

## Who is going to be in my study? Engaging Minority & Vulnerable Populations in Clinical Research

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## Who are the minority & vulnerable populations?

- Children
- Decisionally-impaired
- Economically disadvantaged
- Pregnant Women, Fetuses & *in vitro* fertilization
- Prisoners
- Subordinate individuals
- Under-represented populations/communities

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## Why engage under-represented populations into clinical research studies?

- **It's a matter of representation!**
  - US and local population demographics
  - "Equal opportunity" approach

### NCI Cancer Trials:

- Overall US population participation = 1.7%
- African American participation = 1.3%
- Latino/Latina participation = 1.3%

Data from Murthy et. al, JAMA 291 (22) 2720- 2726: NCI Cancer Trials

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## Why engage under-represented populations into clinical research studies? (con't)

- **It's the law!** Mandated by Congress, 1993 PL 103-43
  - Women and Minorities must be included in all clinical research studies.
  - Women and Minorities must be included in Phase III clinical trials & the trial must be designed to permit valid analysis.
  - Cost is NOT allowed as an acceptable reason for exclusion
  - NIH to support outreach efforts to recruit and retain women, minorities, and their subpopulations in clinical studies.

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## Moving beyond traditional recruitment methods ...

While data is important ....

You will need **people** to get the data.

Therefore, plan in advance:

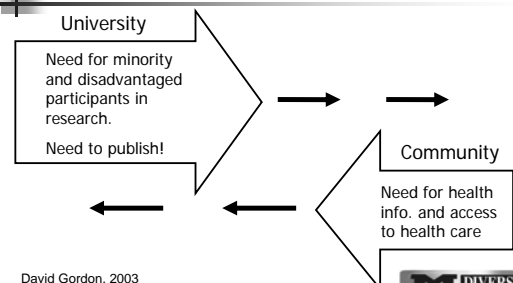
- **Who will be in my study?**
- **What type of study would benefit the community?**

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## Research Community & Under-represented Community Disconnect: Is there mutually beneficial common ground?



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## Barriers to participating in research

(information obtained from local community focus groups & literature search, UMHS Minority Health Research Program 2002-03)

- Suspicious of clinical research and PI intentions. Who really benefits? "Helicopter Research"
- People want access to health care, health education and health screenings not research.
- People want PIs to be concerned about all of their medical concerns not just the organ in the study.
- People and community groups want to participate as colleagues and equals.

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## Barriers to participating in research

(information obtained from local community focus groups & literature search, UMHS Minority Health Research Program 2002-03)

- **Accessibility of the study**
  - Transportation
  - Child care
  - Work schedule
- **Comprehending the study**
  - What study?
  - Don't understand the study or the informed consent process

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## Informed Consent



- Make it easy to read and understand!!!!
- 6th grade - 8th grade reading level.
- Just because someone reads it and signs, does not mean they understand it.
- Use creativity! Explain study using methods such as: talking with participant, showing videos, cards, other visual methods.

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## The Belmont Principles

- These principles will serve as your guide for recruitment & retention of research participants:
  - **Respect** for people by recognizing their autonomy and protecting those with diminished autonomy.
  - *Primo non nocere* (first do no harm) and maximize potential benefits and decrease potential harms.
  - Are the research costs and benefits distributed equally?

Paraphrased from Belmont Report <http://ohsr.od.nih.gov/guidelines/belmont.html>

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## Recruitment & retention guides

- **Remember history**
  - Three levels of hx: US, healthcare disparities and research experience.
    - Tuskegee Syphilis Study, 1932 -1972
    - Birth Control Pill Testing in Puerto Rico, 1960's
    - Pima Indians & NIH Diabetes Study in Arizona, 1965-1995, 1996-1999

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## Recruitment & retention guides (con't)

- **Exceptional service**
  - UMHS is big & overwhelming place!
  - Best study coordinators provide hands-on and clinic to clinic service.
- **Sensitivity**
  - UMHS is a tertiary care center. Or as one person told me "that is where you go to die!"
  - Use layman's terms not clinic terms.

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## Recruitment & retention guides (con't)

- **Patience**

- It takes a long time to build relationships and trust and thus recruit and **retain** participants.

- **Equality & Engagement**

- Treat every participant in your study as your equal. Remember all of us are experts in our lives, our health needs, and community's needs.
- Learn from & care for each of your participants and their families and their lives.

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## Recruitment & retention guides (con't)

- **Cultural Competency & Sensitivity**

Complex combination of knowledge, attitude and skills with regards to gender, race/ethnicity, religion, SES, sexual orientation.

Lynch E. & Hanson, M. *Developing Cross-Cultural Competence: A Guide for Working with Young Children and Their Families*. Paul Brookes Publishing Co., 1992

- <http://gucchd.georgetown.edu/nccc/>
- <http://www.med.umich.edu/multicultural/ccp/index.htm>

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## Recruitment & retention guides (con't)

- **Trust** is built by:

- Open and honest communication.
- Good and positive interactions.
- Staying for the long term and giving back:
  - Study updates via newsletters or email.
  - Study was a benefit to the community.
  - What really happens when the study is over? What is your commitment to staying?

- **Trust is so hard to gain and so easily lost!!!**

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## So what does this all mean?

What you must do is give **RESPECT** to the participants in your study!

- Remember history
- Exceptional service
- Sensitivity & staying for the long term
- Patience, patience, patience!
- Engaged and connected to the person
- Competency working with diverse populations
- Trust is earned ... and easily lost!

