

Study Recruitment Basics

Recruitment Services Program
of the Clinical and Translational Science Institute
Clinical Research Resources Office

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Summary

- Recruitment Services Program
- Recruitment to Clinical Research Studies
- Stakeholders
- 5 Areas of a Recruitment Strategy
- Retention
- BU/ BMC Recruitment Resources
- Role Play

Recruitment Services Program

of the Clinical and Translational Science Institute: ReSPECT

- Supported by DOM, CTSI, OCR
- Provide individualized feedback:
 - Recruitment
 - Retention
 - Resources (www.bumc.bu.edu/crro)
- Community Outreach
- ReSPECT Registry
- Web List of Studies (*coming!*)



Recruitment Services Program

www.bumc.bu.edu/crro


Boston University Medical Campus
Clinical Research Resources Office

This Site 

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Recruitment »


Regulatory »


Training & Education »

[Welcome](#)

Welcome! We're here to help you in your clinical research needs.

Mission Statement: *The mission of the Clinical Research Resources Office is to facilitate the design and conduct of ethical and scientifically valid clinical research by providing a range of services, resources and guidance to support BUMC clinical researchers in planning, submitting, conducting and analyzing their research.*

In fulfilling this mission, the CRRO strives to:

- *Facilitate research* by providing guidance and tools that are relevant, focused, accessible, and current.
- *Be responsive* to needs of the BUMC clinical research community, the needs of research participants, and the changes in regulations and policies guiding clinical research.
- *Centralize expertise and support* for the conduct of clinical research.
- *Foster research participant advocacy* by promotion of best practices to ensure the safe and ethical conduct of clinical research.

The CRRO offers services in the areas of [Recruitment](#) and [Regulatory](#) and provides ongoing [Clinical Research Education Programs](#) as well.

New! [Special Event Workshops: Best Practices for Preparation and Maintenance of Sponsor-Investigator INDs and IDEs](#)

ALSO SEE

- ▶ [MEET THE CRRO TEAM](#)
- ▶ [CONTACT US](#)

Recruitment Services Program

www.bumc.bu.edu/crro-community

CLINICAL RESEARCH RESOURCES OFFICE COMMUNITY



Recruitment Services Program of the Clinical Translational Science Institute (ReSPECT)

Thank you for your interest in clinical research at Boston University (BU) and Boston Medical Center (BMC)!

Our goal is to support the community in learning about clinical research and finding opportunities to participate in research studies.

Please click the links below to learn more about clinical research, the ReSPECT Registry, and to search for studies taking place at BU and BMC.



