Contents

1. Overview

The purpose of this document is to provide investigators conducting research under the purview of the Yale designated IRB[1] (Yale IRB or an external IRB authorized by the Yale Human Research Protection program (HRPP) to provide review of Yale research on behalf of Yale), with an overview of the requirements regarding the recruitment of patients or use of data from patients who have received care at Yale University affiliated clinics, including research centers, or any hospital, clinic, or care center from the Yale New Haven Hospital System (YNHHS) and its affiliates. A table summarizing the requirements for various recruitment methods is included in Appendix 1.

This guide also includes the following additional sections as a reminder:

- Targeted Recruitment of Students, Fellows, Trainees, Faculty, and Employees
- Study-Specific Advertisements

[1] Currently, Yale IRB serves as the IRB of record for Yale and Yale New Haven Hospital investigators. Yale HRPP can also designate an external IRB to serve as the IRB of record for Yale and YNHH. In limited circumstances, Yale designated IRB serves as the IRB for other hospitals within Yale New Haven Health System. Guide on research at YNHH System locations is available in the IRES IRB Library.

- Generic Advertisements
- Number of direct contact attempts with a potential participant
- Reporting Patient/Research Participant Complaints

The recruitment of patients receiving care at unaffiliated locations is outside of the scope of this guide as each location providing care may have its own policies regarding contacting their patients for research purposes or including data of their patients in research.

2. HRPP, IRB, and Institutional Review and Approval of Recruitment Procedures

Recruitment methods and materials must be approved by the IRB prior to initiation of recruitment and must be consistent with the policies and practices of the recruitment site. If the recruitment takes place at Yale or affiliated institutions such as Yale New Haven Health System, the Yale HRPP will review the plan to ensure that it meets the institutional policies. If recruitment is proposed at another institution, outside of the Yale HRPP purview, the HRPP may ask for letters of support or confirmation that the recruitment is acceptable at that institution.

Like with all methods of recruitment, reviewing medical or research records to identify potential participants for a research project or using medical, research, or other records to collect information for research must be described in the protocol and approved by the IRB. Written text or scripts that will be used for recruitment of participants identified via review of records must also be reviewed and approved by the IRB. The IRB may disapprove any method of recruitment if it is not deemed appropriate for the study population. Any modifications related to recruitment must also be reviewed by the IRB. When a non-Yale IRB serves as the IRB of record for Yale research, the proposed recruitment plan is verified by the Yale HRPP office to ensure that it complies with institutional requirements. The verification takes place before the study is authorized by the HRPP to use an external IRB. Any modifications related to recruitment must also be reviewed by the HRPP office. The HRPP office also assists the Yale IRB in order to ensure compliance with institutional policies and other requirements.

Even if a recruitment method is regulatorily permissible and approvable by the IRB, the institution where recruitment is proposed may have more restrictive requirements or impose additional conditions regarding the recruitment of their patients. Institutions may also impose additional restrictions regarding the patient populations, contact methods, and approved technologies that may be used for recruiting study patients. (Medical information officers regularly review and make recommendations on the clinical criteria, messaging and technology used for contacting their patients.)

Institutions holding the records (medical, research, or other such as vital records) have the right to refuse to allow investigators to access records for recruitment or research purposes. They also control how records may be accessed. For example, the Centers for Medicare & Medicaid Services (CMS) imposes different requirements that investigators and IRBs must abide by when requesting access to identifiable data files, limited data set files, or public use data files; Connecticut Department of Public Health requires approval from the Department of Public Health Human Investigations Committee for any research proposing use of identifiable birth data.

3. Definitions

Provider

A Provider means any individual, including, but not limited to, physicians, advanced practice nurses, physician assistants, registered nurses, and pharmacists, social workers, mental health care professional, or others who are required by any law to have a license or certification in order to perform services on behalf of a healthcare entity, who is or has been employed by, or who renders or has rendered services on behalf of a healthcare entity.

Direct Treatment Provider with Ongoing Relationship

A Direct Treatment Provider with Ongoing Relationship is defined as a clinician or other health care provider who has a "reason to know" identifiable health information by virtue of the existing or newly established treatment relationship with a patient in situations where it would be reasonable to expect that the patient views that individual as their provider.

- Examples include pediatricians or family doctors who see patients for annual check-ups, or specialists who meet with their patients and direct their care in their practice.

Direct Treatment Provider Without Ongoing Relationship: Ancillary or Limited Treatment Provider

Providers who provide ancillary care[2] or who do not interact with patients are considered to have an **ancillary** or **limited direct treatment relationship**.

- Examples include providers who provide diagnostic services such as obtaining or interpreting laboratory tests, radiology scans, genetic testing, diagnostic imaging, etc., and clinicians that provide episodic care without specific

[2] Ancillary care refers to the wide range of healthcare services provided to support the work of the direct treatment provider.

follow-up such as Acute Care/Urgent Care/Walk-In Care providers. Similarly, Emergency Medicine clinicians and staff who are not primarily responsible for providing ongoing care would be considered to have an ancillary or limited treatment relationship.

Provider in the same practice group
Providers who are in the same practice or clinic but who do not have a treatment relationship with a patient or where it would NOT be reasonable to expect that the patient views that individual as their provider.

Other Providers
Other Providers refers to providers (see definition above) who do not have any treatment relationship with a patient, are not in the same practice group, and who do not provide ancillary or limited direct care.

