Recruitment of Study Participants

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Overview

- Ethical Principles
- Inclusion of Minorities in Research
- IRB Policies and Procedures
- Recruitment in Clinical Research Studies
  - Factors to consider in developing and implementing recruitment strategies
  - Planning for Retention
  - Challenging situations
- Case Studies

Recruitment of Study Subjects

- Essential to study success
- Often a challenge to meet enrollment targets within specified time-frame
- Enrolling “population of convenience” may limit generalizability of study results.

Ethical Principles

- **Respect for persons** – Individuals should be treated as autonomous agents able to exercise their autonomy to the fullest extent possible, including the right to privacy

- **Beneficence** – Maintaining privacy and confidentiality helps to protect participants from potential harms

Privacy: control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

Ethical Principles

- **Justice -** the benefits and burdens of research are to be shared fairly.
- The potential risks of research should be born equally by the members of society that are likely to benefit.
- A person should not be denied some benefit without good reason; nor should a burden be unduly imposed upon them.

Inclusion of Women and Minorities in Research

- NIH policies
  - Revitalization Act of 1993
  - Inclusion Guidelines, 1994
- Biomedical *and* behavioral research
- Local IRB role

Why is this important?

- “Appropriate representation”
- To test specific hypotheses about differences by race and ethnicity.
- To generate hypotheses about possible differences by race and ethnicity.
- Eligible for an equal share of direct benefits of research (e.g. HIV/AIDS research).
- Characteristic of diseases or effectiveness of therapies in particular populations.

Barriers in the Latino Community

- Language
- Culture and previous experiences with healthcare system.
- Retention and follow up

Strategies

- Use of trained interpreters.
- Translated short form and short study description

  OR
- Fully translated consent form.
- Make sure that goals, risks and demands of the research study are clearly understood by the participants.

IRB Policies and Procedures

- Investigator Responsibilities for Fair and Equitable Subject Recruitment (RA:HRPP:10:07)
- Equitable Selection and Recruitment of Human Research Subjects (RA:HRPP:08:06)

Intranet > Departments > Office for the Protection of Human Subjects > Policies and Procedures

Investigator Responsibility

- It is the investigator's responsibility to use fair and equitable recruitment methods and to avoid practices that place subjects at risk for coercion or undue influence.
- The protocol application form submitted to the CNMC IRB must specify the population(s) to be selected and enrolled in the research (age, gender, ethnicity), and also describe in detail the recruitment strategies and procedures to be used.

IRB Review

- What is the purpose of the research?
- Where will the research be conducted?
- **Will prospective subjects be vulnerable to coercion or undue influence?**
- **What are the inclusion/exclusion criteria?**
- **What subject recruitment and enrollment procedures will be used?**
- What influence might any payments to subjects have?
- **Does the research exploit populations of convenience?**
- **Has the researcher considered representation by gender, age, ethnicity?**

Recruitment Strategies

- What is your target population?
- Who will you need to work with to gain access to this target population?
- What recruitment methods will you use?
  - Face-to-face, Mail, Phone, Advertisements
- When and where will you conduct recruitment activities?
- How will you include non-English speaking participants?
- How will you maximize privacy
- What challenging situations can you anticipate?

Case Studies

- Study of UTIs
- ED-based studies
- HIV surveillance of adolescents

Studies of UTIs

- RIVUR Study = A study of children with UTI who were determined to have a condition called vesicoureteral reflux (VUR)
- CUTIE Study = A study of children with UTI without VUR.
- When a child with VUR gets a UTI, bacteria can move into the kidney and lead to scarring. Scarring of the kidney can be associated with high blood pressure and kidney failure. However, most children with VUR who get a UTI recover without long-term complications.
- The children with VUR were randomized to receive daily prophylaxis with antibiotic or placebo. Children in both studies were observed for 24 months to see if there were any breakthrough/recurrent UTIs and then checked for renal scaring.