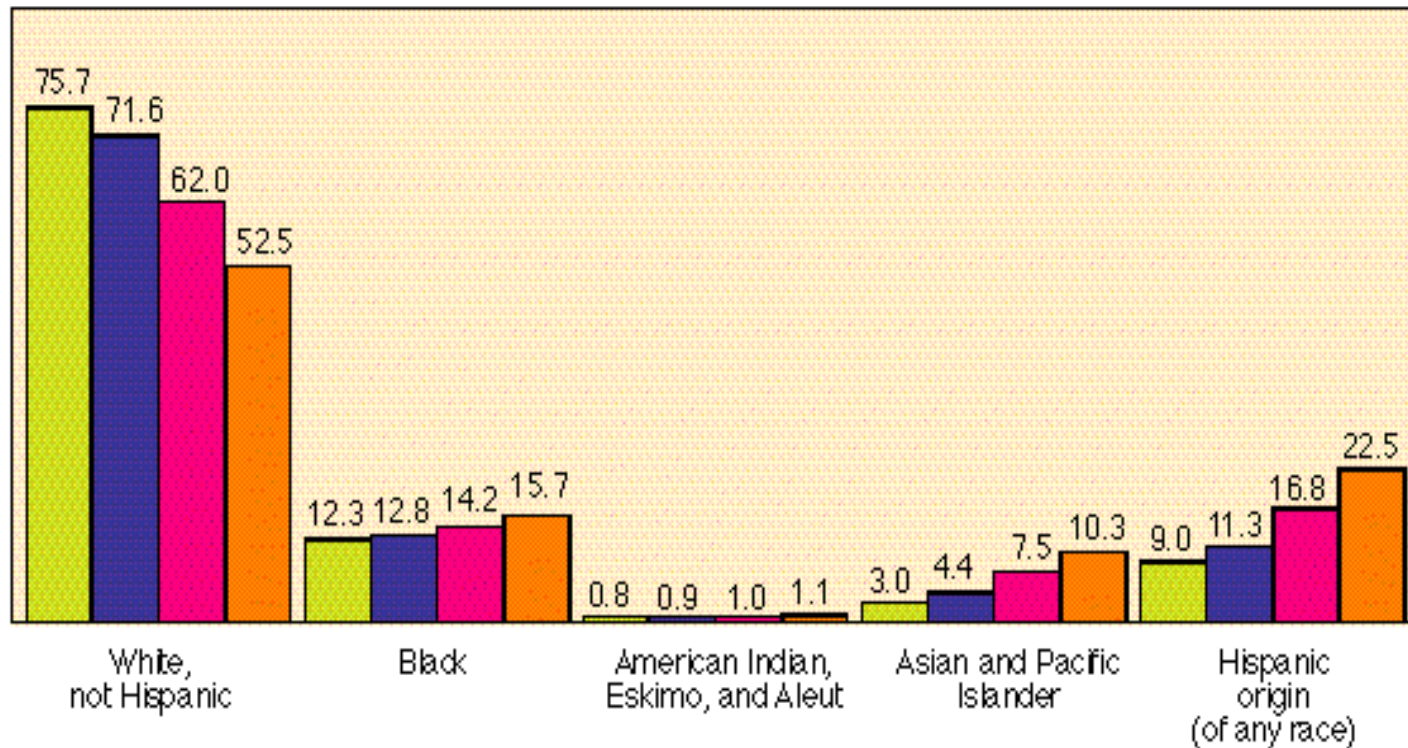
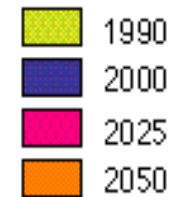
Recruitment to Clinical Research Studies

- BU/ BMC researchers target US, local, BMC, and world populations for research
- USA population trends through 2050
- Local populations snapshot (local recruiting areas):
 - Boston, MA
 - Boston Medical Center

US Population Trends

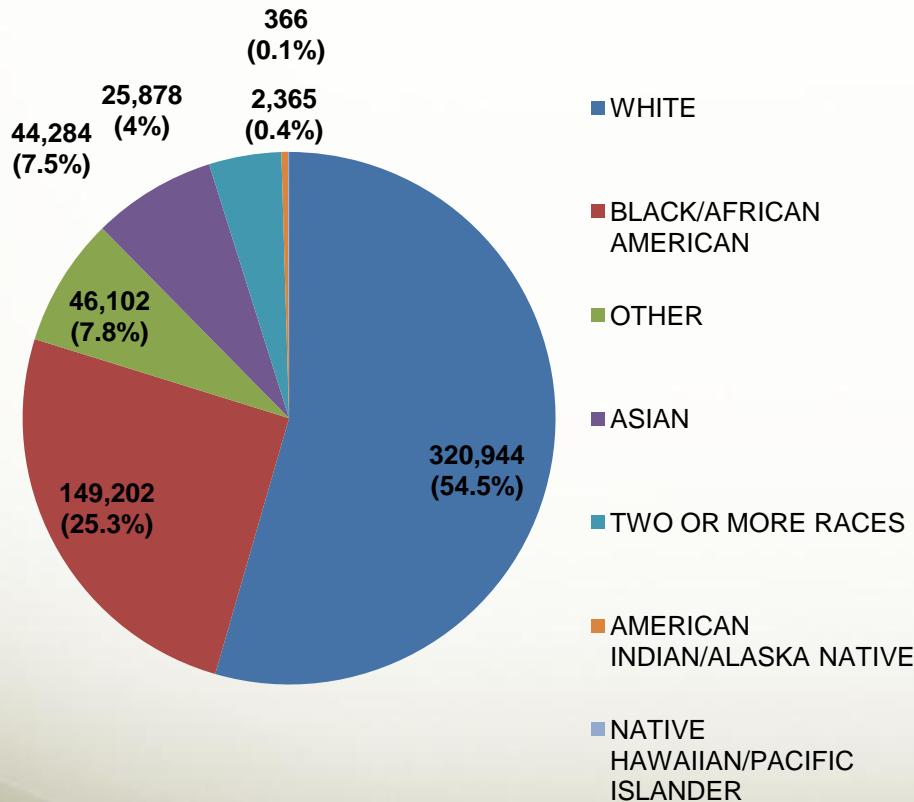
Percent of the Population, by Race and Hispanic
Origin: 1990, 2000, 2025, and 2050