Yale Agent
Individuals who: (1) act on behalf of Yale; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities. Agents can include staff, students, unaffiliated investigators, and volunteers, among others, regardless of whether the individual is receiving compensation. Professional Services Agreement may describe whether contractors or consultants can be considered Yale agents.

Yale Designated IRB
Yale IRB or an external IRB authorized by the Yale Human Research Protection program (HRPP) to provide review of Yale research on behalf of Yale), with an overview of the requirements regarding the recruitment of patients or use of data from patients who have received care at Yale University affiliated clinics, including research centers, or any hospital, clinic, or care center from the Yale New Haven Hospital System (YNHHS) and its affiliates.

4. Secondary Data Research - Research Without Interactions with Participants

Secondary Data Research includes secondary analysis of data that has been collected or generated for a different purpose, such as research, clinical, or other, and where no contact with participants is planned. If the research requires access to identifiable information by **Yale agents** or when the data holder requires a formal IRB determination, then the researcher must obtain an IRB determination of exemption or IRB approval. Note that student and employment records are not considered medical or research records and cannot be released without written consent of the individual to whom the records pertain.

4.1. Secondary Data Research Using Medical Records

Yale and YNHH investigators can request approval to access data from medical records from all entities within Yale and all Yale New Haven Health System entities.[3] Yale designated IRBs do not generally review requests for access to information from medical records for non-Yale or YNHH investigators unless Yale or YNHH is considered engaged in human subjects research[4] conducted by the non-affiliated investigators.[5] Otherwise, such access is generally not allowed.

There are differences in what data can be provided from medical records held by Yale or Yale New Haven Hospital System for analysis depending on whether the research is conducted at HIPAA covered (e.g., School of Medicine) or non-HIPAA covered (e.g., School of Public Health) entities. Yale HIPAA covered components are listed on the Yale HIPAA website.

4.1.1. Medical Record Research at HIPAA covered entities

Yale investigators **from HIPAA covered Yale entities** and YNHH affiliated investigators can request to use identifiable and deidentified information from medical records. Investigators should submit an exemption request (category 4 iii) to the HRPP Office for IRB review. The exemption request must include the following:

- Description of PHI to be obtained from the medical records;
- Request for HIPAA waiver; and
- List of entities where the information is obtained from. An Exemption determination from only one Yale designated IRB is required unless investigators from multiple institutions are involved in conduct of the human subjects research.

[3] Yale IRB can approve research or provide exemption determination and issue HIPAA waivers for research utilizing medical records from all of the YNHH System entities.
4 Engagement rules are described in Office of Human Research Protection (OHRP) guidance: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html.
5 On rare occasions, Yale IRB, in its role as a Privacy Board, may be asked to grant HIPAA waivers to external researchers who request access or receive PHI from Yale/YNHH systems. Such as request is coordinated with Yale and YNHH authorities to confirm that the access may be approved and all appropriate agreements are place.

Requests for information from EPIC must be submitted to the Joint Data Analytics Team (JDAT) by the investigator after the IRB determination with the applicable HIPAA waiver is obtained. Investigators are not permitted to pull information from medical records for research purposes without JDAT's specific authorization.

Data from medical records will only include data from individuals who did not opt-out of research. Investigators who receive permission to review medical records without JDAT services must ensure that no data from individuals who specifically opted-out is included in the research data.

4.1.2. Medical Record Research at non-HIPAA covered entities

Yale investigators from **non-HIPAA covered entities** generally cannot use identifiable information obtained from medical records unless the IRB determines that the investigator has put in place appropriate privacy and security measures to protect the information (e.g., substantially equivalent to the HIPAA Security Rule safeguards and in compliance with Connecticut state law and other applicable regulatory requirements). The investigator must complete appropriate HIPAA training. **Additional institutional approvals may also be required**. Yale may also approve research utilizing limited data set obtained from medical records when the following two conditions are met:

a. The information does not include any of the following HIPAA identifiers:
   - Names
   - Street addresses or postal address information with the exception of town/city, state, and zip code
   - Phone/Fax numbers
   - E-mail addresses
   - Social Security numbers
   - Medical records numbers
   - Health plan beneficiary numbers
   - Other account numbers
   - Certificate and license numbers
   - Vehicle identifiers and serial numbers, including license plates
   - Device identifiers and serial numbers
   - URLs and IP addresses
   - Biometric identifiers such as fingerprints, retinal scans, and voice prints
   - Full face photos and comparable images

b. The protocol includes the following:
   - List of limited allowable uses and disclosures of the information;
   - List of all recipients and users of the data;
   - An agreement from the investigator that the data will not be used to contact individuals or re-identify them;
   - Robust plan to ensure the confidentiality of data and prevent prohibited uses and disclosures; and
   - An agreement from the investigator that the discovery of improper uses and disclosures will be reported back to the HIPAA Privacy Office.

Investigators should submit the exemption request (category 4 ii) to the IRB office. The exemption request must include the following:

- Description of PHI to be obtained from the medical records;
- Request for HIPAA waiver; and
- List of entities where the information is obtained from. Exemption determination from only one Yale designated IRB is required unless investigators from multiple institutions are involved in conduct of the human subjects research.

Requests for information from EPIC must be submitted to JDAT after the IRB determination (with applicable HIPAA waiver) is obtained. Investigators are not permitted to pull information from medical records for research purposes without JDAT's specific authorization.

Data from medical records will include data only from individuals who did not opt-out of research. Investigators who received permission to review medical records without JDAT services must ensure that no data from individuals who specifically opted-out is included in the research data.

