NIMH
National Institute of Mental Health

Points to Consider about Recruitment and Retention While Preparing a Clinical Research Study

The following "points to consider" are meant to serve as a resource as investigators plan a clinical research study and an NIMH grant application. These "points" outline common issues that can impact clinical recruitment and retention, and where applicable, strategies are suggested to address these issues. This document is not meant to serve as a "cookbook" of strategies that will assure successful recruitment and retention, but is meant to provoke thought and discussion. Naturally, each study will have to be tailored to suit the needs of the potential participants, investigators, research institutions, and communities. NIMH hopes that this document will help prepare researchers to address recruitment issues in advance so that the researchers will conduct a successful study while building positive and lasting relationships with the community.

Points to Consider	Examples/Suggestions
Community Engagement • Have you identified the communities that you would like to engage? • What relationships have you established with communities in order to facilitate your study? What relationships will you need to establish? • How will you maintain these relationships? • What strategies will you use to engage different communities before and during your study? • What efforts has your University/Research Institution made in the past to engage these communities? Are there any ongoing collaborations/partnerships at your institution? • What will the participating communities receive in return for their involvement in the study?	**Examples of communities**: Potential participants and their family members, referring physicians, community-based organization directors, state mental health directors, civic organizations, advocacy organizations, faith-based organizations, churches, community centers, health clinics, and the media. **Suggestions**: • Establish relationships with people in the communities that you would like to engage for your study. • Establish a community-based research advisory board to facilitate the planning of your research project. Work with an established board, if it already exists. • Consider using qualitative focus groups to assess the needs and preferences of potential participants. • Develop plans to share the study results in formats most useful to the different communities involved, including participants, families of participants, consumers, and referring practitioners.

	Dissemination of information will be facilitated if there is sufficient diversity within the community-based research advisory board. • Utilize the NIMH Outreach Partnership Program: a network of organizations, departments or agencies independent of NIMH that conducts mental health outreach and education for the public using mental health-related information provided by NIMH or other sources. See a list of Outreach Partners at: http://www.nimh.nih.gov/outreach/partners/partners.cfm
Benefits to participation • What are the benefits to enrolling in this clinical research study, from the perspective of potential participants? How will you determine these benefits? • Does the study design include assessment/treatment strategies that are likely to foster enrollment and retention?	**Suggestions:** • Work with communities through focus groups, interviews, and surveys to develop a list of benefits (as well as barriers, see next item) to participating in the research study. The list of benefits can be communicated to potential participants, and specific benefits can be emphasized when speaking to different audiences. • When communicating with patients, you might emphasize that the study aims to improve our understanding of and treatments for a disorder. When speaking to family members, you could explain that the study will not require a patient to change his/her current treatment program.
Barriers to participation • What are the barriers to participation? • How will you prepare to address each of these barriers? • Will all study costs be covered for the participant? Is there a way to reduce any costs? • Have you considered the language requirements and literacy of proposed participants? • Are you familiar with how English is used by different racial and ethnic groups?	**Examples:** • Participant barriers: time off work, transportation costs, childcare, care for an elderly relative, language differences, out-of-pocket expenses, not wanting to change current medical treatment, not wanting to change physicians, concerns about medication side-effects, limited health insurance reimbursement, mistrust of medical research, fear of stigma associated with a disorder/disease, etc. • Investigator barriers: lack of diversity on the research team, research teams lacking knowledge about the communities chosen for inclusion, ineffective guidance to study staff, recruitment based on convenience, ineffective informed consent processes, limited knowledge about methods to promote a study, limited knowledge of appropriate retention methods, etc.

	Suggestions: • Create an FAQ sheet addressing potential concerns in order to clear up misconceptions. • Prepare recruitment documents using the first language of the target populations, such as Spanish. Take into consideration that the Spanish language differs between countries, thus translation must be performed by an individual who is familiar with the target community.
Informational materials • Have you designed your informational/study materials for your intended audience? • Have you considered working with community organizations that could help prepare, design, or distribute informational/study materials? • Will study materials (consent forms, study instruments) account for different levels literacy and cognitive abilities?	**Suggestions:** • NIMH has templates for the design of different types of informational materials (letters, newspaper articles, public service announcements, etc). Also available are print and electronic educational resource materials (booklets, fact sheets) about different disorders, which can be provided to potential participants and families. Contact the NIMH Office of Communications at http://www.nimh.nih.gov/oc/index.cfm • Use clear and simple language in informational materials. • Provide all materials in the first language of target populations. Besides NIMH resource materials, NIH has health information resources from all institutes (http://www.nih.gov/ as well as MedlinePlus in English (http://www.medlineplus.gov/) and Spanish (http://medlineplus.gov/spanish/).
Planning and Timeline • What is a realistic recruitment timeline? • What is your timeline for protocol finalization, IRB approvals, development of treatment materials or experimental methods, piloting, staff training and certification, development of data collection instruments and systems, tools for quality control, acquisition of treatment products and matching placebo, etc.? • Do you plan to match resources to recruitment over the lifespan of the grant (i.e. funds, personnel)? •	**Suggestions**: • Rebounding from recruitment shortfalls can be difficult as a study progresses. Thus, detailed planning of all aspects of study design and implementation is critical to the success of the study. • Personnel effort should be adjusted accordingly during periods of high/low recruitment. • Prior local studies may provide parameter estimates of the percent of eligible participants.

