



Clinical Trials

Where World Class Care Begins

Research Subject Recruitment

A key to successful recruitment efforts is tapping into diverse resources.

The Office of Clinical Trials (OCT) recognizes that accrual of subjects is vital to the success of any research endeavor; however, this crucial element is often the most elusive. Whether enrollment is stagnant from the outset or suffers inactivity after study initiation, the OCT offers the strategies and support needed to help find and keep subjects in your study. Our recruitment and retention services are designed to assist investigators at all stages of the research process in devising plans for reaching their enrollment targets and in considering which tactics they may employ not just to find patients who meet inclusion criteria but to convert them to active subjects.

Our office is amassing successful recruitment strategies from researchers at Montefiore and the Albert Einstein College of Medicine, as well as from hospitals, universities and research facilities in the New York area and beyond. The result is a succinct amalgamation of approaches that compose the Office of Clinical Trials' POEM Initiative. The **POEM** Initiative stands for **P**rint Media, **O**utreach, **E**lectronic Resources, **M**iscellaneous Strategies and Resources, and this framework offers an informal structure for effecting your overall recruitment plan, which you and your research team should devise in the planning stages of your study (well in advance of your trial activation) and should continue until you have reached your enrollment targets.



PRINT MEDIA

The First Step in Your Recruitment Efforts

Trial summary, brochures, flyers and posters (the OCT can provide templates)

In your initial submission to the IRB, plan to include for approval a general write-up of your study with the printed recruitment materials you will use. Flyers, posters and brochures are standard advertisement tools that can be posted in clinics, in patient areas, on the Internet and anywhere you have permission to publicize your trial. The OCT can provide templates for all of these. A brief summary of your study—in which you convey in lay terms the purpose of the study, the inclusion and exclusion criteria, and the general benefits of participating—are versatile and can be used for recruitment via print or electronic media. Because these resources will be viewed by subjects and prospective subjects, they must be IRB-approved.

Physician “quick reference” guides

Pocket reference guides give basic information about your study, including inclusion and exclusion criteria. Typically provided by your trial's sponsor, these guides should contain a concise summary of your research expressing in lay terms the purpose of the study and the general benefits of participating.

Letters from PI to clinicians and colleagues

Perhaps your most valuable immediate resources for subject recruitment are referrals from your colleagues, clinicians and fellow members of your department and division. One way to reach out to them is with a letter describing the study and the inclusion and exclusion criteria. You may want to request in the letter that recipients post copies of IRB-approved ads and recruitment materials in their patient areas. Letters from the PI to clinicians and colleagues must be IRB-approved.



OUTREACH

Getting Out the Word About Your Study to Others

Utilize your immediate resources:

- Colleagues (within and outside Montefiore and Einstein)
- Other physicians in your division and department
- Your residents and fellows
- Your research team
- Subjects already enrolled in previous studies
- Your sponsor
- Department meetings and Grand Rounds presentations

Make it a habit to announce trials that are currently recruiting at the start of department/division meetings.

Post study information in clinics and areas where residents see patients.

A popular recruitment avenue is to post a summary of your clinical trial for clinicians and department residents. Include a brief description of the study, as well as contact information for the study's coordinator and the

most relevant inclusion and exclusion criteria. These posts can be updated and reposted weekly depending on the offices in which you have permission to post them and your target patient populations. Because these postings are for clinician and resident reference only, they will require IRB-approval. However, be sure to keep these posts accurate, concise and eye-catching (e.g., print them on brightly colored paper).

Direct recruitment at clinics

The study coordinator, in cooperation with the principal investigator (PI) and/or clinicians associated with the study, may recruit participants from Montefiore Einstein clinics. The coordinator should examine patient charts well in advance of the clinic's patient hours to identify individuals who have the diagnosis of interest and who meet inclusion criteria for the study. Placing notes on each chart or otherwise communicating with the clinician via patient records will indicate to physicians which individuals they should follow up to assess interest and eligibility in the trial. Coordinators should regularly examine clinical schedules to determine when eligible patients are being seen and should confer with clinic staff and their PIs as to how the research team can best conduct recruitment during the clinic's patient hours.

Montefiore and Einstein events

Search the Montefiore intranet and Einstein website calendar, watch for flyers and postings around campus, and read the Montefiore Update sent electronically every other week to learn about upcoming events at which you could present information about your research. When you attend these events, be sure to have IRB-approved flyers, brochures and study summaries ready to give to prospective participants in your trial.

Community events and locations where participants routinely gather

Keep an eye out for events that are taking place in the community around Montefiore and Einstein that your target patient population is likely to attend. Be aware that community centers, support groups, recreation facilities and houses of worship are trusted institutions with whom you may be able to partner to facilitate recruitment. Contact event organizers and leaders of these organizations to see whether you can present your research in an effort to educate the nearby community about your study and what you hope to achieve. When you attend these events, be sure to have IRB-approved flyers, brochures and write-ups to disseminate to prospective participants, making sure to emphasize the risks and benefits of participating and to address the reservations and barriers potential participants may face in volunteering.