4.2. Data Research using Existing Registries or Repositories

There are multiple national repositories that provide data for researchers conducting secondary data research e.g., Framingham Heart Study (https://framinghamheartstudy.org/fhs-for-researchers/), or GWAS. Researchers must apply directly to the data holder to receive access to the requested information. Data Use Agreements may be necessary before the data is released to the investigators. Researchers at both HIPAA covered and non-HIPAA covered entities can conduct research with data obtained from these repositories.

Generally, if the data that is released to the investigator is deidentified, no IRB approval is needed. However, if the data holder requires IRB determination of exemption or IRB approval, the researcher must send the applicable submission to the IRB office for review.

Investigators will often create their own databases under IRB approved protocol where data is donated for future research by patients with their consent. The investigators may make data available to others according to the IRB approved protocol. If a researcher wishes to obtain data that is deidentified, no IRB approval is required. If the data is identifiable, IRB determination of exemption under category 4 OR approval with a waiver of consent is required. Researchers at both HIPAA covered and non-HIPAA covered entities can conduct research with data obtained from investigator-held repositories.

Generally, the data from participants will be shared for the purposes that were specified in the consent signed by the patient donors. Under certain conditions, the IRB may issue a consent waiver if the purpose of the secondary research was not specifically included in the original consent form and where the secondary research is not contradicting allowable uses as listed in the original consent document.

4.3. Data Research using Publicly Available Data

Publicly available data refers to data that is accessible to anyone in the general public, without the need for special qualifications, belonging to a specific stakeholder group (e.g., researchers only), permissions, approvals, or privileges.

Examples of publicly available data include:

- data available for public purchase, download or transfer;
- data searchable online by anyone; and
- data available at a physical or online library.

The data holder can determine restrictions for access to the data, rendering the data ‘restricted access use’. This will preclude data from the publicly available category.

Examples of data that is not publicly available include:

- Data seemingly available to public but when there is a reasonable expectation that the data owner would consider it private e.g., data generated in online chatrooms, overheard conversations in public places,
- Social media data labeled as "private" by the data owner, or not readily available without permission of the site Owner/Administrator under the Terms of Service of the site,
- Licensed Data that specifically prohibits re-use,
- Data protected under the Privacy Act, e.g., Taxpayer Identification Numbers,
- Data that have access restrictions, e.g., data only available to clinicians or qualified researchers or may only be accessed on a secure server.

Research that includes use of publicly available identifiable data generally qualifies for IRB exemption determination under category 4(i). Research using identifiable data that is not publicly available will require IRB review and approval, unless the research can meet requirements of category 4 (ii) or (iii).

5. Recruitment Methods for Research with Direct Interactions with Participants

5.1. Approaching Patients at Care Facilities

Generally, only individuals known to the potential participant can approach the patient about a research study. Patients in the waiting rooms or hospital rooms may not be approached by research staff who are not part of the patients' direct care team unless the treatment care provider or attending obtains specific permission from the patient for this activity or agrees that the researcher can approach a specific patient directly.

Depending on where the initial contact takes place, specific approval from the facility or the department may be needed to ensure that clinical operations are not affected by the presence of the researcher or any of the research activities. Departments may require that researchers present at Faculty meetings or Grand Rounds regarding the proposed research.

For example, recruitment at Intensive Care Unit may require three steps:

- Overall permission from the Chair to recruit patients and/or their families for research on the premises of their hospital floor;
- The researcher's presentation at the faculty meeting to ensure that all potential attendings, nurses, and support staff are aware of the proposed research; and
- On the day of the research activities, the researchers will need to introduce themselves to the attendings and obtain permission to approach specific patients to ensure that the proposed research will not interfere with the treatment plan. The attendings and nurses will be in the best position to advise the researchers based on the patients' health status, enrollment in other studies, nature of their medical treatment, wishes to speak to the researchers, schedule, etc.

Yale New Haven Health System entities do not allow interaction with patients with the intent to enroll participants in research by investigators who otherwise do not have privileges at the specific hospital.

In all cases, researchers and study personnel initiating contact with potential participants must have sufficient knowledge of the study to answer questions. They must also be knowledgeable about where to refer a potential research participant should questions be raised about their research rights. All study personnel who contact potential participants must meet the human subjects protection, Good Clinical Practice, and HIPAA training requirements.

5.2. Using Medical Records to Identify Potential Participants

In some situations, investigators may request a waiver of HIPAA authorization for access to and use of medical records to identify potential participants based on inclusion/exclusion criteria defined in the approved protocol. Even when the regulatory requirements for a waiver are met, the institutions where the records are held determine whether access to records can be granted and if so, what data can be provided.

At Yale and institutions within the Yale New Haven Health System, the level of access to data from medical records for purposes of recruitment to research that will involve direct interactions with patients depends on the extent of the investigator's treatment relationship with the patient. The rationale for differences in access is based in a belief that potential participants should be approached in a way that does not erode their trust in doctor-patient confidentiality. At no time can the investigator's desire to recruit research participants override the patients' need to privacy.

The following sections describe allowable recruitment methods for investigators who are also considered direct treatment providers with ongoing relationship with patients, investigators who provide ancillary or limited direct treatment, investigators who are also providers in the same practice group as those with direct and ongoing relationship with potential participants, and other investigators who either are not considered care providers or who do not have any relationship with potential participants. See Definitions section for description of these roles.

