NYULH Research Study & Clinical Trial Recruitment Best Practices Brief

Overview of Research Study & Clinical Trial Recruitment

In order to ensure that medical treatments benefit everyone, all populations should be represented in medical research. Unfortunately, certain populations are have been historically excluded from clinical trials.[1] In 1993, The National Institutes of Health (NIH) Revitalization Act was created to increase the inclusion of clinical research and to decrease health care disparities.[1] A survey of all US randomized control trials published in the last 25 years found that only 4% of research studies achieved adequate inclusion across all populations (n=10,057).[1] Since implementing the Revitalization Act in 1993, NIH-funded studies had a 4-fold increase in study inclusion (from 2.8% to 11.1%), compared with non–NIH-funded RCT studies.[1] Despite the NIH and its affiliated agencies' continued efforts to improve inclusion in clinical research, ~90% of research studies are lacking adequate representation of all populations.[1]

To address this clinical trial participation representation issue, NYU Langone Health (NYULH) investigators and staff must reexamine the recruitment stage of research studies. Patient or participant recruitment involves many steps, including identifying eligible participants, adequately explaining the study to the potential participants, recruiting an adequate sample based on study goals and design, obtaining informed consent, maintaining ethical standards, and retaining participants until study completion.[2] Investigators at NYULH typically use the following direct patient/participant recruitment (DPR) or community-facing strategies to make potential participants aware of their projects:

- Sending letters or postcards (often from the patient's provider);
- Distributing or displaying flyers, pamphlets, brochures, and/or posters;
- Approaching patients one-on-one in their primary care provider's office or local community clinic;
- Conducting or participating in health fairs and/or other community outreach activities;
- Placing phone calls, emails, or sending messages via patient portals or listservs;
- Advertising in university newsletters, local newspapers, radio, or television stations;
- Recruit directly from community liaison groups (e.g., community advisory board, community-based organizations, community health worker networks) or from previous or on-going research studies;

Utilizing community-facing recruitment strategies in clinical trial or research study enrollment is a novel, low-touch method to engage populations experiencing health disparities; however, many research studies at NYULH (and in most research institutions) face challenges when it comes to DPR. Findings from several studies indicates that recruitment to reach all populations requires an investment in time and resources -- investigators report that these strategies often incur higher costs than expected, and that they routinely overestimate the number of racial ethnic participants available and/or eligible for

enrollment in their studies.[2] Even in studies that succeed in recruiting patients inclusive of populations experiencing health disparities, participation or retention rates may be low.[2]

Research has shown that poor recruitment and reach to all populations is commonly rooted in the following challenges:

- lack of adequate planning;
- lack of dedicated time and resources;
- inadequate attention to recruitment strategies;
- poor engagement and lack of understanding and attention to the social, cultural, and historical context of priority communities and populations;
- lack of resources to bolster and strengthen community links and networks;
- lack of cultural competency of investigators and study teams;
- inadequate attention to language access or inclusion of representative research team members with experience with priority communities and populations.[2]

Direct outreach to community participants through electronic health record (EHR) data allows for efficient recruitment and follow-up.[3] This strategy links patient participants with data that fits certain clinical eligibility criteria to research teams.[3] Patient participants can be accessed through Epic, NYULH's EHR system. EHR recruitment has the potential to improve study recruitment.[3] All electronic recruitment material should be health literacy compliant ensuring that all potential participants are contacted using language that is linguistically and culturally tailored. For more information on creating health literacy compliant research materials, review the Health Literacy in Research Best Practice Brief.

Best Practices for Direct Patient Recruitment (DPR)

Before a research study recruits participants, the NYULH Institutional Review Board (IRB) will review your proposed recruitment method protocol for a study (e.g., Direct Patient Recruitment or Electronic Health Record recruitment). Prior to beginning recruitment for any NYULH research study, the Principal Investigator (PI) must receive IRB approval of the protocol, recruitment methods, and any associated recruitment materials. The study protocol must include a recruitment section that details, at a minimum, the following:

- How potential participants will be identified;
- How and by whom participants will be approached about participation;
- When consent will be obtained in relation to the start of study procedures;
- What will be said to potential participants (e.g., a recruitment script); and
- Whether third parties (e.g., not study personnel) will assist with the recruitment of participants.
- If DataCore (an institutional service that provides metadata queries and searches) will be used, the protocol must also address the following:
    - How the data will be gathered from Epic;
    - How the data will be used;

- Who will have access to the Epic search results;
- What data points and PHI will be used for the research;
- When and how the data will be discarded after the data retention period has ended;
- How many times the study team will search Epic during the course of the study and/or how often queries regarding eligible participants will be run during the course of the study;
- How the treating physician will be notified of enrollment if the patient has consented to this notification; if consent for notification is provided and no notification will be made, explain why; and
- A description of how the patients will be contacted.

All recruitment materials must also be submitted for IRB review. Investigators, or their HIPAA-trained staff, who are recruiting their own patients (e.g., patients for whom they provide direct clinical care) may search Epic to generate lists of their own patients for DPR. Once the IRB approves a study that will use direct patient contact or DPR, the PI should arrange for their department chair or division chief to notify applicable physicians about future recruitment plans. If recruitment messages will be sent through MyChart, the patient-facing portal of Epic, a study summary and title must be submitted to and approved by the IRB. If emails will be sent to patients, the full text of the email or texts must be submitted to and approved by the IRB as well. Similarly, if recruitment methods include telephone calls, a telephone script must be submitted to and approved by the IRB. PIs should also take into consideration scripts for voicemails that will be left in the event that a phone call is unanswered.

