MINORITY INCLUSION IN CLINICAL RESEARCH:
Techniques for Recruiting a Diverse Sample

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- women and minorities **must** be included
- cost **NOT** an acceptable reason for exclusion
- NIH obligated to support outreach efforts to recruit and retain women, minorities, and their subpopulations in clinical studies
Can researchers comply?

Barriers and challenges
Barriers to recruitment: Concerns of potential enrollees

- history of clinical research—Tuskegee, Sims procedure

- failure of trust—suspicion of MDs & medical system

- fear of consequences, especially if undocumented

- burdens of participation, especially if low income

- unclear benefits of participation, if no sub-analysis
Advertising a study: Potential barriers to recruitment

- PI may be unfamiliar with neighborhood info channels like media, churches, grocery stores, advocacy groups.
- PI may lack personal contacts such as community leaders, outreach workers, social workers, probation officers.
- PI may experience language & cultural barriers, even a study name may resist translation.
On-Site Enrollment Challenges

- Profiling problem
  - Patients may feel singled out for screening
- Privacy problem
  - Waiting room versus bedside
- Trust issues
  - Staff skills: engagement and rapport
- Language barriers
Literacy & Limited English Proficiency (LEP)

- reading & writing: forms to fill vs oral interview
- medical literacy: the medical knowledge base
- spoken English proficiency
- LEP: data accuracy is affected
  - across generations (using family)
  - with untrained (unrelated) interpreters
  - with trained interpreters
Strategies to address challenges
NIH recommendations

- hire minority staff
- collaborate formally with minority communities
- identify communication channels prior to initiation
- reimburse adequately & provide transportation
- address cultural beliefs, ie involvement of family
- work with institutions around CLAS standards
- pilot instruments and procedures for validity and acceptability among minority populations
- monitor data for differences in enrollment & f/u rates
Project Link: Brief Motivational Interview in the Clinical Setting To Reduce Cocaine and Heroin Use

- 23,669 patients screened 5/98-11/00
- 1232 eligible
- 1175 enrolled (95% of eligible)
- Composition: 62% Black, 24% Hispanic, 14% white
- 82% follow-up rate

Bernstein et al. Drug & Alcohol Dependence, 2004;77:49-59
The Job Description for LINK
Characteristics of Peer Research Assistants

- recruited from the communities we serve
- people skills -- warmth, enthusiasm and confidence
- flexibility -- adaptability to clinical setting
- team approach -- work well with clinic staff
- detail-oriented for data quality & completeness
- bilingual
- people in solid recovery encouraged to apply
Staff Training to Promote Recruitment

- establishing rapport, and asking permission
- human subjects protections and informed consent
- scripted introduction of study
- check list for consent
- adherence monitored by audio/video tapes of role plays and direct observations of screening and informed consent process
Project Link: Recruitment Logistics

- screen administered face to face by bilingual peers
- eligibility questions embedded in health survey
- privacy assured (in office at UCC & exam rooms)
- everybody got something
  - survival guide (info & resources)
  - reimbursement for time and effort
  - appreciation meals provided during study
- co-PI worked on site
- clinic staff oriented to study but did not refer
- no delay or interference with patient care
Studies in Progress

Project RAP (Reaching Adolescents for Prevention)
- a randomized, controlled trial of a peer intervention to reduce drinking, marijuana use and associated consequences among 14-21 y.o. BMC Pediatric ED patients
  (NIAAA Youth Alcohol Prevention Center)

Project Safe
- a randomized controlled trial of a peer intervention to reduce the rate of sexually transmitted diseases among ED patients who use heroin and cocaine (NIH, NIDA)
Recruitment Lessons Learned

- Community participation promotes peer research staff recruitment.
- Peer researcher and the community in-reach model may lead to greater minority inclusion and enrollee trust and participation.
- Active collaboration with clinic staff and space are critical to facilitate patient access and recruitment.