5.2.1. Direct Treatment Providers with Ongoing Relationship with Potential Participant

Clinician-researchers conducting IRB approved studies and who, in their role as providers, have a direct and ongoing treatment relationship with a patient may contact the patient regarding a non-therapeutic study unless the patient has opted out of being contacted about research opportunities. Exception would be a non-therapeutic study involving a disease or condition specifically relevant to the individual patient (that is, a study that would potentially be of interest to the patient).

Direct treatment providers with ongoing relationship with potential participants may also contact the patient regarding investigational therapeutic studies even if the patient has opted out of being contacted about research opportunities.

Clinician-researchers should carefully consider whether an individual who has not received care in the practice for many years is still considered a patient.[6] Patients who changed providers may not wish to receive correspondence regarding research studies from their former healthcare providers. Correspondence with past patients should be justified in the protocol and will require specific approval by the IRB.

Clinician-researchers with a direct and ongoing treatment relationship with a patient may follow-up with the patient if the patient does not contact the study team regarding their interest in participating in a study. They may also request assistance from an approved recruitment service to contact patients. Methods of contact include:

- Phone
- Mail
- MyChart Recruitment (see section 5.2.4.1 for a description)

Both phone and mail contact can be initiated by the investigator or the investigator's research staff, or as part of a service provided by centralized recruitment groups at Yale such as JDAT or the Yale Center for Clinical Investigation Recruitment and Marketing Unit (YCCI Recruitment and Marketing Unit). Investigators should work with YCCI to understand costs associated with such services. Emails are generally not approved unless it is the patient's specific request to receive all correspondence via email.

Investigators wishing to use phone as the primary method to contact their patients must consider the timing of the phone calls as they may seem intrusive, especially if they occur after regular business hours. The number of anticipated calls to participants with the initial recruitment efforts and their timing should be described in the research protocol.

Providers with direct and ongoing treatment relationship may voluntarily contact their patients on behalf of other researchers. Providers who only inform their patients about existing research studies or ask their patients for their permission to release contact information to the researchers are not considered engaged in those studies and should not be listed on the research protocol.

Principal Investigators of IRB approved research studies should not add clinicians with direct treatment relationship with potential participants only for the purpose of easy access to the population. The list of the research staff on the IRB protocol should only include investigators and staff who are considered engaged[7] in the conduct of the research.

5.2.2. Direct Treatment Provider Without Ongoing Relationship: Ancillary or Limited Treatment Providers

The primary methods for recruitment available to researchers who also provide ancillary or limited direct care to the potential participant include:

- MyChart recruitment (see section 5.2.4.1)
- Request the provider with a direct and ongoing treatment relationship (see section 5.2.4.2) to contact the patient on behalf of the researcher

There are situations where clinicians who provide ancillary or limited direct care believe that patients will benefit from participating in the research that may not be known to their providers with the direct and ongoing treatment relationship. In such cases, researchers in this category may obtain approval from the HRPP to contact the patients directly with appropriate permission from the providers with a direct and ongoing treatment relationship allowing them the direct contact. JDAT will work with the researcher and the providers with a direct and ongoing treatment relationship to ensure appropriate permissions are in place. Only individuals who have NOT opted out from research will be included on the list provided by JDAT. Under limited circumstances, patients who have opted out of research may be contacted about the study if the providers with direct and ongoing treatment relationship deem the study appropriate for the patient because of potential therapeutic benefit or specific interest. Under these circumstances, permission from the patient obtained by the provider with a direct and ongoing treatment relationship may be required before contact is made.

In some circumstances, researchers may discover that methods referenced above are not sufficient to recruit research participants. There will also be situations where clinicians who provide ancillary or limited direct care believe that patients will benefit from participating in the research but permission from direct treatment providers with ongoing relationship is not possible

[6] According to the American Medical Association (AMA), an established patient has received care by a healthcare provider in the same practice within the past 3 years. For purposes of this guidance, patient who has not been seen in the practice within the last 3 years is no longer considered a patient. New patient (not receiving care within the last 3 years but presenting to the healthcare provider for purposes of establishing a plan for ongoing management of the patient's care) is considered a patient of the practice.

[7] Engagement rules are described in Office of Human Research Protection (OHRP) guidance: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html.

either because the patient reported not having such a provider or the provider is unknown e.g., patients seen in Walk-In clinics may not provide contact information to their primary doctors who would be considered having direct and ongoing relationship. In such cases, researchers in this category may seek approval from the HRPP to contact the patients directly. The HRPP will review the rationale and the request to ensure it is regulatorily permissible and will facilitate review by the institutional leaders, who have the authority to approve or disapprove the request.

In all cases, this method of recruitment may be disapproved for sensitive research where contact by the direct treatment provider is viewed as more appropriate.

If the direct contact with potential participant is approved, the methods of direct contact may include:

- Phone
- Mail

Both phone and mail contact can be initiated by the investigator or the investigator's research staff, or as part of a service provided by centralized recruitment groups at Yale (JDAT, YCCI Recruitment Unit). Emails are generally not approved unless it is the patient's specific request to receive all correspondence via email.

Investigators wishing to use phone as the primary method to contact their patients must consider the timing of the phone calls as they may seem intrusive, especially if they occur after regular business hours. The number of anticipated calls to participants with the initial recruitment efforts and their timing should be described in the research protocol.

When appropriate, the initial correspondence or calls to the patients must explain that their care providers agreed to the contact for research purposes.