• What resources will be required to retain participants after the recruitment phase is completed? • Have you considered using available local data to generate enrollment/retention estimates that are as accurate as possible?	A Recruitment timeline considers the following critical time points: • Enrollment start date • Enrollment end date • Intervention completion date (date last person will complete study intervention if patient completes the full protocol) • Data lock date (date when all data have been entered, queries resolved, data ready for analysis) • Paper Finalization date (date when outcome manuscript is ready for journal submission)
Recruitment Strategies • What mechanisms will you use to encourage recruitment? • Will you need different recruitment strategies tailored to different racial/ethnic populations? • Do you have a Public Affairs or Media Relations Department at your university that can help you to promote the study to your local media and community? • Does your Public Affairs or Media Relations Department have connections to all of the communities chosen for the study? • Do you have a detailed and piloted plan for community outreach for each group chosen? • How long does it take your IRB to review and approve advertising? • Will you have a dedicated telephone number and/or email address for potential participants to learn more about the study and a response system in place? • Have you determined if there are conditions in the local community that might affect participant support of your project (e.g. the effects of numerous studies and over-sampling, or community activists seeking to influence research projects)?	**Recruitment tools:** Radio ads, newspaper ads, flyers, newsletter articles, FAQ sheets, web sites, public service announcements, press releases, letters to the editor, Op-Ed articles, interviews on TV or radio, etc. For samples of these recruitment tools. Contact the NIMH Office of Communications at http://www.nimh.nih.gov/oc/index.cfm. **Suggestions**: • Match the recruitment tool to the target audience (potential participant vs. caregiver vs. community referral source) and conduct pilot tests. • Make sure all staff who communicate with potential participants receive proper training. • Enter information about your clinical trial on ClinicalTrials.gov. See the NIMH web site on clinical research resources: http://www.nimh.nih.gov/studies/researchers.cfm

Retention Strategies • How will you retain participants? • How will you monitor retention?	**Suggestions**: • Communicate your long-term commitment to the individual and community. • Clearly explain to participants the requirements of the study. For example, "I will need you to see you again one year from now. What is the best way for me to contact you?" • Be flexible when scheduling appointments. • Obtain several phone numbers (home, work, cell) for participants so that you can follow up with them easily. • Send participants small tokens of appreciation that will remind them of the study: birthday cards, refrigerator magnets, pens, etc. • Send out newsletters that report the progress of the study. • Provide services for the participant separate from the research study. • Report research results in formats most useful to the different communities involved, such as participants, families of participants, and referring practitioners. For participants, explain how the findings may ultimately improve their health. To accommodate the busy schedules of health care practitioners, provide a handout that summarizes the findings more succinctly than a journal publication.
Diversity • Do you have realistic recruitment and retention strategies for all populations, especially participants with diverse ethnic, racial, and socioeconomic backgrounds? • Do you have an adequate mix of ethnic, racial, and economic diversity in your community from which to recruit participants? • How do you plan to recruit different racial/ethnic populations? • Do the backgrounds of senior study staff reflect the diversity of the communities that you wish to engage for participation in the study? • Are you training your staff to be sensitive to cultural, racial, and ethnic differences?	**Suggestions:** • Research staff should reflect the diversity of the groups desired for enrollment. For example, staff should represent diversity of racial/ethnic background, language proficiency, and cultural knowledge, in addition to diversity of scientific discipline and research experience. • Establish relationships with respected members of the communities chosen for inclusion. • Work with a representative/liaison of specific communities to obtain ideas for enhancing communication. • Work with local churches, community centers, Spanish radio stations, etc. • Offer all study materials in relevant languages.

• Are you aware that some communities are mistrustful of medical research? How do you plan to address these concerns? • Will your research team work with peers who are knowledgeable about the community? • Are you planning to work with organizations that interact or advocate for diverse populations?	**More information is contained in:** • NIH Outreach Notebook for the Inclusion, Recruitment and Retention of Women and Minority Subjects in Clinical Research http://www4.od.nih.gov/orwh/outreach.pdf • Cancer Clinical Trials: a Resource Guide for Outreach, Education, and Advocacy (NCI) http://www.cancer.gov/clinicaltrials/resources/outreach-education-advocacy • Increasing Diversity in Clinical Trials: Best Practices (Health Disparities Symposium for NIAID) http://www.niaid.nih.gov/healthdisparities /HDSYMPOSIUM/proceedings2/
Staff • How do you plan to train your staff to perform the study protocol? • How will you train staff to assume greater responsibility/independence? • How will you replace key staff, if other staff members are not sufficiently experienced and/or trained to assume those responsibilities? • How will you maintain "staff balance" for this study/trial (i.e. assigning staff among various trials)?	**Considerations:** • Staff training directly impacts recruitment and retention. • Because of the lengthy commitment to complete a clinical study, there will likely be turnover in staff. • Plan for ongoing training for the replacement staff as well as refresher training for all staff.
Multi-site considerations • What is the maximum number of participants that your site has the capacity to screen, enroll, and follow up with at the same time? • Have you chosen sites that can access the target populations and have a realistic likelihood of recruitment success? • How will you train and certify staff at all clinical sites? • How will you ensure that your sites will adhere to a common protocol? • Are there plans for ensuring and monitoring fidelity to the protocol?	**Considerations:** • Multiple sites are used because the topic being studied requires a large and diverse sample size that is beyond what one site can achieve alone. However, many sites fail to enroll their target sample sizes, leaving the total sample inadequate. • As a study progresses, sites tend to fall into the categories of strong and weak enrollers. As enrollment goals slip behind, study leaders often decide to allow the strong enrollers to "over-recruit" in order to meet the overall sample size goal. However, because part of the site selection involves balance of geography, type of clinic, and racial/ethnic diversity, the post-design imbalance in enrollment across sites often impacts statistical analysis in a manner rarely considered.

