How to Win Friends (*at the IRB*) and Influence People (*to join your study*)

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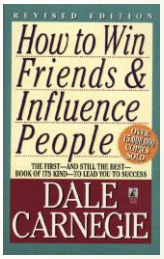

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Learning Objectives:

+ Learn about HRPP Policies on recruitment methodology and institutional requirements

+ Identify pitfalls in common recruitment strategies and pick-up tips on how to avoid them in your next IRB submission

+ Discover what recruitment approaches the IRB *almost* always approve and which ones we don't (and why!)

+ Put what you've learned into practice working through recruitment case studies and examples

What Qualifies as Recruitment?

Informing potential subjects about the research (in person or otherwise)

Providing potential subjects with information about the research (flyers/copy of the consent form) without consenting them

Providing potential subjects with contact information for the study team

Asking potential subjects if the PI may contact them to tell them more about the research, the 'warm hand-off'

Recruitment vs. Screening

- Study screening procedures are frequently confused with study recruitment. The two activities may overlap but are distinct.
- Recruitment includes all activities where information is *provided to* the prospective participant while screening includes *obtaining* information from or about prospective participants.
- Screening examples:
  - EMR review
  - Screening survey with prospective subject
  - Blood draw
- This presentation focuses on 'recruitment' but we will discuss EMR prescreening as it's a common first step to a study's recruitment scheme

Ethical Concerns and Principles

- **Respect for privacy:** Does the recruitment strategy respect an individual's reasonable expectations for privacy? Will patients be upset when they learn researchers not involved in their care have read their medical records without permission?
- **Lack of pressure:** Is the study introduced in a way that allows subjects ample time to consider, with no undue pressure because of timing of the request, who makes the request, how the request is made, or the offering of excessive inducements? Will patients be put in a situation where they may hesitate to say "no" to their own physician? How will pressure be minimized?
- **Unbiased presentation of the study**: Is all information accurate, balanced and free of misleading emphases that make the study excessively attractive? Is the information as complete as is appropriate for each stage of recruitment?
- **Avoiding the therapeutic misconception:** Patients tend to believe a clinical trial — or anything proposed by health care providers — will benefit them, even if they're told there is no assured benefit. Does the recruitment strategy work to counteract this misconception?
- **Conflicting concerns of care providers and patients**: Subjects may prefer that someone involved in their care contact them about research, but they may find it hard to say "no" to a care provider. Clinicians may find their clinical judgment in conflict with a desire to enroll patients in their research.

https://irb.ucsf.edu/recruitment

What does the IRB need to know about your recruitment procedures?

- How you will identify your population- **IDENTIFY**
- How potential subjects will receive information about the study – **CONTACT AND INFORM**
- Why you chose your target population - **SUITABLE POPULATION**
- Whether you have access to your target population for recruitment- **WHERE**
- How you will protect the confidentiality and privacy of all the potential subjects, whether or not they participate - **CONFIDENTIALITY PROTECTIONS**

Active vs. Passive recruitment:

Active recruitment:

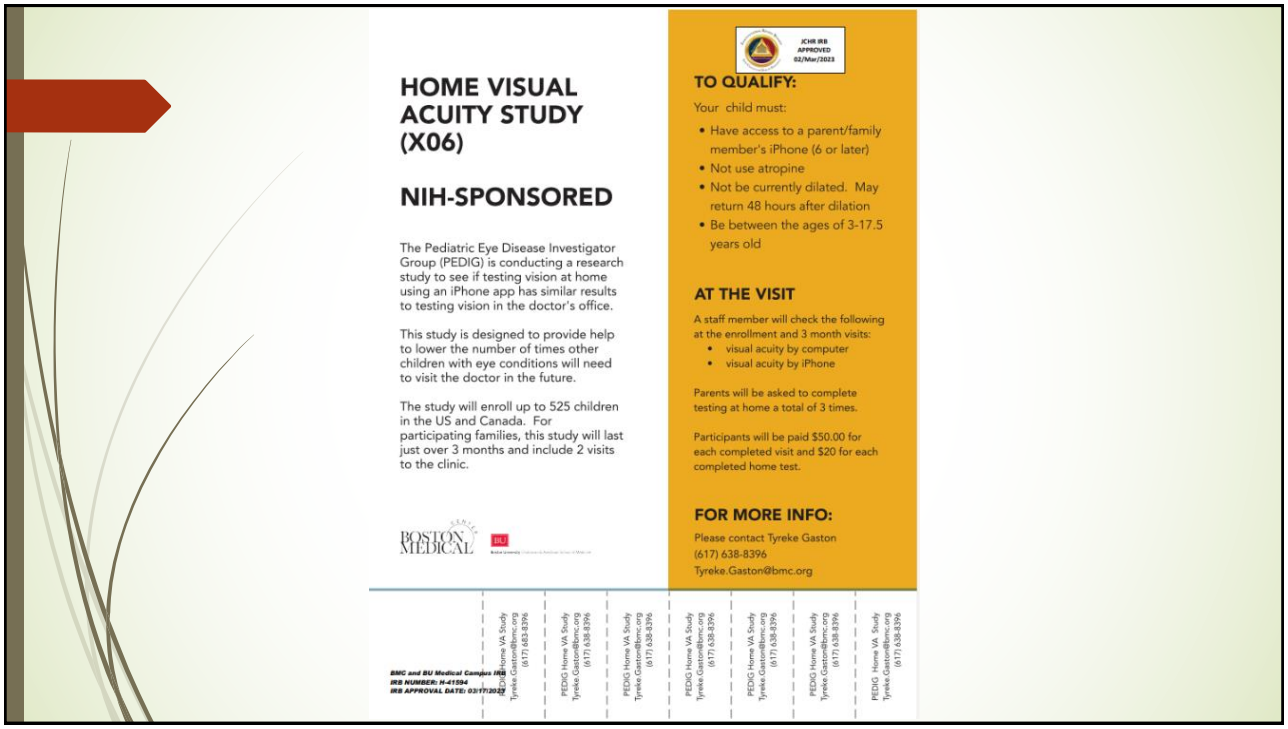
- Specific targeted population
- EMR screening for eligibility/Listservs for specific populations
- "You contact them"