5.2.3. Provider in the Same Practice Group

The primary methods for recruitment available to researchers who also are considered providers in the same practice as the providers with direct and ongoing relationship with the potential participant include:

- MyChart recruitment (see section 5.2.4.1)
- Request the provider with a direct and ongoing treatment relationship (see section 5.2.4.2) to contact the patient on behalf of the researcher

Clinician-researchers should carefully consider whether an individual who has not received care in the practice for many years is still considered a patient.[8] Patients who changed providers may not wish to receive correspondence regarding research studies from their former healthcare providers. Correspondence with past patients should be justified in the protocol and will require specific approval by the IRB.

In some circumstances, researchers may discover that methods referenced above are not sufficient to recruit research participants. There are also situations where providers in this category believe that patients will benefit from participating in the research that may not be known to their providers with the direct and ongoing treatment relationship. In such cases, researchers in this category may obtain approval from the HRPP to contact the patients directly with appropriate permission from the providers with a direct and ongoing treatment relationship allowing them the direct contact. JDAT will work with the researcher and the providers with a direct and ongoing treatment relationship to ensure appropriate permissions are in place. Only individuals who have NOT opted out from research will be included on the list provided by JDAT. Under limited circumstances, patients who have opted out of research may be contacted about the study if the providers with direct and ongoing treatment relationship deem the study appropriate for the patient because of potential therapeutic benefit or specific interest. Under these circumstances, permission from the patient obtained by the provider with a direct and ongoing treatment relationship may be required before contact is made.

In all cases, this method of recruitment may be disapproved for sensitive research where contact by the direct treatment provider is viewed as more appropriate.

If the direct contact with potential participant is approved, the methods of direct contact may include:

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Both phone and mail contact can be initiated by the investigator or the investigator's research staff, or as part of a service provided by centralized recruitment groups at Yale (JDAT, YCCI Recruitment Unit). Emails are generally not approved unless it is the patient's specific request to receive all correspondence via email.

Investigators wishing to use phone as the primary method to contact their patients must consider the timing of the phone calls as they may seem intrusive, especially if they occur after regular business hours. The number of anticipated calls to participants with the initial recruitment efforts and their timing should be described in the research protocol.

The initial correspondence or calls to the patients must explain that their care providers agreed to the contact for research purposes.

5.2.4. Providers and Investigators Without any Treatment Relationship with a Potential Participant

Investigators and providers without any treatment relationship with potential participants generally may not contact a patient directly regarding a potential study. However, the following options are available:

5.2.4.1. MyChart Recruitment

The IRB may approve a recruitment method using messaging to potential participants to their MyChart accounts (or the MyChart account of the guardian in case of minors). JDAT will build an Epic query to identify all patients that meet study criteria and who have not opted out from research. Patients who have an Epic MyChart account and meet basic inclusion/exclusion criteria will be notified of the study through an IRB-approved MyChart message. Patients who are interested in hearing more about the study can either contact the researcher directly or indicate within MyChart that they wish to be contacted by the research staff. If a patient indicates that they are not interested in the study, they will not receive any additional messages about the study within Epic, and their information will not be shared with the research staff.

The text used for MyChart messaging must be approved by the IRB. It has to describe the study in general terms and indicate that no identifiable information was provided to the research team. The investigator must take special care in drafting messages for research studying conditions that are considered sensitive such as research on mental health. Instead of stating that the patient seems to be meeting eligibility criteria, the message can simply state that the study is looking for volunteers. See Appendix 2 for examples of the message templates. Additional templates are provided in the Library section of IRES IRB system.

5.2.4.2. Request the Provider with a Direct and Ongoing Treatment Relationship to Contact the Patient

JDAT can provide a list of patients potentially eligible for a study, including contact information in the form of a phone number and mailing address, to a direct treatment provider with an ongoing relationship with the potential participant. Researchers from both HIPAA covered entities and non-HIPAA covered entities can request the provider with a direct and ongoing treatment relationship to contact their patients to:

- obtain their permission to be contacted directly by the research team member, or
- provide the patient with the contact information to the researcher.

In such situations, providers with direct treatment relationship who agree to contact their patients on behalf of the researchers are not considered engaged in those studies and should not be listed on the protocol.

5.2.4.3. Using Yale Recognized Centralized Recruitment Groups

Yale may approve use of centralized services to investigators to help with recruitment efforts. Centralized recruitment groups may specialize in a specific population or a disease but they will offer services to a variety of studies and/or investigators and are not limited to a specific protocol or an investigator. An example of a centralized recruitment group is the YCCI Recruitment and Marketing Unit. Investigators should work with YCCI to understand costs associated with such services. If JDAT completes the initial mailing of the letters to the patients or provides the list of potential participants to the centralized recruitment group, investigators can utilize the recruitment group to also conduct follow-up with those who have not responded. JDAT will coordinate with the group and the investigator to ensure communication e.g., how the list will be provided to the group, division of responsibilities between JDAT and centralized recruitment group. Scripts or recruitment letters used by recruitment groups must be approved by the IRB during the review of the protocol utilizing the centralized recruitment groups.

In addition to mailing potential participants and engaging in the follow-up activities related to communication with patients identified by JDAT via medical record review, centralized recruitment groups may, under an IRB approved protocol, create a repository of individuals who agree to be contacted for future studies. See section # 6, Recruitment of Participants Using Repositories, Registries, or Recruitment Databases, below.