(Middle-series projections)

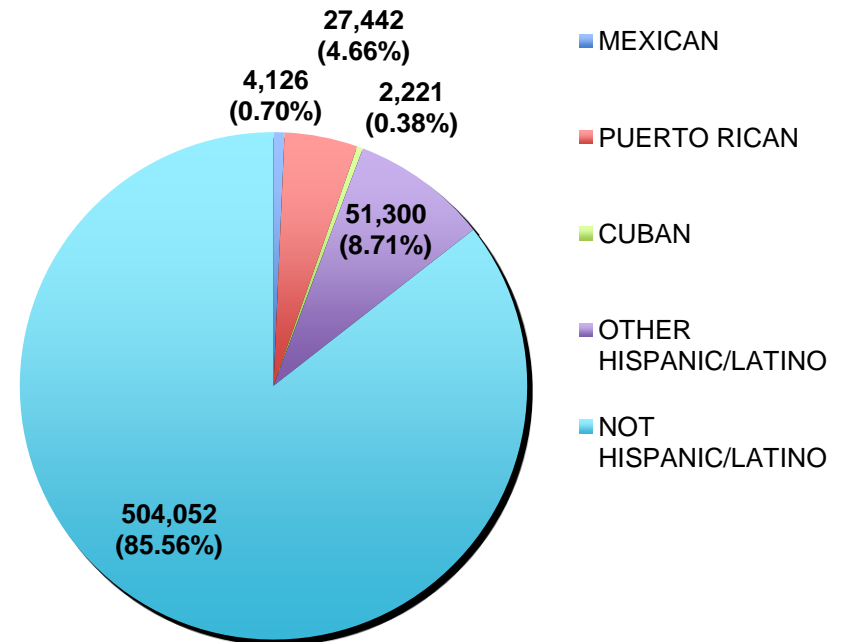


Local Population snapshot: Boston, Massachusetts (US Census 2000)

