Research Subject Registry: A Critical Tool for Successful Recruitment
Some years past, we made splitting the atom looked like a breeze.

Then we put a few men on the moon with relative ease.

When we put our minds to it,

Seems we always can do it.

But I dare you to enroll for three colonoscopies.

*Norman Goldfarb, Journal of Research Best Practices, September 2012 Volume 8 Number 9*
Learning Objectives

- Understand the current landscape of research subject recruitment/enrollment
- Review day to day challenges of recruitment and enrollment
- Review recruitment team model and strategies
- Discuss the what, how, why of the research subject registry
- Review Case Studies
Well below half of medical treatments patients receive are supported by adequate scientific evidence (IOM 2007).

Often trials never recruit the number of people needed, others accrue far too slowly, and the scale of need is substantial.

In the United States in 2009, there were almost 11,000 clinical trials testing various medical interventions, mostly (59 percent) new drugs. Collectively, it was hoped these trials would enroll some 2.8 million people (IOM, 2010a).
Daily Challenges: Building Relationships

- Complex Eligibility Requirements (Screening and Day –x)
- Screen Failure Rates
- Retention
Daily Challenges: Building Relationships

Awareness
- According to CenterWatch, 94% of people recognize the importance of participating in clinical research in order to assist in the advancement of medical science. Yet 75% of the general public state they have little to no knowledge about the clinical research enterprise and the participation process. (www.ciscrp.org)

Trust
- Still dealing with Guinea pig mentality
- Stakeholder message: Is it the same? What is it?

Responsiveness
- Community
- Professional
Recruitment Challenges

Timing

• Sponsor Communications linger
• “Go” often sudden
  — Depending on final IRB approval, signed contract, drug availability
• Enrollment timelines often discussed in the absence of recruitment team
• Cost
DCRU Recruitment Model

* Dedicated Recruitment Team (4 people)
  Not all full time
  PRN staff

* Study support
  Full Support
  Partial Support
DCRU Recruitment Model

**Full Support**
- Develop Recruitment Materials for IRB submission
- Develop Recruitment Action Plan
- Place and manage advertisements
- Manage incoming calls
  - Prescreening (telephone script)
- Schedule appointments

**Partial Support**
- A la carte (from Full Support)
- Identify potential subjects In-house Data Warehouse Repository
- Community Events
Recruitment Strategies

- In-house Data Warehouse Repository
- Online advertisements (dukehealth.org)
- Clinic Screens
- Broadcast and print media (TV, newspaper, magazines, etc)
- Social media
- Community Events
- Volunteer Registry
Research Volunteer Registry

What

IRB approved protocol
Recruitment Tool
August 2010

Purpose

Collect information about potential subjects who agree to allow their personal information to be recorded
Access to information within the database to identify subjects who may be eligible for future studies
Research Volunteer Registry

Why

- Maintain consistency
- Ensure compliance
- Robust metrics
- Established relationships
Research Volunteer Registry

How

Mapped work flow

Defined data collection
- Contact information, phone number, street address, email address, MRN, demographics, profile information (ht, wt, smoker, child bearing potential), specific medical condition

Approach as any other protocol
- Recruit within DCRU
- Advertise (print, radio, web postings, TV, transit, etc)
- Community Events-Promote awareness
- Speaking engagements
Volunteer Registry Metrics

- Healthy: 40%
- T2D: 18%
- HTN: 16%
- Gout: 14%
- Asthma: 5%
- Hypercholesterolemia: 7%
Case Study #1
Healthy (Phase 1)

Target 16
2 Cohorts of 8

*IRB Approval
May 10, 2011
*Contract Executed
May 10, 2011

Recruitment start
May 19, 2011
Enrollment Complete
June 20, 2011
Case Study #1: Healthy Volunteers

116 contacted

- 73 Email
- 43 Telephone

Spoke to 95

- Registry: 58 (61%)
- Online: 17 (18%)
- WOM: 17 (18%)
- Referral: 2 (2%)
- Flyer: 1 (1%)
Case Study #2
Gout (Phase 2)

Target 8

*IRB Approval
June 22, 2011
*Contract Executed
August 11, 2011

Recruitment start
August 19, 2011
Enrollment Complete
September 16, 2011
Case Study #2: Gout (Phase 2)

- 26 Email
- 26 Telephone

38 calls received

- Registry: 32 (84%)
- Online: 1 (3%)
- WOM: 4 (10.5%)
- Community Event: 1 (3%)
Case Study #3
Gout (Phase 2a)

Target 20
Cohorts of 4
(3, 0, 4, 6, 7)

*IRB Approval
November 8, 2011
*Contract Executed
March, 2011 & Nov. 23, 2011

Recruitment start
November 20, 2011
Enrollment Complete
Case Study #3
Gout (Phase 2a)

- Registry: 16 (4%)
- Online: 12 (3%)
- WOM: 49 (12%)
- Flyer: 4 (1%)
- TV: 243 (61%)
- Newspaper: 45 (11%)
- Jobfinder: 23 (6%)
- Unknown: 5 (1%)

397 calls received
Conclusions

* Registry is a critical tool
  Quick enrollment

* Not always best option

* Fills the recruitment time gap

* Inexpensive or free
Future Plans

★ Maintenance Phase

Newsletters

Clean up
  — Withdraw consent
  — Update demographics and health status

★ Continue to add subjects
Questions?

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References


http://www.ncbi.nlm.nih.gov/books/NBK92111/