6. Recruitment of Participants Using Repositories, Registries, or Recruitment Databases

Investigators may create and maintain a list or registry (also referred to as recruitment database or repository) of research participants who previously took part in, were screened for but deemed ineligible for other research studies, or who have expressed interest in future research participation. In each of these scenarios, the individual must provide consent for their information to be retained for recruitment for future research participation. In addition, investigators must provide such individuals the opportunity to remove their name and any information from the list or registry at any time.

The development of a recruitment list or registry requires IRB approval. The IRB must ensure the appropriateness of the data elements to be maintained on the individuals; the privacy, confidentiality, and security measures associated with the data set; and the scope of access related to the list or registry.

In general, investigators may directly contact individuals on IRB-approved recruiting lists or registries for future research consideration in accordance with the terms of the IRB approval. The 'Help Us Discover' project is one example. The Help Us Discover *Volunteer Engagement registry* (one of the Help Us Discover project aims) provides investigators with a resource of persons who have voiced a willingness to be contacted about participating in clinical trials at Yale through the registry. If an investigator wishes to recruit potential research participants from an established and IRB-approved recruitment list or registry, this must be clearly indicated in the IRB application.

The use of federally funded clinical trial registries (for example, Clinicaltrials.gov) is not considered by Yale to be a recruitment method requiring IRB approval. Therefore, copies of the information posted on Clinicaltrials.Gov need not be attached to the protocol submitted to the IRB.

7. Using a Third Party to Recruit Potential Participants

IRB review and approval is required when a third party is used for recruitment purposes such as to inform potential subjects about a research opportunity. IRB review and approval is also required of all materials used by the third party to inform potential research participants of the study, such as "Dear Patient" letters. Examples of a third party include community physicians or school administrators who are asked to provide their patients or students with information regarding a research study. Third parties may also include commercial entities hired to aid in recruiting research volunteers. Third party recruiters may provide the research contact information directly to the potential participant. The collection of additional research-related information used to determine eligibility cannot be conducted by the third party.

8. Targeted Recruitment of Students, Fellows, Trainees, Faculty, and Employees

Researchers cannot directly recruit students[9], fellows, trainees, faculty, and employees[10] to be research subjects as convenience sampling. Targeting students, fellows, trainees, faculty, and employees who are also patients is generally not allowed. However, indirect recruitment (e.g., through flyers, large-group emails in which all students in a department are included, etc.) and enrolling a patient who happens to be a student, fellows, trainee, faculty, or an employee is generally allowed.

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[9] According to HRPP Policy Manual, Investigators enrolling their own or their institution's students or trainees in research must:

- Not directly interact for recruitment purposes with students, fellows and trainees who report directly to the investigator unless one of the special situations applies (see Special Situations below).
- Ensure that students understand that they may choose not to participate in the research and that their decision will not affect their grade/class standing. Avoid using class time to recruit or engage in the research.
- Limit the use of extra credit as compensation; it should not significantly increase a student's overall grade.
- Provide students with an equal alternative to participation, which should be comparable in terms of effort, time commitment, and credit given.
- Outline procedures in the research protocol to ensure that students will not be subject to undue influence or coercion and to ensure that each student's privacy will be respected.

[10] According to HRPP Policy Manual, Investigators enrolling their own or their institutions employees in research must:

- Not directly interact for recruitment purposes with employees that report directly to the investigator unless one of the special situations applies (see Special Situations below).
- Engage in recruitment and consent activities outside of the presence of the employee's supervisor(s) whenever possible.
- Ensure that employees understand that they may choose not to participate in the research and that their decision will not affect their employment or performance evaluation.
- Outline procedures to ensure that employees will not be subject to undue influence or coercion and to ensure that each employee's privacy will be respected.
- Ensure that steps are taken to avoid informing supervisors whenever possible of employees who decline participation.
- Conduct the research procedures out of sight of other employees whenever possible. For example, surveys or questionnaires could be given to employee participants to complete online or at home and mail back to the investigators instead of asking all employee participants to convene in a room on-site, which could identify them as research participants to their superiors and co-workers.

Researchers wishing to recruit their own students, fellows, trainees, faculty, or staff to participate in research must submit a plan for IRB review and approval, or in an amendment for an ongoing study with the following information including:

- Description of the group or individual(s) to be enrolled;
- Rationale for inclusion of the group;
- Relationship of the group or individual(s) to the study team, including supervisory relationships;
- Importance of including the group or individual(s) in the study;
- The person who will consent the group or individual(s) and how the possibility of coercion will be minimized; and
- Process for ensuring objective analysis of study results.

In addition to IRB approval, the appropriate School or department approval may be required and must be obtained when the investigator intends to conduct recruitment among students (e.g., researchers specifically focusing on Yale School of Medicine students must obtain an approval from the departmental committee created to review and approve research targeting medical students). Similarly, investigators who wish to send a mass email to students, fellows, trainees, faculty, and employees about their research may be required to obtain specific departmental approvals from the Provost's Office, Office of Public Affairs, Internal Communications, Yale College Deans, YNHHS Section Chief or appropriate hospital administrator, and other appliable parties and departments, depending on the targeted audience.

Note: Research personnel directly involved in the conduct of a specific study cannot be enrolled into that study. In addition, special considerations or restrictions may apply in a situation where an individual is in a leadership role because of privacy, confidentiality, or other concerns. Additional requirements and considerations are outlined in the Yale HRPP Manual.