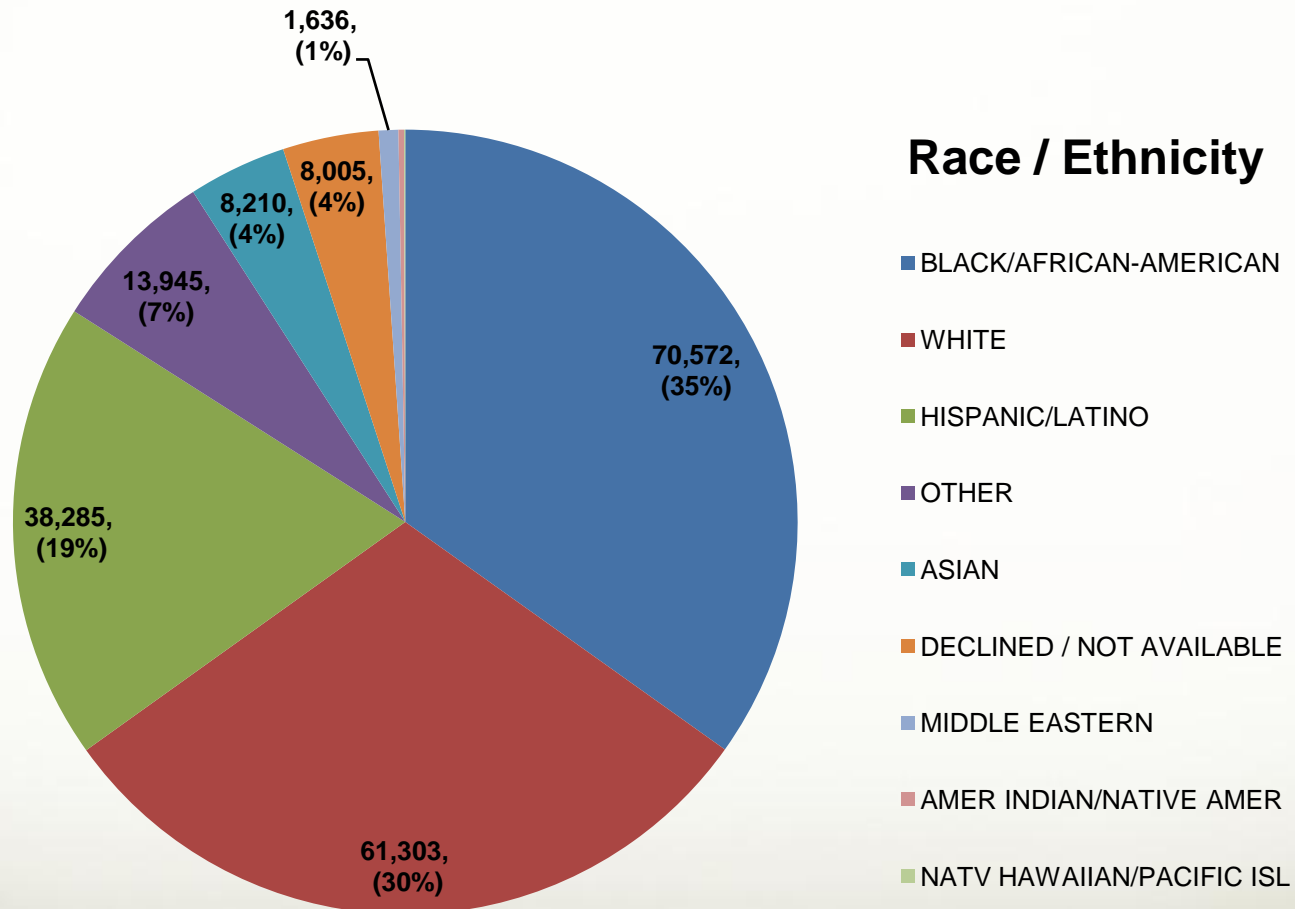
Boston, MA General Population Profile



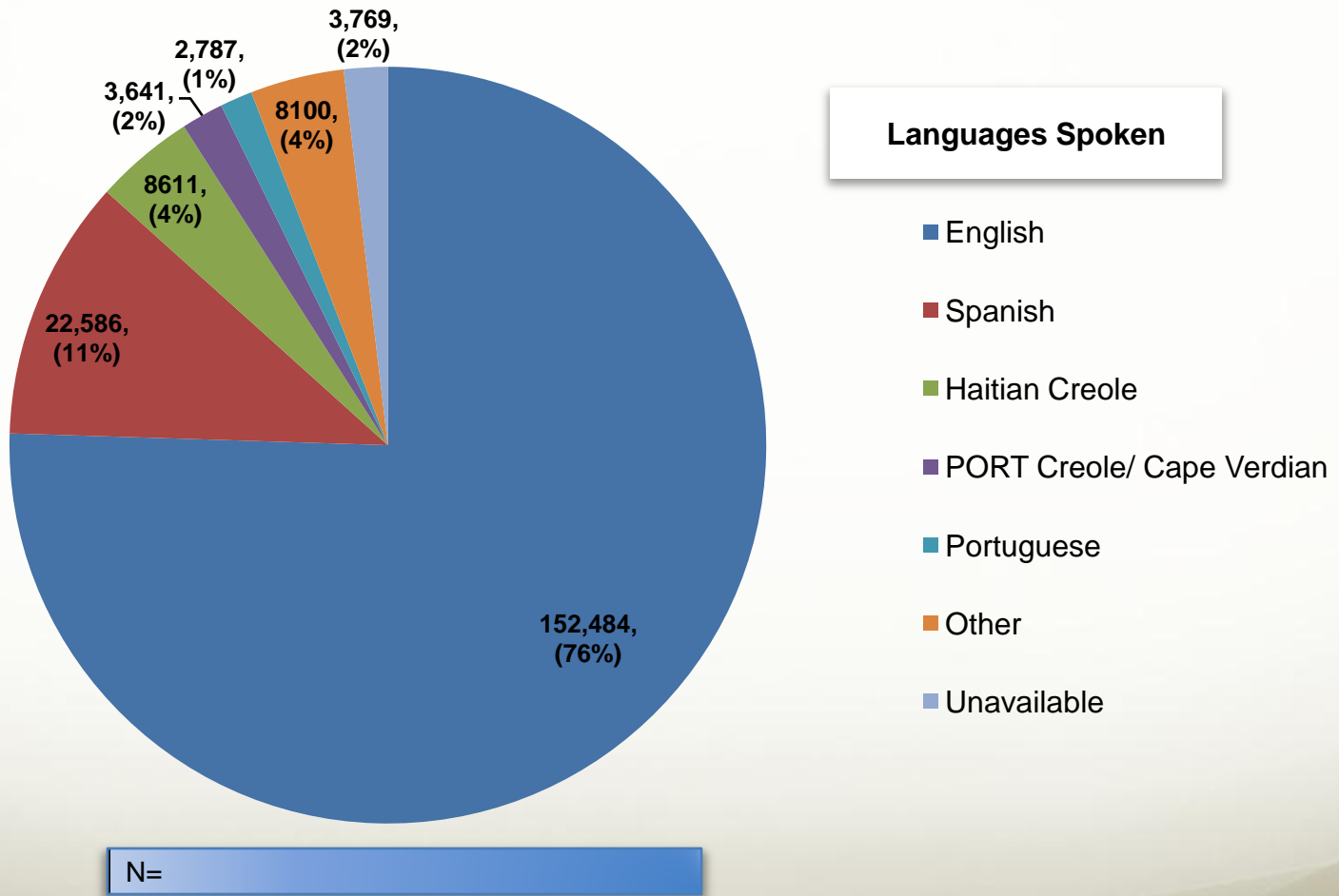
Hispanic/Latino Population Profile



Boston Medical Center 2010 Patient Profile (Race/ Ethnicity)



Boston Medical Center 2010 Patient Profile: Languages Spoken



Clinical Research Recruitment & Retention: Stakeholders & Motivators

Stakeholder: Person who has a specific interest in the outcome or success of a project. We are all directly or indirectly concerned with advancement of science and improvement of health outcomes.

University/ Medical Center (Researcher/Coordinator)

- **Careers:**
 - **Professional advancement**
 - **Prestige**
 - **Research \$\$ for the institution**
- **Self or family member with condition**
- **Altruistic Desire**
 - **Help fellow man**
- **Contribute to the advancement of science (e.g. vaccines, new treatments, etc.)**

Potential study participant

- **Prestige of participation**
- **Self or Family member with condition**
- **Altruistic Desire**
 - **Help fellow man**
- **Contribute to the advancement of science**
- **Compensation/Remuneration**



Clinical Research Recruitment: Barriers



Barrier: Something that blocks or is intended to block or slow passage of completion of an outcome.

