently published review article on the ethnic diversity of 379 NIMH-funded clinical trials published between 1995 and 2004, Mak and his colleagues reported that despite the NIH guidelines requiring minority inclusion in federally-funded research, fewer than half reported complete race/ethnicity information on participants and all minority groups, other than African Americans, were underrepresented [6]. These authors and others [3, 7] argue that a widespread distrust of the research and medical community is potentially a significant barrier to assuring appropriate representation of diverse groups in the subject pool of major research programs. In addition, several socio-cultural barriers have also been postulated to explain the underrepresentation of minorities in medical research [8-13]; however, few of these reports are based on empirical research. With this limitation, some barriers which have been suggested have face validity, such as lack of awareness about research studies [14], fear of being used as guinea pigs [15,16], economic barriers [14, 17, 18], communication issues [14, 19], the failure to actively recruit certain under-represented groups for studies [13, 15], fatalistic attitudes towards diseases or conditions [20], negative attitudes towards study staff [21].

> While these studies focus on culturally-diverse groups, these findings likely have relevance for other under-represented groups who are not actively involved in the mainstream, such as individuals with disabilities and/or family members who may have limited education and limited resources.

In addition to addressing these barriers identified in the literature, we can also borrow from theories of behavior change, which argues that under-represented groups may agree to participate in research because they believe:

- It's the right thing to do
- It's their right
- Something good will happen
- Something bad will stop

Universal Design Principles for CBPR and PAR should include the following:

1. Information should be provided to maximize comprehension by potential subjects, regardless of their education and reading ability.
2. Information should be provided to address potential fears and misconceptions subjects may have, and to create a motivation or desire to participate.
3. Participation should be designed to have minimal "cost" to subjects (economic barriers).
4. Research activities should be planned to build a relationship between the scientific community and the community of beneficiaries, and facilitate a strong sense of trust in research and the scientific community.
5. Outreach to under-represented groups should be targeted and conducted by people from the community targeted.

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ISSUES IN AND STRATEGIES FOR IMPLEMENTING UNIVERSAL DESIGN PRINCIPLES IN BIO-MEDICAL AND GENETICS RESEARCH

1.   Information which is accessible, understandable, and meaningful creates trust and confidence in the research effort.

Common Problems:
The research community's "obsession" with human subjects protections, i.e., to reduce the likelihood of subjects agreeing to participate in research without full knowledge of the potential untoward results of the proposed research, frequently leads to complicated documents aimed at communicating with potential subjects and beneficiaries of research. These documents are characterized by:

A.   Text-dense communication documents.

B.   Documents which tell everything, omit nothing, say it more than once.

C.   Too much information – can't see the forest for the trees—heavy burden on the consumer to comb through the document to identify "What is essential to know?" so s/he can understand what is being communicated and/or make an informed decision.

D.   Different words used for the same thing in different documents (e.g., outreach material descriptions of procedures, may be different than how they are described in informed consent).

E.   Disclosure of information on all possible risks, without appropriate weighting of risks by probability and importance. In so doing, researchers inadvertently introduce fear or suspicion, diminish informed consent and prevent capable, potentially willing subjects from considering participation in research through what might be viewed as "excessive" disclosures.

F.   Organization of information is driven to demonstrate researcher's compliance with human subjects regulations, but not driven by the subject's need for information.

Possible Solutions: [Note: These suggestions have varying responses from IRBs. Work must be done nationally to educate IRBs to balance legitimate requirements for human subjects protections with the requirement to provide accessible, comprehensible information to human subjects and the beneficiaries of research]

A. Identify the most essential information. Avoid including non-essential information.
B. Use simple language. Overly simplified language actually can be problematic if important information is lost. Step 1 is crucial as a check to determine whether the essential information has been provided.
C. Use the active voice, not the passive voice.
D. Give information in different ways. Direct written communication may not always be the most effective way to communicate some information.
E. Utilize pictures which are accurate representations of the information you are trying to communicate.
F. Chunk information in groups of 1-2 concepts at a time. Long strings of concepts require a great deal of effort on the subject's part to understand everything that is being communicated.
G. Create audio-recordings of information and/or computer-based interactive information that describe the research. This helps with people who have limited reading ability. At the same time, this group may also not have internet skills or a computer. However, if this set-up is available with a research recruiter who can help them, this would be an effective way to recruit subjects and walk them through informed consent.
H. Use the same words and pictures in all documents—e.g., recruitment materials, informed consent, consumer-friendly research findings.
I. The length of the information document is not as important comprehension as how the information is organized.