9. Study-Specific Advertisements

The IRB must review and approve the final copy of all study-specific advertisements including printed material, newsletters, social media, internet advertisements, telephone, email, video, and audio scripts. Any changes to the IRB approved advertisements must be submitted to the IRB as a modification for review and approval. The YCCI Recruitment and Marketing Unit is available to assist researchers with advertising material. Before placing the IRB approved recruitment materials in the locations where patients receive care, the investigator must obtain approval from the clinic or practice to do so.

10. Generic Advertisement or Press Releases (Announcement, Bulletin, News Release, etc.) and Newsletters

Researchers who wish to use a non-study specific generic advertisement, press release, or newsletter may do so without IRB approval as long as the information contained in the document does not include the following:

- Name of the specific study
- Eligibility – inclusion and exclusion criteria
- Investigator or specific research study personnel names
- Sponsor of the study
- Payment information (compensation/reimbursement) for participation
- Specific contact information (name, telephone number, etc.)

General study newsletters that are not distributed as recruitment materials do not require IRB review, but researchers may consult with the IRB if there are questions about the generic materials. Researchers may also consult with the YCCI Recruitment and Marketing Unit for assistance.

11. Number of Direct Contact Attempts with Potential Research Participants

Researchers and staff allowed to directly contact potential research participants should plan for a maximum number of contact attempts to avoid a perception of harassment. Generally, no more than three (3) contact attempts should be made before considering the potential participant as not interested in research.

12. Reporting Patient/Research Participant Complaints

Complaints from patients/research participants about unwelcome recruitment calls must be submitted to the IRB-of-record as Reportable New Information (RNI).

13. References

The Joint Data Analytics Team (JDAT) website: https://medicine.yale.edu/ycci/researchservices/systems/epic/datarequests/

YCCI Recruitment and Marketing Unit website: https://medicine.yale.edu/ycci/researchservices/supportservices/recruitment/

Yale Mass Email Approvals: https://yale.service-now.com/it?id=service_offering&sys_id=f21f57b0db8b1300df80a5094b96195f

14. Revision History

Date	Version	Description of Revision
07/19/2021	1.0	New Document
12/03/2021	1.1	Appendix 2: • Revised example of language for JDAT recruitment for MyChart and mail Sections 3.2 and 3.4.2 • Clarified that clinicians with a direct treatment relationship should not be listed on the IRB approved protocol if their only role is to inform their patients about existing studies they are not otherwise engaged in.
12/02/2022	2.0	• Added a section on research with publicly available data, • Clarified types of treatment relationship with potential participants, • Added examples of local requirements for direct recruitment of patients;

Appendix 1

Summary of Recruitment Strategies: Direct Contact in Care Facilities, Recruitment of Participants Identified via Medical Record Review, Registries, Secondary Data Research

Recruitment Strategy	Investigator from Yale HIPAA Covered Entities or YNHH with Direct Treatment Relationship	Investigator from Yale HIPAA Covered Entities or YNHH with Ancillary or Limited Direct Treatment Relationship, Providers in the Same Practice Group	Investigator from Yale HIPAA covered entity or YNHH without Treatment Relationship	Investigator from Yale non-HIPAA covered entity
1. Secondary Research				
Review of medical records to use identifiable data for secondary analysis research o *Qualifies for exemption determination with HIPAA waiver*	YES	YES	YES	NO
Review of medical records to use limited HIPAA identifiers for secondary analysis research o *Research with exemption determination with HIPAA waiver or IRB approval with consent and HIPAA waivers for non-HIPAA covered investigators*	YES	YES	YES	YES but only with additional attestations from the investigators
Review of medical records to use de-identified data for secondary analysis research o *Research receiving exemption determination with HIPAA waiver*	YES	YES	YES	YES
Secondary Research using Data from Repositories	YES	YES	YES	YES
Secondary Research using Identifiable Data that is Publicly Available o *Research receiving exemption determination with HIPAA waiver*	YES	YES	YES	YES
2. Direct Contact with Patients at Care Facilities				
Approaching patient on the premises of the care facility e.g., waiting room, hospital room, Emergency Department	YES	YES but only after the attending or a member of the primary care team obtains permission from patient to be approached by the Investigator	YES but only after the attending or member of the primary care team obtains permission from patient to be approached by the Investigator	NO
3. Medical Record Review				
Using phone or mail to contact patients identified via medical record review with JDAT providing a list of patients and contact information to the researcher	YES	YES but only with approval from HRPP and provider with a direct and ongoing treatment relationship to contact the patient	NO	NO
Using phone or mail to contact patients who provided permission to be contacted to their treatment provider/provider with direct and ongoing treatment relationship	N/A	YES	YES	YES
Using mail to contact patients identified via medical record review with JDAT providing a list of patients and contact information to the researcher with specific permission from the providers with direct and ongoing treatment relationship	N/A	YES	NO	NO
Mailing letters to patients identified via medical record review with JDAT sending the letter and researchers NOT receiving any identifiable information	YES	YES	YES	YES
MyChart messaging	YES	YES	YES	YES
Employing services of Yale recognized centralized recruitment group such as JDAT or YCCI's Study Recruitment and Marketing unit to help with recruitment or to conduct follow-up with patients who have not responded to initial mailing by JDAT	YES	YES	YES	YES
4. Recruitment Registries or Repositories				
Identifying potential participants using IRB approved recruitment repositories such as the Help Us Discover Volunteer Registry where the patients have consented to contact about research	YES	YES	YES	YES
5. Use of Third Party				
Using sponsor or another third-party services for centralized recruitment to send letters to their mailing lists, conduct screening procedures, etc.	YES	YES	YES	YES
6. Targeted Recruitment of Students, Fellows, Trainees, Faculty, and Employees				
Targeting students, Fellows, Trainees, Faculty, and Employees especially those with a direct reporting relationship with a researcher or a member of the research team.	MAYBE	MAYBE	MAYBE	MAYBE
7. Study Specific Advertisements				
Study-specific advertisements including printed material, newsletters, social media, internet advertisements, telephone, email, video, and audio scripts	YES	YES	YES	YES
8. Generic Advertisement or Press Releases (Announcement, Bulletin, News Release, etc.) and Study Newsletters				
Non-study specific generic advertisement, press release, or newsletter	YES	YES	YES	YES