Passive recruitment:

- Broader population with less stringent inclusion criteria
- Flyers, social media postings
- "They contact you"

What are the requirements for recruitment material?

- A clear statement that this is *research* and not treatment
- A statement about the *purpose* of the research
- *A summary of the inclusion criteria*
- *Time commitments* and other commitments for subjects
- *Where* the research will take place
- *Contact information* for study staff
- *The institution's logo* (when appropriate)
- *Reimbursement/other payments*


HOME VISUAL ACUITY STUDY (X06)
NIH-SPONSORED
The Pediatric Eye Disease Investigator Group (PEDIG) is conducting a research study to see if testing vision at home using an iPhone app has similar results to testing vision in the doctor's office.
This study is designed to provide help to lower the number of times other children with eye conditions will need to visit the doctor in the future.
The study will enroll up to 525 children in the US and Canada. For participating families, this study will last just over 3 months and include 2 visits to the clinic.
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JCHR IRB APPROVED 02/Mar/2023
TO QUALIFY:
Your child must:
• Have access to a parent/family member's iPhone (6 or later)
• Not use atropine
• Not be currently dilated. May return 48 hours after dilation
• Be between the ages of 3-17.5 years old
AT THE VISIT
A staff member will check the following at the enrollment and 3 month visits:
• visual acuity by computer
• visual acuity by iPhone
Parents will be asked to complete testing at home a total of 3 times.
Participants will be paid $50.00 for each completed visit and $20 for each completed home test.
FOR MORE INFO:
Please contact Tyreke Gaston
(617) 638-8396
Tyreke.Gaston@bmc.org
BMC and BU Medical Campus IRB
IRB NUMBER: H-41594
IRB APPROVAL DATE: 03/17/2023
PEDIG Home VA Study
Tyreke.Gaston@bmc.org
(617) 638-8396


COME JOIN THE COMMUNITY WALKS RESEARCH STUDY!
Interested in joining a study?
Well, we want you to participate!
• We'll measure your physical activity level & ask you to fill out a survey
• 3 visits over two years
• Earn $40 per visit ($120 in total)
• Participate from home and online; no trips to the clinic area needed
For more information:
Call or text: Jennifer (781) 223-2331, Meli (617) 694-4206,
Dariela (857) 260-5179, or call us at the office (617) 414-6656
You can also send us an email: CommunityWalks@bmc.org
BMC and BU Medical Campus IRB
IRB NUMBER: H-42219
IRB APPROVAL DATE: 02/23/2023
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COMMUNITY WALKS

Recruitment materials should NOT include:

- Any *exculpatory language* (statements waiving or appearing to waive any legal rights or providing a release from liability for negligence)
- Any terms, such as "*new treatment,*" "new medication," or "new drug," without explaining that a test article is investigational, that is, has not been approved yet
- The *amount may NOT be emphasized* by using large, bold, underlined, italicized font or by putting this information first in the ad before the study purpose, procedures, and time commitment.

BUMC & BMC have institutional requirements for recruitment materials

- This includes flyers, brochures, social media ads, etc, that are shared/posted.
  - This does not apply to letters sent directly to subjects
- All applicable recruitment materials require review by the BMC Communications and Marketing Department, BUSM Communications Office, GSDM Communications Office, or BU School of Public Health Communications (depending on the PI's home institution) prior to use.
  - You must attach the Communication's Office certificate of approval
- This is an institutional, not an IRB requirement.

