# Recruitment of Research Subjects

This guidance document provides information about different methods of recruitment and issues related to the protection of subjects in research.

Recruitment of subjects is a challenging aspect of research involving human subjects. Recruitment of subjects must be equitable and include racial, ethnic, educational, socioeconomic, and gender diversity appropriate to the condition that is being studied. All recruitment efforts must respect personal rights to privacy and confidentiality, be compliant with Health Insurance Portability & Accountability Act (HIPAA) regulations and avoid coercion of subjects.

Selecting appropriate recruitment methods depends upon how the potential subject was initially identified. Potential subjects can be identified in several ways. This document outlines areas to consider when developing recruitment methods. All recruitment materials must be submitted for IRB review and approval.

## Identifying Potential Subjects

There are several ways an individual may be approached to determine their interest in participating in a research study. The recruitment method you use depends on how the potential subject was initially identified.

Prospective subjects may be identified through hospital records when Investigators have a treating relationship with potential subjects or through an EPIC search when Investigators do not have a treating relationship with potential subjects.

Any form of contact, including telephone contact, mail/internet questionnaire or direct mailings must be approved by the IRB. Medical records, patient registries, clinical databases and referrals from treating physicians can be useful resources to identify potential subjects. When using this method of recruitment, it is essential to take precautions in ensuring patient privacy. Privacy is an important aspect of human subject protection and is one of the required regulatory findings made by IRB. Detailing the method of recruitment will be an important factor that will impact IRB review.

**Recruitment when a treatment relationship exists (Indirect contact)**

The active participation by the patient's primary/specialist health care provider (usually a physician, who is known to the prospective subject and has first-hand knowledge of the patient's medical history) in the recruitment process is the preferred method of contact. This method ensures that consideration is given to the appropriateness of an individual patient's participation in the research prior to recruitment and respects the patient’s privacy.

If the research team does not include the primary/specialist health care provider as a member of the study team, a recruitment method may include asking the health care provider to:

* Discuss the study with their patient/prospective subject (in person or by telephone) and provide the study physicians contact information, to interested individuals.
* Through the use of a recruitment letter (refer to guidelines for use of recruitment letters below)
* Obtain the patient's permission to be contacted by study staff

**Recruitment when no treatment relationship exists (Direct contact)**

Investigators who do not have a treating relationship with the prospective subject’s treating physician or the prospective subject directly, may still attempt recruitment of these populations of NYU Langone patients by:

* Accessing contact information from medical records. This entails the use of DataCore services and is permissible as part of an activity preparatory to research (with certain conditions).

DataCore is a support service available to assist in the collection, processing and management of clinical research study data at NYU Langone. DataCore, based in the Medical Center IT Department and overseen by the Clinical and Translational Science Institute and its Population Health, Biomedical Informatics and Translational Library Programs will provide a range of services.

If you plan to use this direct contact method with a population where no treatment relationship exists, your recruitment method may need to include a way to advise the treating physician of the targeted populations of the study and provide some details should the patient contact them physician directly.

* General Advertisements, Media Sources and Social media

(see below for more details regarding this method of direct contact)

**Existing relationship with prior research subjects**

Investigators who have previously obtained full consent and authorization to contact a research subject as a result of a previously approved research project, may contact his or her former research subjects provided that the subject agreed to be contacted for information on future research conducted by the same principal investigator or co-investigator(s).

### IRB Submission

Any of the methods described within this document require IRB approval before subjects are approached their or their data/specimens are accessed and/or stored.

IRB review will evaluate all documents and methods of recruitment to ensure recruitment methods will not be coercive, will not unduly influence potential subject and will protect the privacy of potential subjects. To address these requirements a protocol must include a recruitment section that describes:

* How potential subjects will be identified,
* How and by whom subjects will be approached about participation,
* When consent will be obtained in relation to the start of the study procedures
* What will be said to subjects (use of advertisements, radio scripts etc.)
* Whether third parties (calling centers/centralized screening centers) will assist with recruitment of subjects.
* Any documents that will be used (letters, telephone scripts, in person introduction scripts, advertisements, emails, letters to the patient’s physician or other healthcare provider known to the patient, etc.)

Investigators are permitted to obtain information or biospecimens for the purpose of recruiting, screening or determining the eligibility of prospective subjects without informed consent if either of the following conditions are met:

* The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
* The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

While there is no need to obtain consent or apply for a waiver of consent when obtaining data or specimens for the purpose of recruitment, screening and eligibility determination, federal regulations require an IRB to review and approve the selection of subjects, including recruitment method.