Appendix 2

MyChart Messaging Templates

Suggested Language to describe MyChart recruitment in the Protocol:

For additional recruitment, we will utilize the Joint Data Analytics Team (JDAT) to identify potential (*specify disease/condition*) subjects via diagnostic codes (*specify general categories*) and laboratory codes (*specify general categories*), via Epic. Once identified, potential subjects will be sent a message via MyChart that provides information about our research study and information on how to contact study personnel if they are interested in participating. [*Flyers, YCCI resources and*] MyChart messages will contain (*specify as appropriate for this study):* contact telephone numbers (*choose as appropriate-- a password protected call-in hotline with voice messaging system, a password protected iPhone with voice messaging system),* and a dedicated Yale email: *XXX*@Yale.edu. Each of these contact methods are accessible only to the following study personnel: *(specify).*

Adds if these resources will be used:
We will also use the YCCI resources to assist in subject recruitment. These resources include the YCCI recruitment center, the YCCI website, social media and Help Us Discover database to identify and notify patients.

Suggested Language for MyChart recruitment message:

The following wording will be used in the letter or MyChart message patients receive via JDAT describing the study and inviting them to participate:

If you have _____(xyz condition, possible other criteria) and are at least _____ years old, you may be eligible to participate in a free and confidential research study investigating _____. If you enroll, _____(study details-what will happen, compensation if any).

To learn more or to see if you are eligible to participate, click on "I'm interested" or call the 'Help us Discover' recruitment call center at 1-877-978-8343.

This message is automated and is sent in an electronic manner based on your health record; no one has been inside or viewed your medical chart. No action by you is required. You may ignore this message or click "No, thank you." Thank you very much for considering being a part of research at Yale.

To learn about future research opportunities, you may also create a volunteer profile through the Research Tab in MyChart.

To opt-out of all future research communications, please call the 'Help us Discover' recruitment call center at 1-877-978-8343 and select #3.

Telephone Script for Calling Patients:

The entire recruitment script must be reviewed and approved by the IRB. Below is a sample template for a format that the script may follow.

1. Introduction of Investigator or Research Staff
   Hello, (confirm that you have the correct person if you are contacting a specific patient or potential subject)

   Is this a good time for a call? My name is _____. I am a [nurse, physician, study coordinator] at [Yale Medicine, Yale New Haven Hospital, etc.] and I am working on a research study with [name the PI].

   You received information about this study in/ from _____ [describe how and when, i.e. in your admission packet the day you came to the hospital, from the brochure the admission nurse gave you, from your doctor during your pre-op visit yesterday, etc.]

2. Immediate opportunity to opt-out
   I'm here to follow up on _____[the brochure, the flyer, the conversation with your doctor, etc.] and to see if you are interested in hearing more about our study. Is it OK for me to continue?
   - If individual says "no, not interested", stop, thank the person for their time but do not continue.
   - If he/she says yes, then continue or make plans to revisit at a more convenient time.

3. Make a BRIEF statement about why they were selected. Make sure the individual understands that this research is separate from the clinical care the individual is receiving. For example:
   - Example: I'm calling you to see if you'd like to be in the research study. This study is not part of your care or treatment here at Yale New Haven. Whether or not you decide to hear more about the research won't affect your care.

4. Ask if he/she is interested in hearing more details.
   So, are you interested in hearing some details about the research study?
   - If not interested, thank the individual for taking the time to learn more about the study.
   - **If interested, then move to the information from the consent form about the study.**

Mail Recruitment Language Template:

Dear 'Patient Name':

If you have (xyz general condition, possible other criteria) and are at least (add lower limit of age limit), you may be eligible to participate in a confidential research study investigating (add what study is about). If you enroll (study details, what will happen, compensation if any). To learn more or to see if you are eligible to participate, please call the research team for the study at (add study team phone number, if applicable) or email at (add study team email, if applicable, must be @yale.edu or @ynhhs.org). To learn more about this study, you may visit (add study URL, if applicable).

This letter was generated in an automated fashion. No action by you is required. You may ignore this letter if you are not interested. To respect your privacy, we will not contact you unless you contact the study personnel first. Thank you very much for considering being a part of research at Yale. To opt-out of all future research communications, please call the 'Help us Discover' recruitment call center at 1-877-978-8343 and select #3.

If you want to learn more about future research opportunities, please visit yalestudies.org, email helpusdiscover@yale.edu, or call 1-877-978-8343 for more information.

Thank you for your consideration of this research.

Yale 'Help us Discover'
Yale Center for Clinical Investigation (YCCI)