Electronic resources for event information include the following:

- Montefiore Update emails
- Montefiore intranet events calendar
- Norwood News (www.norwoodnews.org)
- Bronx Times Events section (www.bronx.com/events.html)
- Bronx Times Events Calendar (www.bxtimes.com/sections/calendar)
- Riverdale Press Events Calendar (www.riverdalepress.com/calendar.html)
- Bronx Penny Pincher Events section (www.bronxpennypincher.com)
- Links to specific Bronx neighborhoods at the Bronx News website (<https://sites.google.com/site/bronxnews/homepage>)
- American Towns (www.americantowns.com/ny/bronx/events)
- The Bronx Tourism Council (www.ilovethebronx.com)
- Eventbrite (www.eventbrite.com/directory/New+York/Bronx)
- Bronx Mall (www.bronxmall.com/cal)
- Zvents (www.zvents.com/bronx-ny/events)
- Bronx News Network (www.bronxnewsnetwork.org/p/whats-going-on_23.html)



ELECTRONIC RESOURCES

Fast and Effective Dissemination of Trial Information

Websites for clinical trial posts and recruitment:

CenterWatch

(www.centerwatch.com)

CenterWatch hosts one of the largest online databases of clinical trials that are actively seeking patients. You can post IRB-approved ads and descriptions of your studies, which prospective participants may search by medical condition, therapeutic area and location. To post your trial on this site, please send an email to OCT@montefiore.org.

ResearchMatch.org

(www.researchmatch.org)

ResearchMatch is an online recruitment resource that is designed to match two groups of people: ResearchMatch Volunteers (individuals who wish to learn about studies in which they may participate) and ResearchMatch Researchers (those who register their studies with the ResearchMatch site). For more information about posting your trial on this site, please send an email to OCT@montefiore.org.

ClinicalTrials.gov

(www.clinicaltrials.gov)

Established and maintained by the National Institutes of Health (NIH), ClinicalTrials.gov is a registry and searchable database of over 120,000 drug and device clinical trials being conducted worldwide. Investigators may post information about their IRB-approved trials at no cost, and prospective participants can likewise search the database for free. If you would like your protocol to be registered with the NIH and your trial information to appear on ClinicalTrials.gov, please send an email to OCT@montefiore.org.

New York City section of Craigslist.org

Craigslist is an international website on which individuals can post and respond to classified ads and forums devoted to an array of topics. Divided by city or geographic region, the website offers a free and widely viewed means of bringing IRB-approved advertisements and descriptions of your trial to the attention of potential subjects.

Adding recruitment text to the “Volunteers” subsection of the “Community” area of the site has proved to be a valuable means of bolstering enrollment numbers for many researchers.

Organization websites for target conditions

Regional and national organizations dedicated to the therapeutic area or patient population of focus in your trial may also be able to provide you with resources for recruitment. The International Obsessive Compulsive Disorder Foundation, for example, devotes a portion of its website to active research advertisement and sends a monthly newsletter in which investigators may place advertisements for their studies. These websites may also feature lists of area treatment providers and support groups you can reach out to for advertisement and referrals. Visit the CenterWatch site for links to these pages based on specific therapeutic areas of interest (www.centerwatch.com/news-resources/general).



in your area, from colleagues and fellow clinicians and from exploring the websites for area hospitals and universities.

Tracking and metrics from previous trials

For seasoned researchers, a time-tested strategy for knowing where you are going is to thoroughly understand where you’ve been. By recording the demographics, recruitment sources and progress of subjects from previous trials, researchers can treat recruitment as a science by generating tangible, quantifiable data that can be used to evaluate the effectiveness of recruitment strategies and to uncover participant resources that have yet gone untapped.

Newspaper ads

In the Bronx and broader New York area, there is a wealth of newspapers and other media available for advertising your research study. You can find contact information for the most popular local media on the Einstein-Montefiore Institute for Clinical & Translational Research (ICTR) website at www.einstein.yu.edu/centers/ictr/clinical-trials. Advertising prices for newspapers vary by the publication and the size of the

advertisement. However, many papers have “Community Calendar/Events” sections that permit free advertising. Note that any advertisement for publication must first be approved by the IRB.

Interviews with the principal investigator or researchers affiliated with the trial

Interviews with the PI or sub-investigators attached to your trial—whether for print or electronic media—are excellent means of reaching diverse subject populations. At Montefiore, work with the Office of Public Relations to contact local news outlets, publications and online resources dedicated to reporting medical or clinical trial developments to gauge their interest in publishing information about your research. Go to <http://www.montefiore.org/public-relations> or call 718-920-4011. At Einstein, the best way to reach the team is to send an email to sciencenews@einstein.yu.edu. Be sure to check with the sponsor of your trial before initiating any media activity so as to verify that the interview is permissible and what, if any, details about the trial you are authorized to divulge.



MISCELLANEOUS STRATEGIES AND RESOURCES

Text-messaging services for subject recruitment and retention

The Office of Clinical Trials is looking into ways to employ text messaging services for subject recruitment and retention. Such a system would allow you to utilize mobile text messaging in conjunction with your existing advertising efforts to identify and screen potential subjects. By placing a numeric code that is specific to your study on your advertisements and recruitment materials approved by the IRB, you may allow any prospective subject who has a mobile phone to answer questions about the basic inclusion and exclusion criteria

for your trial. You can then receive notification of individuals accessing the code and reach out to them, whether shortly after their initial contact or in real time via instant notification. Please send an email to OCT@montefiore.org if you are interested in taking advantage of this technology.

Direct call campaigns to clinicians, treatment providers and support group leaders for referrals and requests to post advertisements

The contact information for these campaigns can be found through Internet searches of these resources

You will need IRB-approval before posts can be made.

Office of Clinical Trials

Office of Clinical Trials

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The Office of Clinical Trials on YouTube:
<http://www.youtube.com/watch?v=QVvA4Eei-el>

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