• Do you have plans for "backup" sites, should they become necessary? • Have you considered the impact of potential unbalanced enrollment across sites? • Have you specified conditions under which a site may be terminated?	
Coordinating center for multi-site studies • Does the coordinating center(s) have expertise in multi-site leadership? • Do the coordinating center leaders have a clear mandate from site investigators? • Have the leaders demonstrated a capacity to make decisions and keep the project moving forward? • Does the coordinating center senior research team have the ability to assess and advise in matters concerning racial and ethnic diversity? • Have you outlined the organizational structure (e.g. committees) of the coordinating center? • Has the administrative structure and function been clearly defined? • Do you have processes for resolving disputes and disagreements?	**Considerations:** • Problems may arise when the coordinating center is located at one of the participating data collection sites. The coordinating center must ensure a clear line of responsibility, confidentiality of data, and a strong firewall to prevent cross-talk. • The study leader must have a clear mandate from colleagues to assume a position of authority. The leader must have the experience and confidence to be able to consider all points of view and to make a decision in spite of disagreement. • During study implementation, the coordinating investigators need to review data without allowing their knowledge to influence decision-making at a site level. • Conflict may arise if a clinical site is under-recruiting, and the site is also the coordinating center.
Sample Size • Is the design flexible enough to permit enrollment of a diverse sample? • Are the inclusion criteria too narrow, such that you will have unusual difficulty finding people who qualify for the study?	**Considerations:** • Strict inclusion criteria restrict the eligible number of participants and increases the amount of time and resources dedicated to screening. • Studies may require that people are screened at successive stages, requiring significant time and expenditure of resources on subjects who never enter the study.

Institutional Review Board (IRB) and Data & Safety Monitoring • Are the risks to participants minimized as much as possible through sound research design and the use of safety-focused procedures? • Are participants selected fairly? • Is a plan in place for seeking and documenting participants' informed consent? Are consent documents culturally and developmentally appropriate for all study populations? • Is the informed consent document both legally and ethically sound? • Have provisions been made for monitoring the data collected to ensure the safety of participants as the trial progresses? • Have provisions been made to protect the privacy of participants and the confidentiality of data collected during the study?	**Considerations:** • IRBs consist of people who are qualified to evaluate new and ongoing clinical studies on the basis of scientific, legal, and ethical merit. • The IRB determines whether the risks involved in a study are reasonable with respect to the potential benefits. • The IRB has the authority to approve, require modification, or disapprove of research to ensure protection of human subjects. • IRBs monitor the ongoing progress of a study, from beginning to end. • Most institutions that carry out clinical studies have their own IRBs. • Failure to obtain IRB approval will delay the progression of a study. • All institutions carrying out a NIMH funded intervention study must establish a data monitoring system commensurate with the risks, complexity, and nature of the trial. See the NIMH website on Data and Safety Monitoring: http://www.nimh.nih.gov/researchfunding/safetymonitoring.cfm
Pilot studies • Have you piloted all relevant aspects of the methodology including recruitment, screening, assessment, randomization procedures (if required), treatment and experimental methods, data entry, etc.? • Has retention of participants been achieved for pilot studies? For how long?	**Considerations:** • Complex designs are often needed to answer important questions that cannot be addressed with simple designs, but pilot studies may be required to develop an achievable recruitment plan.
When the study has been completed • How will you thank participants? • How will you disseminate the research results to all communities involved? • How will you maintain the relationships that you have forged with the communities?	**Suggestions:** • Send thank you notes to participants and other communities that were involved in the study. • Report research results in formats most useful to the different communities involved, such as participants, families of participants, and referring practitioners. For participants, explain how the findings may ultimately improve their health. To accommodate the busy schedules of health care

	practitioners, provide a handout that summarizes the findings more succinctly than a journal publication. • Maintain contact with your established community-based research advisory board and other community representatives/liaisons. • Establishing and maintaining positive relationships with your community may facilitate your future research studies, as well as the studies of your colleagues.