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## Research community & under-represented community disconnect: Common Ground

University

- Health care information on relevant topics
- Health care triage information
- Education about where research is needed and partnership in research design
- Community participation in mutually selected projects
- Feedback to community on results of research

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## Who are and how do we recruit the vulnerable populations?

- Children
- Decisionally-impaired
- Economically disadvantaged
- Pregnant Women & Fetuses
- Prisoners
- Subordinate individuals

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## Children

- Speak directly with child! Eye to eye!
- Watch your body language ...children observe everything!
- Children = families. Work with families on their terms.
- Explain the study and what will happen in the study in understandable terms.

• "Celebration of children."  
Personal communication, D. Ruzicka, 2006

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## Decisionally-impaired

- Be clear on what is treatment and what is research.
- Decision-making capacity is a broad spectrum based on condition and situation.
- Ability to make decisions can fluctuate - need to have on-going consent.

Research Involving Individuals with Questionable Capacity to Consent: Points to Consider, NIH, March 11, 1999

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## Economically-disadvantaged

- Level of payment could be seen a coercion.
- Basic life needs come first! How can being in your study be a benefit to the participant?
- Transportation: taxi cab vouchers?
- Child care: provide a place for the participant's child(ren).

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## Pregnant women & fetuses

- Informed consent must include impact on both the woman and the fetus.
  - If research provides direct benefit to the woman, only her signature is required.
  - If research offers direct benefit to fetus, signature of mother & father required.
- How can being in your study be a benefit to the the woman/fetus?
- Transportation: taxi cab vouchers?
- Child care: provide a place for the woman's child(ren).

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## Prisoners

- Clear rules and regulations which guide prisoner research.
- Work with your IRB closely! IRBMED does have a prisoner advocate.
- Keep in mind:
  - Informed consent must be obtained without coercion.
  - Avoid confusing access to healthcare with clinical research.

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## Prisoners

<http://grants.nih.gov/grants/policy/hs/prisoners.htm>

1. The proposed research meets the requirements for one of the categories of permitted research;
2. Any possible advantages or compensation to the prisoner for participation in research, when compared to the general living conditions and opportunities in the prison, are not so great that they impair the prisoner's ability to evaluate the risks and benefits of the research in the limited choice environment of the prison;
3. The risks involved in the research are commensurate with risks that non-prisoner volunteers would accept;
4. Procedures for the selection or recruitment of subjects are fair to all prisoners and cannot be arbitrarily influenced by prison authorities or prisoners. Unless the PI provides the IRB with written justification for following other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
5. The information is presented in language that is understandable to the subject population;
6. Adequate assurance exists that Parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
7. When the IRB deems it necessary, provisions have been made for follow-up examinations or care after for participants after the end of their participation, taking into account the varying sentence lengths, and participants will be informed of this fact.

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## Subordinate individuals

- The relationship to the PI could be seen a coercion.
- Research recruitment and retention must be voluntary. Decision not to participate should not negatively impact relationship.
- Examples of:
  - Professor (PI) with college students
  - Supervisor (PI) with staff

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## People of color



- Be an active member of the community!
- Ask/listen for the important health issue(s).
- Ask for community input during the study design, implementation, and results.
- “Give back” based on community needs.
- Stay for the long term; avoid “helicopter research.”
- Translate study documents and have someone who can speak the language.
- Citizenship status.

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## When recruiting participants, remember kindergarten rules!

Give **RESPECT** to the participants in your research study!

- **Golden Rule:**  
Do unto others as you would like done unto you.
- **Platinum Rule:**  
Do unto others as they would like done unto them.

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## Additional Information

1. Literature Sources
2. Web Resources

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## Literature Sources

Beasley D. **Common barriers to enrollment can be overcome by using targeted recruitment strategies.** Applied Clinical Trials. June 1 2006. <http://www.actmagazine.com/appliedclinicaltrials/>

Israel BA, et al. **Review of Community-Based Research: Assessing Partnership Approaches to Improve Public Health.** Annual Review of Public Health. 1998. 19:173-202.

Kalfoglou A, Boenning D. **Exploring Public Confidence in Clinical Research,** Journal of Investigative Medicine. 2000. 48 (6): 393-394.

Swanson GM, AJ Ward. **Recruiting Minorities into Clinical Trials: Toward a Participant Friendly System.** Journal of the National Cancer Institute. 1995. 87(23): 1747-1759.

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## Federal Gov't: Special Populations Health Statistics Web Sites

- <http://www.iom.edu/CMS/18007.aspx>
- <http://childstats.gov/>
- <http://www.cdc.gov/nchs/fastats/>
- <http://www.omhrc.gov/>
- <http://www.cdc.gov/nchs/otheract/grants/minpop/minpop.htm>

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## NIH Resources on Special Populations

- <http://grants.nih.gov/grants/policy/hs/populations.htm>
- <http://grants2.nih.gov/grants/funding/children/children.htm>
- [http://grants.nih.gov/grants/funding/women\\_min/women\\_min.htm](http://grants.nih.gov/grants/funding/women_min/women_min.htm)
- [http://grants.nih.gov/grants/policy/hs/faqs\\_applicants.htm](http://grants.nih.gov/grants/policy/hs/faqs_applicants.htm)

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## Resources on Information for the Protection of Human Subjects

- <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>
- <http://ohsr.od.nih.gov/guidelines/nuremberg.html>
- <http://www.hhs.gov/ohrp/>
- <http://ohsr.od.nih.gov/>
- <http://www.med.umich.edu/irbmed/research.htm>
- <http://www.cisr.org/>

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## Recruitment & Retention guides....

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- Sensitivity & staying for the long term
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