For more information, see below:

- IRB Website: http://www.bumc.bu.edu/irb/submission-requirements/general-submission-requirements/guidance-for-recruitment-and-screening/research-study-recruitment/
- BU CR Times: https://wwwapp.bumc.bu.edu/ocr/ClinicalResearchNewsletter/article.aspx?article=756
- Promotional Toolkit: https://www.bumc.bu.edu/irb/files/2019/07/Research_Study_Recruitment_Promotion_Toolkit.pdf

Approaches *almost* always approved

- Flyers
- Advertisements (radio, TV, websites)
- Word of Mouth
- Review of medical records
- Tabling / Community events
- Recruitment registries/future research permission
- Clinician referrals
- Recruitment at time of clinical appointment
- Opt-out letters (mail, MyChart, etc)
- Listservs

NOTE: IRB approval is required but not always enough to move forward with your proposed strategy.

Recruitment: Unique Challenges
and potential alternatives

Cold calls	• Opt-out letter, including MyChart messages 'signed' by someone known to the subject
Approaches in the waiting room	• Clinic staff hands a flyer when checking in
Direct patient approach by the study team in the clinic	• Warm handoff by known clinician
Recruiting the same day as a clinical procedure	• Sending recruitment material ahead of procedure with follow-up phone call
Snowball sampling where investigators is getting list of potentially eligible people's contact info	• Subjects hand flyers to potentially eligible people with investigators' info

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BOSTON UNIVERSITY

Sun Lee, MD
72 East Concord Street C3
Boston, MA 02118
Date:

Recipient Name
Street Address
City, State Zip Code

Dear [Recipient]:

We are contacting you to see if you may be interested in hearing about a research study. Your obstetrician gave us permission to contact you about this research study.

It is important for pregnant women to take enough iodine because it helps to make thyroid hormone – a hormone that the baby needs for development. Sometimes, certain chemicals can make it difficult for the thyroid gland to use the necessary iodine to make thyroid hormones. In this research study, we are studying how iodine and other chemicals (such as perchlorate and thiocyanate that are present naturally in soil and water) affect thyroid hormone levels in pregnant women and their babies.

If you participate in this study, you will meet with one of the study investigators twice during your regular appointments at the prenatal clinics at Boston Medical Center. At each visit, you will complete two short questionnaires, which can also be done online in advance. We will collect urine and blood samples from you when you have your usual blood draw for your doctor. At the time of delivery, with your permission, we will collect blood from the placental cord. We will also review your baby's medical record to gather necessary health information. We will not have any direct contact with your baby or you during delivery. You do not have to take any special medications or supplements for the study.

If interested, please contact the research team at 617-414-2979 for more information.

If we haven't heard from you, we will call you 2 weeks after sending this letter. To opt out of this phone call, please contact the research team at 617-414-2979 to let them know that you are not interested in participating in this research study. We will delete all voicemails to protect your confidentiality.

Thank you for your time and consideration.

Sincerely,

Sun Lee, MD

The Most Common Issue

Lacking sufficient detail to assess scheme.

- *"We're going to recruit from our own patients in the XXX clinic".*
  - Who is going to approach? PI or RA?
  - How are you going to approach? In-person? Over-the-phone?
  - When is this approach – during scheduled clinical appointment?
  - Will you be using any scripts? Any flyers?
  - Where is the approach going to take place?
  - Are you going to approach everyone or only some?
    - How will you choose?
    - Will you be doing a pre-screen in the chart before approaching?

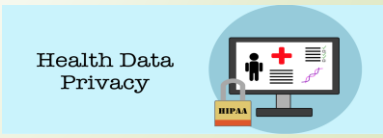
HIPAA requirements for Recruitment/Pre-screening

When accessing PHI w/o authorization, the IRB must grant a HIPAA waiver. To do this, we need to assess:

1. Why you need PHI
2. Why it's impracticable to get HIPAA authorization from patients
3. How you'll protect the PHI
4. When you'll destroy identifiers.

You should only be assessing the absolute minimum to make an eligibility determination.

<u>This isn't a chart review.</u>



Issues with HIPAA - Recruitment/Pre-Screening

#1 - You're pre-screening via medical records or reviewing the daily clinic schedule, but the HIPAA section is not completed

#2 - You've completed the HIPAA section but the data points, storage, procedures, justifications, etc refer to the main study. The HIPAA section **ONLY** refers to the data, storage of data you need **BEFORE** consent/authorization.