When requesting information from DataCore the protocol must address:

* + How the data will be gathered from Epic (e.g DataCore will request a report)
	+ How the data will be used (be specific regarding the purpose e.g. subject identification, informing subjects, initial discussion of subject eligibility, etc.]
	+ List of the study team members who will have access to the Epic search results
	+ All data points and PHI that will be used for the search
	+ When the data will be discarded after use and how the data will discarded
	+ Parameters (how many times the study team will search Epic over the course of the study and/or how often queries regarding eligible subjects will run during the course of the study)
	+ The method used to notify the treating physician (if any, and if no explain why)
	+ A description of how the patients will be contacted (email, phone, mailed letters etc)

*Please note*

* *When sending recruitment information by email: Send Safe secure email MUST be used to contact patients. NYU Langone does not permit sending any patient health information via unencrypted email.*
* *Use of Bellevue should never be listed on any communications, including in a signature. Bellevue is a separate Legal and HIPAA entity.*

### Tools Used For Recruitment

### Recruitment Letters

Recruitment letters are frequently prepared by the study staff and can be signed by investigator alone or with the primary/specialist health care provider.

The letter should explain the purpose of the research, and provide a brief description of the nature and extent of involvement, e.g., duration of participation and study procedures.

Potential subjects must be allowed to "opt in", depending upon the nature of the research. When the research involves sensitive or personal information, such as illegal behavior, drug or alcohol use, mental illness, sexual behavior or other sensitive issues, the IRB may require more stringent "opt in" procedure be followed when recruiting subjects.

*Opt out language regarding recruitment in general should be included in the all original forms of written communication (see IRB templates)*

## Advertising

The message content of all direct advertising for research subjects, i.e., advertising that is intended to be seen or heard by prospective subjects, must be reviewed and approved by the IRB prior to distribution, posting, publication, or broadcasting. Direct advertising includes, but is not limited to newspaper, radio, TV, bulletin boards and the internet. Please refer to the NYU SoM Guidelines for Advertisements.

Unlike potential subjects identified through private medical information, those responding to advertisements have initiated the first contact and therefore, have implicitly given their permission to be contacted by study staff.

**For further guidance on advertising see the Guidance document on Advertisements for Recruiting Subjects**

***Recruitment using social media***

IRB review and approval prior to implementation of social media or online advertising is required. The recruitment section of your protocol should describe specific platforms intended for use.

Investigators must identify procedures of any social media platform or online advertising venue. When using this method please include in your submission ot the IRB online platform’s Terms of Use(TOU)and Conditions or established policies and procedures. Privacy policies, prohibited content, and limitations on location and frequency of postings are sometimes found in the user instructions or Frequently Asked Questions (FAQ) instead of the TOU (e.g., Craigslist FAQ).

## Special Considerations

## Recruitment of Employees/Students

Studies involving subjects who are directly supervised by the investigator(s) or who are the investigator's students should be avoided and will usually be disapproved by the IRB. In this setting, there are confidentiality problems and issues of coercion or obligation (either real or perceived) which are best avoided entirely. It is acceptable to advertise for volunteers in approved areas in the investigator's department or within the hospital (following hospital guidelines) and allow individuals in the department who are not directly supervised by the investigator(s) to participate in research studies.

## Recruitment of Subjects From Among the Investigator’s Own Patients

When recruiting potential subjects from among their own patients, investigators must consider the possibility that their patients may feel obligated to participate because they are being asked by their treating physician. For the investigator, maintaining a dual role as investigator and treating physician may create subtle conflicts and ethical tension, while for the patient/subject it may create some uncertainty. Investigators should reinforce with their patients that participation is voluntary, that they do not have to participate, and the decision not to participate will not affect their care, now or in the future. Any plans to minimize the possibility that patients will feel obligated to participate, e.g., initially contacting patients about the research in writing and allowing patients to make further inquiries if they are interested, etc. should be outlined in the protocol.

***“Passive” Consent (or Opt Out procedures)***

In most cases, the IRB **will not** approve methods of recruitment that include passive consent. This method involves requiring potential subjects to reply (send back a postcard or to telephone) only when he or she **does not** wish to participate. With ethical principles of respect for person in mind, this recruitment method can cause harm to subjects as individuals who may become unwitting participants. The IRB may consider this method only when careful thought is used in developing a plan. A plan should include but is not limited to:

* Ensuring potential subjects have received the recruitment and study related materials,
* Materials are available in the varied languages of the target population,
* Potential subjects are given an opportunity to speak with the researchers if they are confused by the instructions or need to discuss the study further,
* Privacy concerns for certain types of research (e.g., research involving sexually transmitted diseases or psychiatric illness, or drug or alcohol abuse) are addressed.

### “Active” Consent (or Opt In Procedures)

The recruitment letter should include a telephone number to call or a postcard to return if the subject is interested in learning more about and/or participating in the study. The investigator may not contact subjects who have not called or returned a postcard indicating interest in learning more about the study.

In either case, care should be taken to ensure that letters are properly addressed to avoid delivery to an incorrect party, and return postcards must not contain information regarding the patient's medical condition, medication or diagnosis.

## Alternative Recruitment Approaches

The guidelines listed above may not be applicable to every situation that arises in the research process. Carefully justified alternative approaches will be considered on a case-by-case basis. The IRB Office staff will offer guidance to investigators upon request.