Guidance: Recruitment Methods for Clinical Research Studies

Recruitment Activities
Examples of allowable recruitment methods are listed below, but are not limited to the below. All methods must be approved by the reviewing IRB prior to use. Contact the IRB of record if you are unsure if a recruitment method is allowable. For information on what is not allowed from the NSLIJHS Office of the Institutional Review Board (OIRB), see "Recruitment Activities Not Allowed" described in the NSLIJHS IRB policies. If using the OIRB, all recruitment activities must be submitted and approved in accordance with OIRB Policy: Recruitment Methods. Additional policies may apply and approval from the Marketing Department may be required in certain instances, such as when advertising outside the NSLIJHS, paying subjects, or recruiting potentially vulnerable populations.

Social Networking/Social Media Recruitment
Examples of Social Networking/Social Media Recruitment are:
- NSLIJ Facebook and NSLIJ Twitter posts and ads
  - The NSLIJ Facebook and Twitter pages may be good recruitment methods depending on the type of audience you are targeting, understanding the security limitation of using social networking websites, and how frequently you would like to communicate with your audience. You can use the NSLIJ Facebook and Twitter pages to recruit regardless of your IRB of record. To help decide if using NSLIJ and Twitter pages would be a useful recruitment method for your study population, please contact the OIRB at 516-562-3101. Usage of social networking sites is limited to NSLIJ Facebook and Twitter because there is already an established health system monitoring plan in place to protect against HIPPA violations as well as other regulations for security purposes. Requests to recruit via NSLIJ Facebook/NSLIJ Twitter are to be submitted to the IRB of record at the time of initial submission, continuing review, or as a modification. The IRB of record will review and once the request is approved, the IRB of record should forward the request to the OIRB who will send to the Social Media Specialist for the Public Relations Department to create the post or advertisement on NSLIJ Facebook/NSLIJ Twitter. If the review is done by BRANY’s IRB, the approved post or advertisement will be sent directly from BRANY to the Social Media Specialist at NSLIJ.
  - If you would like to create a NSLIJ Facebook post, there must be a stand-alone web page (i.e. the Feinstein Clinical Trials Webpage) to which the NSLIJ Facebook post will link.
  - NSLIJ Facebook ads vs. NSLIJ Facebook posts. Facebook ads have a fee, but it should be less than the cost of a newspaper advertisements. In addition, Facebook ads will have to be approved by the health system’s Marketing Department and the IRB of record before posting. If you have money for advertising, Facebook
ads are highly recommended versus Facebook posts for the following reasons: 1) Ads are more enduring and may have greater marketing potential. For example, as the post get older, it is displayed further down on the Facebook page and may not be readily seen by Facebook users. However, an ad will appear on the right hand side of Facebook users’ pages and can be readily seen depending on the users’ profiles and settings at every log-in. 2) Facebook ads will have a greater impact than newspaper advertisements. 3) Facebook ads have the ability to target very specific demographics while Facebook posts do not.

- **NSLIJ Health Blog**
  - A blog is a type of website that is updated with new entries of commentary, descriptions of events, or other material such as graphics or video and may allow visitors to leave comments and even message each other. The NSLIJ Health Blog may be a good place to advertise clinical research studies because there is already has an established health system monitoring plan in place to protect against HIPPA violations as well as other regulations. Requests to recruit using the NSLIJ Health Blog are to be submitted to the IRB of record at the time of initial submission, continuing review, and modification requests. The IRB of record should forward the request to the OIRB who will send to the Social Media Specialist for the Public Relations Department to create the post for the blog. If the review is done by BRANY’s IRB, the approved post or advertisement will be sent directly from BRANY to the Social Media Specialist at NSLIJ.

**Internet/Electronic Recruitment**

Examples of Internet/Electronic Recruitment are:

- Internet listings of clinical trials (e.g. Craigslist, CenterWatch.com)
- Study-specific website
- Internet basic trial information (e.g. ClinicalTrials.gov)
  - If using the OIRB, please refer to the NSLIJHS Policy GR020 Requirements for Registration of Clinical Research Studies on registering clinical trials to www.clinicaltrials.gov.
- E-News Bulletin
  - The following is the language to use for E-News Bulletin recruitment:

  **Research Volunteers Needed**

  *The [insert Name of Hospital/Department] is looking for [insert types of volunteers/gender/age needed] to participate in a research study aimed at investigating [insert what is being investigated in simple terms] to [insert aim of study, such as to better treat patients of a certain illness; can be omitted if too lengthy or technical]. Compensation and transportation is provided [omit if not applicable]. For more information, call [insert Name and contact phone number, email or web link].*
 Requests must be approved by the IRB of record before being submitted to E-News Bulletin. Requests must be submitted to E-NewsBulletin@nshs.edu by 12pm Tuesday on the week you wish the submission to be posted.

**Direct Contact**

Examples of recruitment via Direct Contact are:

- Approaching a potential subject in-person or via telephone by the PI or research personnel
  - Direct contact for a study by a clinician/investigator or treatment staff is allowed. This group already has access to a patient's identifiable health information by virtue of the treatment relationship and may approach the patient about participating in the study without HIPAA authorization. After a subject is approached for recruitment, such communication shall be noted in the patient's medical record.