#3 - Missing details or poor justifications (see next slide for a cheat-sheet)

HIPAA - For recruitment

If you need to look at MRs or the daily clinic schedule, please state "YES" to the HIPAA section

Q3. Any patient presenting with XXXXX (from patient eligibility criteria)

Q4. Estimated start and end date of range of records needed in mm/dd/yyyy format.

Q5. All the datapoints you need to assess eligibility and to be able to approach the patient (date of appointment). Don't forget the identifiers: MRN (to access chart), Name, and Dates

Q7. Identifiers: MRN, name, dates, contact info - as applicable

Q8. "Recruiting without already knowing that the potential subject is probably eligible would require an inordinate amount of time for study staff and ineligible subjects" or similar

Q9. "Approaching ineligible subjects would waste their time and be confusing; eligible and interested subjects will provide authorization during consent." or similar

Q10. "All identifiable information will be transmitted, stored, analyzed, or otherwise exist only on electronic systems that meet the standards for protection of PHI at Boston Medical Center." NOTE: BMC requires all PHI to be stored on either Box.com, REDCap, or the Dept drive w/ encryption & password protection.

Q11. "Identifiers will be destroyed as soon as eligibility has been determined for a potential subjects" or similar. NOTE: Often times need to keep identifiers through recruitment period to prevent rescreen. If you're doing this, state it here with note that list of names/mrns destroyed.

Recruitment: Special Situations

- Recruitment using Community Health Centers

Contact Roz Schomer for more info: Roz@bu.edu

- Recruitment of HIV positive subjects

Per Mass. Law, there are special protections

- Recruitment and access to data from a PART 2 clinic

Determine whether your targeted clinic qualifies as a PART 2 clinic by looking at help text and contact the analyst for additional paperwork

- Non-Engaged recruitment for an external site

Check out this CR Times article: https://wwwapp.bumc.bu.edu/ocr/ClinicalResearchNewsletter/article.aspx?article=713

- International research

Rely on the local site for guidance and local regulations/context

Social Media

- The BMC/BUMC IRB does not have any formal guidance or policies specific to social media; however, here are a few best practices:
- All requirements and prohibitions previously stated for "off-line" approaches apply to social media recruitment, including that all posts need to be vetted through the applicable communications office and the IRB.
- Do not friend anyone; accessing private groups needs to be done through permission after disclosure of purpose
- Given the sensitivity of the topic, you may consider making the post "non-commentable" to prevent people from putting their name, contact info, and health information on a public post. If not sensitive or a closed group, not as much a concern. In any event: it is important to monitor the post if people can comment.
- Interaction with subjects should be moved to a more secure platform as soon as possible (e.g. avoid using Facebook messenger to schedule visit)
- Expectation that strategy is respectful (no deception to gain access, transparent, don't lurk to collect data, etc)

Take a swing:

- PI wants to recruit subjects who are HIV positive to test out a non-FDA approved experimental drug. PI proposes doing a medical record pre-screen and then calling potential subjects – most are not their own patients.
- Script states, "Hello, I'm a doctor at BMC. We looked at your medical record and see that you have HIV. We're testing out a new treatment. Would you like to know more?"

What is wrong with this scenario?

How can it be fixed?

Take a swing:

- PI wants to collected discarded tissue from biopsies to test a hypothesis about possible markers for cancer. She will also need to draw blood from subjects.
- She proposes to approach subjects on the day of their invasive diagnostic biopsy procedure to consent them and request a blood sample

What is problematic about this scenario?

How can she obtain tissue and blood without compromising subjects?

Take a swing:

- PI wants to do a study on socioeconomic determinants of health, minority status and ear infections in children using a survey
- They propose to station RAs in the waiting area at the pediatric clinic to approach subjects who seem, only by visual assessment, to fit the inclusion criteria with a recruitment script outlining the study question

Is this acceptable?

How should they go about recruiting subjects instead?

Take a swing:

Do you have trouble sleeping at night?

Counting minutes on the clock instead of sheep?

Maybe we can help! We're testing a new drug treatment called, Putchatosleep. (Risks include never waking up)

You could earn $3,000!!!!

Call Dr. Jones at xxx-xxx-xxxx

Resources:

Recruitment Requirements

CR Times article on recruitment

Recruitment Script

How to conduct research with CHCs

HRPP Policies and Procedures

Thank you!

- Jamie Merrill, MPH, CIP
  - 617-358-6557
  - jcm57@bu.edu
- Lin Themelis
  - 617-358-5302
  - lint@bu.edu
- Main IRB: 358-5372 & medIRB@bu.edu
- Resources:
  - https://www.bu.edu/crtimes/
  - https://www.bumc.bu.edu/irb/inspir-ii/inspir-ii-instructions-for-investigators/
  - http://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/

Questions?
Comments?
Reflections?
Feedback?