Group #	Study Name	VUR	Prophylaxis?
Group 1	RIVUR	Yes	Yes (Antibiotic)
Group 2	RIVUR	Yes	No (Placebo)
Group 3	CUTIE	No	No

ED-based research

- ED studies are needed to answer key questions about the prevention and management of acute illnesses and injuries in children and youth.
- Diverse consortium of hospitals – urban, rural, suburban
- Intravenous Magnesium for Sickle Cell Vasoocclusive Crisis (MAGIC): Children with sickle cell disease are at risk for acute vasoocclusive crises, the most frequent of which are pain crises. The usual treatment for pain crises, intravenous fluids and pain medicine, has changed little over the past three decades. The purpose of this study is to determine the safety and efficacy of intravenous magnesium in shortening the duration of a pain crisis when added to standard care in children with SCD who are hospitalized for an acute pain crisis. This is a multi-center, randomized, double-blind, placebo controlled trial.

HIV surveillance of adolescents

- Five neighborhoods in in Cityville have higher than average cases of HIV, especially in young men. These neighborhoods also have a number of other social problems including a large number of abandoned homes, few to no afterschool programs for young people and high crime rates.
- Target population: 12-24 year old young men that have sex with men

Accessing Target Population

- Inclusion/exclusion criteria
- May enroll different sample of population depending on how and where you recruit subjects.

Accessing Target Population

- Investigators must limit their search for potential subjects to those whose records fall within the scope of their responsibility
- It may be necessary to secure a subject's permission to be contacted by an individual who is not involved in his/her care, or to ask another individual to assist an investigator in approaching subjects.
- Accessibility of patient information in the Electronic Health Record puts additional focus on privacy

Collaborators and Gatekeepers

- Who is are the key members of the research team?
  - Physicians, nurses, other providers
  - Staff
  - Patients, parents, family members
  - Community organizations
    - Example: Cultural organizations, schools
    - Not just for CBPR, but to improve recruitment to all studies that involve members of the community

Methods: Face-to-face

- Ideal: Potential participants are introduced to study staff by patient's primary provider
- Acceptable:
  - Study staff introduce themselves to patients and families in a respectful manner
  - Provide printed materials
- Inpatient units, emergency department, outpatient clinics, community locations, homes.
- Importance of avoiding bias in who is approached
- Privacy/confidentiality issues

Timing

- When possible, recruitment should be avoided during stressful times for patients and families.
- Potential participants should have ample time to decide whether or not to participate.
- When possible, potential participants should receive written information before being approached.
- Consider both time of day and day of week for face-to-face recruitment

Methods: Recruitment by Mail

- For CNMC pts that have left the hospital or clinic, initial contact must be by mail, which must include the option to opt-out of further contact.
- Letter must be signed or co-signed by the primary physician who cared for the child (or a representative of the department or division that cared for the child)
- "Cold Calling" - Telephone surveys may not be conducted before a letter is sent allowing potential subjects to decline further contact.

Recruitment Materials

- IRB must review exact wording for all recruitment tools, such as flyers, audio or videotaped ads, print ads, email solicitations, internet websites, scripts, and other recruitment methods and materials intended for the recruitment of prospective research participants.
- Public Relations and Marketing must review and approve materials PRIOR to IRB submission.

Recruitment Materials

- Advertising must include specific information:

  purpose of the study, summary of eligibility criteria, summary of procedures required, name/address of investigator or research facility, location of research, amount of time required and/or duration of study, brief list of participation benefits, compensation provided (if applicable, best for amount to not be specified), person to contact for further information.
- Whenever possible, potential subjects should receive written information about a study prior to being approached in person.

Importance of Retention

- Important to minimize barriers to both enrollment and retention
- Critical part of planning
- Ethical and scientific responsibilities

Ineligibles and Refusals

- What should be tracked for ineligible participants?
- Why important to track ineligibility and refusals?
- Is there a time when it is appropriate to re-contact?

Personnel

- Background and qualifications
- Training (initial and ongoing training that is specific to individual protocols)
- Team approach to addressing challenging situations
- Importance of diversity

Community Engagement

- Some research may involve broad partnerships
- Engage partners early, not after all decisions have been made
- Consider inviting key members of the population to assist with protocol development activities (Community Advisory Boards, youth representatives)
- Importance of sharing results
- Community partnerships

Other pointers

- Importance of explaining that even screening questions are optional
- Be careful about not giving information to pts that they may not yet know
- Make sure you are speaking with the right person
- Clear instructions for how to handle situations where eligibility is unclear
- Preventing bias in who is approached

Case Studies

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