Institution/ Researcher/ Coordinator

- *Where to begin*
- *Knowledge of the community*
- *Grant time constraints*
- *IRB process is lengthy: Submission & Approval*
- *Low recruitment budget*
- *Support :Institutional (PI/ research team) vs. Community(leaders)*

Community member & Study Participation

- *Time (work schedule)*
- *Location (not convenient)*
- *Concerns about side effects of intervention (drug/ device)*
- *Fears of placebo vs. intervention*
- *Unknown outcome*
- *Required Medical exams and tests*

i.e. Blood tests, MRIs, CT Scans, X-ray , biopsies, machines, and diagnostic tests

Other Community Barriers....

- Child care or adult dependent care,
- Job flexibility, time availability,
- Limited or no ability to travel to research sites,
- Limited access to other resources (e.g. reliable phone, internet, etc.),
- Language, and/ or family, community, and cultural influences.
- Change in personal situation: divorce, break-ups, death in the family, etc.

“Common sense is the collection of prejudices acquired by age eighteen”.

~Albert Einstein



You (Self-awareness)

- You....
 - Attire?
 - Perfume/ cologne?
 - Hair style? Jewelry?
 - Behavior? (*close talkers)
- What is your body language – what does it say?
- Are you being attentive?
 - Eye contact, listening, responding to questions, soliciting questions, being culturally aware/ sensitive, etc.)



THE DENZEL WASHINGTON VENN DIAGRAM

■ GLASSES ■ FACIAL HAIR ■ GLASSES & FACIAL HAIR ■ ALL THREE!
■ HAT ■ HAT & GLASSES ■ HAT & FACIAL HAIR



MAXIM.COM

Awareness of the Community

- What do you know about your target population's knowledge about clinical research (Barrier)?
- Are you aware of some of the fears that this community has about being involved in clinical research (historical, anecdotal, etc.)?
- Have you thought about how to address them when, and if, they come up?
- Whether your target population is adequately and appropriately informed of research opportunities.

Experts assert...

- Problems with communication
 - Not aware of studies that are going on
- Mistrust
- Concerns persist about personal safety & loss of confidentiality
- Consents (longer & more complex)
- Goals of research are not well understood
- Subjects often do not get results from the study
 - Importance of research
 - Lack of information to take action



“A person who never made a mistake
never tried anything new.”

~ Albert Einstein



The Recruitment Team



No “I” in team

- The whole team needs to be thinking about recruitment
- Everybody has a role in the outcome of the recruitment and retention of the target study population
- How can you better communicate with your research team/ PI your needs to recruit and retain research participants....
 - Are you working in silos or as a team in developing your recruitment and retention materials?
 - Are your schedules supportive of recruitment/ retention?
 - Do you provide adequate, if appropriate, reimbursements for travel, food vouchers, and compensation for time and effort involved?

Trust?



Where does mistrust come from?

- Legacy of Slavery
- The Tuskegee Syphilis Study (1932-1972)
- Civil Rights Era
- Legacy and persistent discrimination
- Previous “bad” experience in a research study and/ or patient care
- New Immigrant vs. 1st, 2nd, etc. generations.
- Country origins (torture, dictator/holocaust, etc.)
- Lack of cultural sensitivity in research practice
- Persistent disparities in healthcare
- Language barriers/ Fear of deportation

Source:

1. Lisa Cooper, Lecture titled “The Importance of Communication and Cultural Competence in enhancing Research Participant Recruitment “ April 30, 2010, ICTR Meeting .
2. Harris Y, Gorelick PB, Samuels P, Bempong I. Why African Americans may not be participating in clinical trials.
3. J Natl Med Assoc. 1996;88:630–634. Corbie-Smith G. The continuing legacy of the Tuskegee Syphilis Study: Considerations for clinical investigation. Am J Med Sci. 1999;317:5–8

There is value in cultural competence....