- Referral from an investigator or physician who is not part of the research team (inside or outside the Health System)
  - If the treating clinician is not part of the research team but still has access to a patient's identifiable health information by virtue of the treatment relationship, that treating clinician may also approach a patient about participating in another investigator’s study. This treating clinician may also discuss a patient's eligibility with the research personnel as long as all information about the patient has been de-identified. If the research personnel think the de-identified patient would be eligible for the study, the treating clinician could then obtain the patient's permission to give the research personnel the patient's name or give the patient the investigator's contact information. Such communication should be noted in the patient's medical record.

  **Example of Note**
  
  *I discussed the possibility of referring the patient to [insert doctor or team] for [describe research study]. The patient agreed to the referral and to sharing information about his/her condition with the investigator. [If an Optional Authorization for Research Contact was IRB approved and used, state this as well.]*

  If the treating clinician's direct contact to the patient or the patient's prior authorization is impracticable, the investigator may ask the treating clinician to approach the patient him/herself. This assumes that the investigator is a member of the NSLIJHS workforce. However, if an investigator is NOT a member of the workforce at NSLIJHS and wishes to review medical records of subjects there preparatory to research, he/she must obtain approval by submitting a request for a partial waiver of HIPAA authorization (see OIRB Form 4c).

**Indirect Contact**

Examples of recruitment via Indirect Contact are:

- Word-of-mouth
Word of mouth recruitment is generated by obtaining contact information of potential subjects through the networks of eligible study participants. Examples of word-of-mouth include the use of brochures with tear-off cards for a family member or friend to complete and mail in and subjects providing the research site with contact information for family and friends to enable the research site to send recruitment advertisements.

- Referral from an investigator or physician who is not part of the research team (inside or outside the Health System)
  - A clinician or investigator who is not part of the research team may give a patient another investigator's name and contact information for potential consideration into a study. The patient may then choose to contact that investigator directly. This clinician may also send a letter to the patient about how to join an IRB-approved study as long as the content of the letter is approved by the investigator’s IRB of record. Chart/database review

- Investigators may use medical records, or other private information, including databases, that they would normally have legitimate access to as part of their clinical practice in order to identify potential research subjects. Once a potential subject is identified, the investigator may contact the subject via direct contact or using another IRB-approved recruitment method.

- An investigator may need to review charts/databases to which he/she does not have legitimate access in order to identify potential research subjects. If the investigator is part of the workforce of NSLIJHS, then no special permissions are needed as all members of the workforce have access to this information. However, if the investigator is from outside NSLIJHS, then he/she does not have legitimate access to PHI and a partial waiver of authorization for recruitment must be obtained from the IRB (see OIRB Policy: Partial Waiver of Authorization). Once the investigator identifies patients s/he would like to contact, the investigator should receive the permission of the treating clinician before making contact with the patient (see examples of recruitment via direct contact).

- Optional Authorization for Research Contact
  - At the discretion of the NSLIJHS study site, an investigator who is not part of the NSLIJHS research team, may use the Optional Authorization for Research Contact form to obtain a patient's permission to be contacted by investigators at NSLIJHS to discuss his/her possible participation in research. The Optional Authorization for Research Contact is approved for use by the IRB. An investigator may ask a clinician or other investigator to use it on his/her behalf without obtaining approval by the IRB.

  - By signing the Optional Authorization for Research Contact form, a potential subject, or his/her Legally Authorized Representative (LAR), agrees to allow his/her name, date of birth, address, telephone number, and diagnosis to be shared with investigators. After receipt of the signed authorization, the investigator may contact the potential subject to discuss possible participation in a research study.
The patient or his/her LAR must be given a copy of the signed Optional Authorization for Research Contact form. A copy of the signed form must also be kept in the patient's record at his/her doctor's office and in the study's critical documents at the investigator's office.

**Printed Advertisements (NSLIJ and general public usage)**
Examples of recruitment via Printed Advertisements are:

- **Dear Doctor Letter**
  - Unlike all other recruitment methods, IRB review and approval is not required.
- **Dear Patient letter**
  - In most cases, contacting potential research subjects by letter will occur only when that subject is familiar with the person writing the letter. If personal information about the subject is necessary in order to identify them as a potential participant (such as having a certain disease or clinical condition) then the contact shall come from a person that they would expect to have that information about them (e.g. their physician, a disease-related organization to which they belong, etc.). The recruitment plan in the protocol/addendum/application materials should state how the list of names/addresses/email addresses will be obtained.
- **Flyers, posters, pamphlets, brochures, newspaper, postcards**

**Audio-Visual Recruitment**
Examples of Audio-Visual Recruitment are:

- Television or radio commercials
- Internet videos
- Video recordings or CDs

**Other recruitment methods**
If another recruitment method not described in this guidance is to be used, submit it for review to the IRB of record. If using the OIRB, approval will be given when it has been determined that the three recruitment principles and General Requirements listed in [OIRB Policy: Recruitment Methods](#) are met and are applicable.