Managing Multi Site Research

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Multi Site Clinical Studies

- **Enrollment potential**
  - Baseline data
  - Pilot

- **Geographic Considerations**
  - National
  - Regional

- **Ability to collaborate**
  - Colleagues in research
Multi Site Clinical Studies

Telemedicine approaches to evaluating acute-phase retinopathy of prematurity: e-ROP (observational study)

- Evaluate a telemedicine system to detect eyes of at-risk babies in need of a diagnostic exam by an ophthalmologist experienced in ROP.
  - Validity
  - Reliability
  - Feasibility
  - Safety
  - Cost-effectiveness
    - Population: 2000 Infants with BW<1251g

Pennsylvania adolescent smoking study (RCT)

- COMPERE THE EFFICACY OF MOTIVATIONAL INTERVIEWING (MI) to structured brief advice (SBA) on reducing smoking in adolescents
  - Study groups: MI or SBA intervention
    - Population: 330 teen smokers (14-18 years of age)
Multi Site Clinical Studies

PASS – 3 sites

Clinicaltrials.gov # NCT01264276

e-ROP-12 sites
Multi Site Clinical Studies
Office of the Study Chair

- Fiscal Responsibility
- Scientific Oversight
- Regulatory and Reporting Responsibility
- Coordinating with Funding Agency - ClinTrial.gov registr.
- MOP Development
- Convening/Coordinating DCC and other Resource Centers
- Chairing/Serving on:
  - Data Coordinating Center
  - Executive Committee
  - Operations Committee
  - Editorial Committee
  - Technical Group Meeting
  - DSMB/DMOC
Administration - Paperwork In Place

- Contracts
  - Sub Awards (PSA/RSA)

- Conflict of Interest (COI)
  - All PIs (Clinical Centers & Resource Centers)
  - DMOC/DSMC/DSMB members

- Confidentiality Agreements
  - Certificate of Confidentiality

- Human Subjects Training/ HIPAA Certification

- IRB
IRB Consideration

♦ IRB of Record Agreement
  • Penn/CHOP
  • Other Clinical Centers
    – Responsibilities of the IRB of Record – continuing review
    – Responsibilities of the relying institution - compliance

♦ Clinical Centers’ IRB Approvals
  • Multi-site IRB Regulations Variability
  • Drafting of the Research Protocol
    – Standard of care at some clinical sites → Waiver of Consent
    – Research procedure at some clinical sites → Informed Consent

♦ Central IRB service (e.g. WIRB)
e-ROP Organization

National Eye Institute

Data Monitoring & Oversight Committee

e-ROP Study Headquarters
Children’s Hospital of Philadelphia
University of Pennsylvania

Executive Committee

Data Coordinating Center and Image Reading Center
Center for Preventive Ophthalmology & Biostatistics
University of Pennsylvania
Philadelphia

Inoveon ROP Data Center
Oklahoma City

Clinical Centers
-Baltimore
-Boston
-Calgary
-Columbus
-Durham
-Louisville
-Minneapolis
-Nashville
-Oklahoma City
-Philadelphia
-Salt Lake City
-San Antonio

Technical Group

Operations Committee

Data Forms Development Committee

Imaging Management Committee

Editorial Committee
Protocol Training and Certification

- Training in Study Procedures
- Training in Data collection/CRFs
- CRF Notebook
- Certification
  - General Knowledge Assessment
  - Role Specific Knowledge Assessment
  - Skill review certification – Certification #
- Technical Group Meeting (annual)
  - MOP review, consent and recruitment techniques, data review/submission
- Site Visits
# Child as Research Subject  Recruitment Challenges

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<th>e-ROP</th>
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<td>Vulnerable Population</td>
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<tr>
<td>Access to teens</td>
<td>Volatile medical status</td>
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<td>Confidentiality</td>
<td>Access to Parents</td>
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<td>Lack of Perceived Benefit</td>
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<td>Access to Study site</td>
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<td>Changing motivation</td>
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<td>Psych-social complexities</td>
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<td>Legal Complexities</td>
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Recruitment

- **Clinical sites:**
  - Adolescent Medicine at Children's Hospital (CHP)
  - Adolescent In-patient Unit at CHP
  - Primary Care Center at CHP
  - Family Medicine (Shadyside, Matilda Theis)
  - Children's/UPMC at Turtle Creek
    - Children's Community Pediatrics (CCP)
  - Pittsburgh, Oakland, & Bloomfield offices
  - Emergency Department at CHP
  - Dental Department at CHP
  - Pulmonary, Allergy, and Immunology clinics at CHP
  - East Liberty Family Health Center

- **Community sites:**
  - Recreation Centers
  - Tobacco Free PA Websites
  - Job Corps
  - Focus on Renewal
  - Planned Parenthood
  - Woman, Infants and Children (WIC)
  - Local Church
  - Race for the Cure
  - American Cancer Society
  - American Lung Association
  - American Respiratory Alliance
  - City/County pools
  - Schools

- **Media:**
  - PAT Bus Cards (East Liberty Garage) (6/08)
  - CHP Quarterly Newsletter: Promises
  - CHP phone waiting message
  - UPMC *Extra*
  - Pittsburgh Parent Magazine
  - City Paper
  - KennyTales
  - Craig's List
  - Flyers posted in local neighborhoods
  - Facebook/MySpace
Data Review/Site Visits

• On site review
• Remote review
  – Data integrity (check against source documentation)
  – Consents
  – Storage
Data Management

- Security and Integrity of data mgnt. system
- Database architecture
- Validation rules–computer driven data editing
- Pilot

**Monitoring of Data Quality - QA**

- General Reports (accrual, quality, completeness)
- Special Report (e.g. safety)
- Edit Queries
- Data Cleaning
General Quality Assurance and Monitoring

- Protocol Amendments – versions
- CRF Amendments – versions
- MOP Changes - versions
- Data collection spot check
- Site Visit Follow-up
- Re-certification
- Mid-Study Site closing
- Mid-Study Site initiating
Multi Site Clinical Studies

It takes a Village!

Questions?