Example: AGRE Brochure and FAQs, before and after modification.

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2.   Information and communications with research beneficiaries should build trust and create a motivation or desire to participate.

Common Problems

Many researchers expect subjects to participate for altruistic reasons or assume that subjects value research as much as they (the researchers) do. They also assume that because they are highly educated and experts in their field, subjects should trust them. This is especially prevalent in the hard sciences. Many potential subjects who are under-represented in research do not know what research is, let alone how it impacts their lives, nor do they fully understand why they should participate in research when they have other more pressing issues to deal with. As for the trust issue, it is hard for individuals to trust someone they have no contact with and to trust someone they cannot understand.

Possible Solutions:
   A.   Pre-Recruitment Relationship Building.
       1)   Spend time meeting and understanding the targeted population, to identify their fears, misconceptions, and what will motivate them to participate. Go to their meetings, their support groups, their events as a visitor. You don't need to speak (unless it's requested). Tell them you just want to get to know them. Many groups will be honored that you came just to get to know them.
       2)   Organize educational events which highlight researchers from the project. These researchers will need assistance to "translate" their talks into consumer-friendly language. Again, they will need assistance to cover what the audience wants to know, not necessarily what they would provide to an audience of their peers.
   B.   Research Ambassadors. Budget for a part-time research ambassador from the community you are targeting. We suggest you utilize someone who works for a community-based agency so they already have a large sweep of connections. The individual will need to be bilingual (as most information will be in English), and bicultural if at all possible. It is not clear whether a person with higher level training, such a graduate student would be as good or better than a community worker (who may have a steep learning curve). Depending on the qualifications of the individual in this position, their responsibilities may vary.

> 1) Community outreach and recruitment worker will focus on organizing events and inviting participants where research staff will explain the nature of the research. This individual is likely to be more successful in getting potential subjects to attend recruitment and informational sessions than someone who is not from the community.
>
> 2) A bilingual/bicultural research staff person would be able to explain the research to potential subjects.

C. Give gift cards to people attending research information and recruitment sessions. Most under-represented groups also have limited income, so economic barriers are very real, even if they may be interested.

> 1) There is a great debate that providing monetary incentives to participate in research is "coercive" for low-income groups who may do anything for the money or tangible reward offered. This concern must be balanced with the reality of economic barriers for subjects who may be potential subjects.

D. Post-Research Follow-Up. Giving back to the community after the research is done.

> 1) Organize educational events where researchers share information about research which has already been conducted, which may have relevance for the population you are targeting. Too often communities never hear back from scientists about the research they participated in.
>
> 2) Develop and disseminate consumer-friendly educational materials which are easy to understand. This is part of relationship building.
>
> 3) Continue to go back to the community even when you are not recruiting for a current project. You may need to come back in 2-3 years and they won't have forgotten you. It's all about relationship!

Unresolved Issues:

1. Most research budgets do not budget for these Universal Design Features arguing that there isn't enough money for the research itself. Increasingly, federal grant makers are requiring partnerships with community and more representative subject pools so the research is more generalizable.

2. We are utilizing Fiesta Educativa, a community-based education, information and referral organization for Latino families who have children

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with disabilities as our community partner for our NIH Partners in Research Grant. Their role is to help the project do outreach and recruitment for study activities. However, the Director of Fiesta was required to be certified in human subjects protections. We are not clear as yet, whether we can provide a modified Human subjects training to her outreach workers who are the Research Ambassadors for the project. While we agree that some training/certification is needed by all entities who have contact with potential subjects, we are in the process of modifying the NIH Human Subjects online course, to respond to the information needs of community partners who participate with researchers.

When implemented correctly, this principle intrinsically builds trust between research subjects and the beneficiaries of research and the research community, which is perhaps the most important principle of universal design in research.