- Ability of research team to engage and recruit effectively:
 - Understands meaning of culture and knowledgeable about different cultures
 - Consider hiring a diverse team reflecting target population
 - Provide culturally and linguistically appropriate materials
 - Be aware of health disparities & discrimination affecting minority groups

5 Areas of a Recruitment Strategy

1. Awareness
2. Education
3. Communication
4. Risk
5. Convenience



Source: Adapted from "Clinical Research Recruitment and Retention Tactics – 1001 Ideas to Enhance Study Awareness and Encourage Participation in Clinical Trials," Clinical Research Performance Partners, Inc.,

Author: Harper, Beth, <http://www.clinicalperformancepartners.com/>

Recruitment Services Program of the Clinical And Translational Science Institute: ReSPECT

Recruitment: Awareness

- Who needs to know about your study and why?
- Where is your source of research volunteers coming from?
- What are you doing to attract people to your study? Is it the most cost effective way to reach your target?
- Who will develop your materials (flyers, ads, etc.) & what approvals do you need?
- Are you adequately staffed?

Source: Adapted from “Clinical Research Recruitment and Retention Tactics – 1001 Ideas to Enhance Study Awareness and Encourage Participation in Clinical Trials,” Clinical Research Performance Partners, Inc.,

Author: Harper, Beth, <http://www.clinicalperformancepartners.com/>

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Recruitment: Education

- Who needs to be educated about different aspects of your study?
 - Potential Participant
 - Family
 - Primary Care Physicians
 - Community Leader (e.g. church)
 - Community at large
- What tools/ materials are needed to supplement the consent?



Source: Adapted from "Clinical Research Recruitment and Retention Tactics – 1001 Ideas to Enhance Study Awareness and Encourage Participation in Clinical Trials," Clinical Research Performance Partners, Inc.,
Author: Harper, Beth, <http://www.clinicalperformancepartners.com/>

Recruitment:

Communication (Credibility)

- Who is the most credible to the potential study volunteer to present the study and respond to questions?
 - Investigator
 - Clinician/ Nurse Practitioner
 - Research Nurse/ Study Coordinator
 - Community Advocate
 - Patient Navigator
- Are study materials understandable?



Source: Adapted from "Clinical Research Recruitment and Retention Tactics – 1001 Ideas to Enhance Study Awareness and Encourage Participation in Clinical Trials," Clinical Research Performance Partners, Inc.,
Author: Harper, Beth, <http://www.clinicalperformancepartners.com/>

Recruitment: Communication

Requires IRB approval

- Direct advertising, which is intended to be seen by the potential subject.
- “Dear Patient” letters.
- Press Releases.
- Materials distributed at health Fairs
- Websites

Wording Does Not Require IRB Approval

- Materials for professional referrals.
- Word of Mouth
- News coverage
- Internet Databases of Research Studies or Registries of Clinical Trials:

www.clinicaltrials.gov



Source: “Advertising and Recruitment Guidelines,” CR Times: September 2005

Recruitment: Risk

- Are the study risks and benefits explained by the most appropriate study staff member?
- Provided in a way that is understandable and appropriate?
- Is there a qualified person (MD, NP) available at all times (if required) to answer calls and address concerns as needed in a timely fashion?
- Do you provide emergency contact information?



Recruitment: Convenience

- How much flexibility are you and your team willing to provide? Office hours?
- Can you provide participant transportation to site, reimbursement for travel, or can you go to their home or a place convenient in the community?
- Have all reasonable and ethical considerations regarding compensation been explored & considered for a participant's time and effort?



Retention....

- A research participant should feel valued and appreciated from the first contact to the end of the study. (e.g. thank you cards, etc)
- Study instructions should be simple and clear to support participation.
- One out of every four participants stay with a study until study completion. (Center Watch 2005).
- Attrition reduces statistical power, creating biased estimates of effects of intervention, and generalizability of study results.



Source: Adapted from lectures by Itrich, Jefree, Senior Communications Recruitment Specialist, ADSC Administration, University of California, San Diego. Training: SCOPE – Summit for Clinical Ops Executives, March 8-9, 2010 – “Retention Begins with First Screen Call” and “Development of Effective Strategies for Recruitment of Minority Populations into Clinical Trials

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Retention: An ounce of prevention...

Pondering some reasons why subjects drop out of studies:

- The subject doesn't understand the importance of remaining in the study.
- The study requirements are too burdensome.
- Feeling rushed or afraid to ask 'dumb' questions.
- A change in personal situation.
- **Unfriendly people at study site; poor relationship with study staff.**

Retention success...

