Recruitment to Clinical Trials

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Agenda
- Barriers to recruitment
- Recruitment strategies
- NIH resources

Introduction
- Validity of clinical research studies are dependent on:
  - Recruitment of adequate numbers of a required participant population
  - Retaining participants
  - Ensuring the protocol is followed

Recruitment Statistics
- Up to 80% of all trials miss their enrollment deadlines
- 45% of all delays in clinical trials can be attributed to poor patient recruitment

Barriers to Participation
- CLINICIAN
- SYSTEM
- PATIENT

Clinician Centered Barriers...
- Time Constraints
- Lack of support staff
- Impact on doctor-patient relationship
- Concern for patients
- Clinician bias
- Loss of professional autonomy
...Clinician Centered Barriers

- Obtaining consent
- Poor financial reimbursement
- Lack of interest in the specific research question
- Fear of Not Being Kept Informed about Patient’s Care

System Barriers

- Protocol Issues
- Expense
- Competition
- Sponsor-centered
  - Adequate Funding
  - Site Selection
  - Investigator Selection

General Population Barriers

- Lack of Awareness
- Mistrust
- Demands of the study
- Preference for a particular treatment
- Concerns about side effects
- Comfort level with physician
- Language and literacy
- Loss of privacy
- Portrayal as guinea pig
- Misperceptions
- Geographical Limitations
- Financial Considerations

STRATEGIES

Center for Information and Study on Clinical Research Participation (CISCRP)

Top Reasons People Choose to Participate in Clinical Trials

<table>
<thead>
<tr>
<th>Reason</th>
<th>Percent of Respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>To advance medicine</td>
<td>31%</td>
</tr>
<tr>
<td>To help improve the lives of others</td>
<td>29%</td>
</tr>
<tr>
<td>To help improve my condition</td>
<td>18%</td>
</tr>
<tr>
<td>To earn extra money</td>
<td>6%</td>
</tr>
<tr>
<td>To receive free medical care</td>
<td>3%</td>
</tr>
</tbody>
</table>

Source: CISCRP, 2010-2012, people worldwide
Center for Information and Study on Clinical Research Participation (CISCRP)

Study Volunteer Ratings of Clinical Research Staff Professionalism

<table>
<thead>
<tr>
<th>Professionalism Level</th>
<th>Percent of Respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very Professional</td>
<td>81%</td>
</tr>
<tr>
<td>Somewhat Professional</td>
<td>15%</td>
</tr>
<tr>
<td>Somewhat Unprofessional</td>
<td>4%</td>
</tr>
<tr>
<td>Very Unprofessional</td>
<td>1%</td>
</tr>
</tbody>
</table>

Source: CenterWatch survey of 1,045 study volunteers, 2012
Other Strategies

- Protocol specific
- Length of Study
- Choice of Control Groups
- Inclusion/Exclusion Criteria
- Procedures Performed
- Maintain accurate screening logs
- Other clinics
- Advocacy groups

Recruitment Plan

- Study population should be appropriate for the research question being asked (representative of the study population with the disease)
- Inclusion/exclusion criteria should be explicit
  - The more stringent your exclusion criteria the more difficult it will be to recruit
  - Lack of appropriate exclusion criteria leaves the study open to potential confounders
- Inclusion of Women and Minorities—Regulatory
- Added scrutiny for recruiting vulnerable populations

Retention of Subjects

- Keeping subjects in the study
- Key factors to success
  - Protocol Design
  - Patient Education
  - Informed “Decision”
  - Customer Service
Summary
• Several barriers
• Strategies to overcome barriers
• Recruitment & retention are related and affect the validity of the study results
  • Organized efforts should be made throughout the study to enhance both
• Plan up front for recruitment & retention

Resources Available Through the NIH CC
• Office of Patient Recruitment (OPR)
• Clinical Research Volunteer Program (CRVP)
• Contact information
  • Dinora Dominguez
  • Mandy Jawara
  • 301-496-4763

OPR Services
• Toll-Free Telephone Information and Referrals Service in English and Spanish
• A critical first step - Telephone Prescreening
• Recruitment Consultation

CRVP Services
• Program began in 1954
• Objectors to the war were given the opportunity to substitute research for military service
• Wanted to be referred to as “NORMAL”
• Services:
  • Reaching Healthy Volunteers
  • Recruit, Register, and Compensate Research Volunteers
  • Compensation Guidelines on Remuneration

http://clinicalcenter.nih.gov/recruit/

ResearchMatch
Research. Discovery. Hope.
Questions