For study teams that are not permitted to search Epic for DPR, patient contact information must be obtained through electronic health record databases (e.g., DataCore or Epic) as the requirements for screening patients may be different for certain studied. Study teams using Epic for recruitment screening purposes must follow the NYULH Standard Operating Procedure step-by-step guide (click here to access, login using your Kerberos ID).

Best Practices for Electronic Health Record (EHR) Recruitment

The IRB reviews all proposed studies that require EHR recruitment. If the IRB recommends that a study should utilize EHR for recruitment, PIs are not required to contact patients' treating physicians prior to recruitment, and can contact patients/participants via MyChart messages, phone calls, or email. In this instance, the PI or study team member must complete the appropriate data report request form depending on the type of data requested:

- If the report is a one-time retrospective report, submit the DataCore Service and Support Intake Form, located here.
- If the study team requires real-time information from Epic, the request should be submitted through the "Application Access and Enhancement" form in the MCIT Support and Services catalog located here.
    - For the question "Request Type" select "Application Enhancement."

- For the question "Application Details" select "Epic Research."
- Under "Additional Comments," describe the details of the patient population to be screened.

Upon DataCore/Epic Research review of the information request, the study team will be provided with a report containing the information requested. This report will be provided either by NYULH email or within Epic, depending on the data requested and the needs of the study team. Once potential participant contact information is obtained, a research team can connect to participants through either MyChart, email, telephone or through ResearchMatch.

EHR Recruitment using MyChart

The preferred method of electronic communication for all NYULH patients is MyChart messaging. MyChart is the NYULH patient portal which provides patients access to their electronic medical records and enables them to manage their health information. Study teams can recruit patients using EPIC through MyChart messages. If a study team recruits patients through Epic using MyChart messages, the PI or their designee can navigate DPR using the Reporting page in Epic. At the top of the report, will be a button "Send Recruitment Request." Clicking this button will email all patients in the current report with an active MyChart Account. The patients will then receive a message in MyChart containing the lay summary of the study and the brief study title.

Some best practices for using MyChart recruitment include:

- Send multiple messages
- Send a copy of the recruitment message to yourself to confirm the message sent
- Longer, more descriptive messages are better than shorter, brief messages
- Include a link or QR code to recruitment message to facilitate enrollment

EHR Recruitment using Email or Telephone

EHR recruitment via email requires that all emails are securely sent using the NYULH encrypted email system to patient email accounts. If the study team sends emails to patient email accounts, all recruitment emails which are sent to a non-NYULH email address must be sent using IRB approved email text. If a study team recruits via phone calls to patient mobile phones or landlines, telephone calls should be made using an NYULH landline or mobile phone. Consideration should be given to whether or not a voicemail will be left in cases in which the phone call is not answered, as well as to the content of any potential voicemails. Any voicemails left for patients should be limited to include the name, phone number, and affiliation of the caller. Only IRB approved voicemail script should be left in voicemails.

In accordance with NYULH Privacy and Security policies, study teams who contact patients via email and/or by telephone must record and store the following information on each patient each time the patient is contacted:

- Full name

- Date of Birth
- Epic medical record number (MRN)
- Date contacted
- Study for which patient was contacted

Information on patients contacted via MyChart is automatically recorded within Epic and does not require separate record-keeping. This information must be provided to the Epic Research team, the Privacy Officer, or their designee as requested.

EHR Recruitment using ResearchMatch

ResearchMatch is a free online tool designed to link people who are trying to find research studies and researchers who are looking for research participants. Researchers can use the registry to search the non-identifiable profiles (such as age, gender, race, health status, and medications) of potential volunteers from across the country. A researcher may access the registry to conduct a feasibility search, which enables them to view aggregate data in order to generate a hypothesis or explore recruitment potential for a study, or to recruit participants for an IRB-approved study. To sign up, go to the website and register for researcher feasibility access. To use the registry to recruit for a specific study you must obtain IRB approval. To access ResearchMatch, the website can be found here. For more information, contact the NYU ResearchMatch liaisons at nyuresearchmatch@nyulangone.org.

Tips & Resources

For guidance on how to find Research Study Participants, visit the CTSI Recruitment and Retention Core website.

For any questions relating to EHR recruitment using EPIC or DataCore, contact the Datacore liaison at datacore@nyulangone.org.

For more information on research recruitment, contact the Recruitment and Retention Core (RRC) coordinator at #CTSI-RRC@nyulangone.org , or the central OSR SOP mailbox at OSRSOP@nyulangone.org.

To get patient insight on preferred communication methods for study recruitment, the RRC Patient Advisory Council (PACR) is a resource that research teams can utilize. To set up a time to meet with the RRC PACR, contact the RRC coordinator at #CTSI-RRC@nyulangone.org.

Works Cited

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3. Zimmerman, L. P., Goel, S., Sathar, S., Gladfelter, C. E., Onate, A., et al. (2018). A novel patient recruitment strategy: patient selection directly from the community through linkage to clinical data. Applied Clinical Informatics, 9(01), 114-121.

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