- Be welcoming! Smile! Be cheerful!
- Answer all questions thoroughly and explain every aspect of the study.
- At the end of the conversation ask if he/ she has any more questions.
 - Tell me what your questions are...
- Engage the caregiver if there is one.



Source: Adapted from lectures by Itrich, Jefree, Senior Communications Recruitment Specialist, ADSC Administration, University of California, San Diego.
Training: SCOPE – Summit for Clinical Ops Executives, March 8-9, 2010 – “Retention Begins with First Screen Call” and “Development of Effective Strategies for Recruitment of Minority Populations into Clinical Trials.”

Recruitment Services Program of the Clinical And Translational Science Institute: ReSPECT

Retention success, continue....

- Once someone enrolls, be positive and motivating, and support them being accountable.
- Provide study schedules, reminder calls before study visit, list of study contacts, thank you notes, etc.
- Be accessible.
- Study Swag – t-shirts, mugs, bags, pens, magnet, bookmarks, balloons.
- Waiting area with snacks, beverages, current magazines.



Don't
forget
IRB
approval!

Boston University /Boston Medical Center: Recruitment Support

- Clinical Research Resources Office: ReSPECT & Registry
 - Consultation services regarding IRB and grant applications, assistance with materials development, and recruitment strategies
 - ReSPECT Registry
- BMC Corporate Communications
 - Stamps flyers for you to place in pre-designated locations around the BMC campus
 - Staff Email
 - Development and dissemination of press release
 - Facilitate Media Contacts
 - Web
 - Radio
 - TV news
- Boston University Marketing
 - Creative support in developing a study image
 - Development of Brochures, Flyers, Study Cards, Banners, etc.

ReSPECT Registry

Registry

- The registry is:
 - For people interested in research study participation.
 - For researchers seeking research volunteers.
 - Linked to medical records.*
- The registry staff contacts registry members about potential studies.
- *Researchers and registry staff do not have direct access to medical records.
 - Initial query of registry database
 - Secondary query done by CDW

Without the Registry

- Finding people interested in research study participation:
can be costly with a low yield...
- Research team may have to go through several steps* to finally connect with an eligible potential study participant.

(Wait on PCP referrals, place ads, flyers, send out emails, direct mailings, several screenings, and field a lot of calls that yield no enrollees)

Registry Recruitment

- ***1,392 people in the registry as of March 10, 2011***
 - ***Goal to recruit Thousands!***
- We recruit from:
 - Boston Medical Center: Menino Pavilion and East Newton
 - Boston University School of Medicine lobby
 - Boston University – George Sherman Union (GSU) Charles River
 - Community Health Fairs/ Events/ Special Meetings
 - Over the phone & the web
- Age range of registry members: 18-82 years old. Contact us for more information regarding demographics of registry participants.
- Currently 6 Pilots underway: 4 Healthy Subject studies/ 2 Intervention Studies
 - Results: 14 enrolled into studies (42 names with contact information given to investigators)

Role Play - Skit



Background

Script for recruitment of subjects for an Intervention Study. Target population is identified through clinic records and patient appointment schedules for PDT acne treatment by a BMC dermatologist.

Background: Photodynamic Therapy (PDT) is the most recent advance in treating moderate, to severe cystic acne. Now patients can avoid the mood depression, birth defects, dryness and other harsh side effects that result from taking systemic oral drugs such as Accutane. The process begins with a topical sensitizing agent, Levulan. Levulan is applied to the skin and then activated with the correct wavelength of light.

This study plans to use another FDA approved drug called “MAKE-U-BEAUTIFUL” instead of Levulan... which was an FDA approved drug for arthritis The coordinator assumes the person she is approaching is her potential subject, because the young woman has arrived at the appointment time that she was expected at.

Wanted..... Research Participants!

(Note: We are required to be ethical in our recruitment practices...)



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Acknowledgments

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