# Research Recruitment at Yale & Yale New Haven Health System

## *Revised 410 Recruitment Guidance Document*

Yale University
Human Research Protection Program
Version: 3
Effective Date: 9/9/2024

# Overview of 410 Recruitment Guidance

Yale

- The purpose of the 410 Recruitment Guidance is to provide investigators under the purview of the Yale University Human Research Protection Program (Yale HRPP) with an overview of the requirements regarding the recruitment of patients and use of data from patients who have received care at Yale University affiliated clinics, research centers, or any hospital, clinic, or care center from the Yale New Haven Health System (YNHHS) and its affiliates.

- Yale and Yale New Haven Health researchers are considered under the purview of the Yale HRPP if they are conducting human subjects research activities as agents of Yale or YNHHS, regardless of which IRB serves as the reviewing IRB.

- All research projects under purview of Yale HRPP must be submitted in IRES IRB, the HRPP/IRB electronic submission system, for IRB review or for request to use an external (non-Yale) IRB as the reviewing IRB.

# Training Agenda

Yale

| Agenda Item | SLIDE # |
|---|---|
| Summary of 410 Recruitment Guidance Revisions | 4-5 |
| 410 Recruitment Guidance – Document Navigation | 6-7 |
| Review and Approval of Recruitment Procedures | 8-9 |
| Key Definitions | 10-11 |
| Recruitment Methods for Secondary Data Research | 12-13 |
| Recruitment Methods for Research involving Direct Interactions with Participants | 14-16 |
| Recruitment of Participants Using Repositories, Registries, or Recruitment Databases | 17-18 |
| Using a Third Party to Recruit Potential Participants | 19-20 |
| Targeted Recruitment of Students, Fellows, Trainees, Faculty, and Employees | 21-22 |
| Study-Specific Research Advertisements | 23-24 |
| Methods of Contact | 25-27 |
| Recruitment Templates (MyChart, Phone, Mail, Text Message) | 28-30 |
| Learning Exercises: Is Recruitment Appropriate or Not? | 31-36 |
| Resources and Contacts | 37 |

Research Recruitment at Yale & YNHHS

# SUMMARY OF 410 RECRUITMENT GUIDANCE REVISIONS

# Summary of 410 Recruitment Guidance Revisions

Yale

**Main revisions to 410 Recruitment Guidance include:**

- Revision to allowable methods of using medical records to identify and contact potential participants;
- Revision to allowable recruitment involving direct interactions with participants;
- Added section on using phone, mail, email, and text messaging to contact participants;
- Added MyChart recruitment templates and examples of other recruitment scripts;
- Revised generally throughout for formatting/clarity; &
- Web links updated.

Research Recruitment at Yale & YNHHS

# 410 RECRUITMENT GUIDANCE – DOCUMENT NAVIGATION

# 410 Recruitment Guidance – Document Navigation

Yale

**Yale University**
**Human Research Protection Program**
**Guidance: Recruitment of Patients or Use of Data from Patients for Research**
**Version 3.0: 9/9/2024**

**Hyperlinked Table of Contents**

Contents



**General information on IRB requirements, procedures, and definitions related to research recruitment**

**Procedures for secondary data research recruitment without participant interaction, including use of medical records for research**

**Procedures for research recruitment through direct participant interaction, including identification via medical records and approaching patients directly**

**Requirements for research advertisements**

**Appropriate recruitment contact methods**

**Appendix 1: Table summarizing research recruitment strategies**

**Appendix 2: MyChart and other research recruitment templates**

Research Recruitment at Yale & YNHHS

# REVIEW AND APPROVAL OF RECRUITMENT PROCEDURES

# Review and Approval of Recruitment Procedures

Yale

- Recruitment **methods** and **materials** must be approved by the IRB and must be consistent with the policies and practices of the recruitment site before recruitment may begin:
  - This includes reviewing medical or research records to identify potential participants for a research project.
  - 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.
  - If the recruitment takes place at Yale University or affiliated institutions such as Yale New Haven Health System (YNHHS), the Yale HRPP will review the plan to ensure that it complies with institutional policies.
  - If recruitment is proposed at another institution, outside of the Yale HRPP's purview, the HRPP generally will ask for letters of support and/or confirmation that the recruitment is acceptable at that institution.
    - **Please note, other institutions may have more restrictive participant recruitment policies and can impose additional conditions above and beyond Yale and YNHHS recruitment policies.**
    - 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.

# Research Recruitment at Yale & YNHHS

## KEY DEFINITIONS

# Key Definitions

Yale

- **Treatment Provider/Clinician:** 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, and who is or has been employed by, or who renders or has rendered services on behalf of a healthcare entity

- **Clinician-researchers:** Researchers who are also clinicians or treatment providers either at Yale, YNHHS, or other entities.

- **Provider with a direct and ongoing treatment relationship:** 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.**

- **Yale/YNHHS Agent:** Individuals who: **(1)** act on behalf of Yale/YNHHS; **(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.

- **Reviewing IRB:** An IRB authorized by the Yale HRPP to provide review of research on behalf of Yale/YNHHS. Yale IRB serves as the IRB of record for Yale and YNHHS. The HRPP can designate an external (non-Yale) IRB to review research activities conducted by Yale/YNHHS agents.

Research Recruitment at Yale & YNHHS

# RECRUITMENT METHODS FOR SECONDARY DATA RESEARCH

# Recruitment Methods for Secondary Data Research

Yale

- **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 or YNHHS agents, then the researcher must obtain an IRB determination of exemption or IRB approval.

- Yale investigators **from HIPAA covered Yale entities** and YNHHS affiliated investigators can request to use identifiable and deidentified information from medical records for research purposes. Investigators should submit an exemption request (category 4 iii) to the Yale 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.

  - **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. Data from medical records will only include data from individuals who did not opt-out of research.**

- 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. Use of identifiable data from medical records for investigators from non-HIPAA covered entities does not meet exemption criteria.

# Research Recruitment at Yale & YNHHS

## RECRUITMENT METHODS FOR RESEARCH INVOLVING DIRECT INTERACTIONS WITH PARTICIPANTS

# Recruitment Methods for Research involving Direct Interactions with Participants

Yale

- **Approaching Patients at Care Facilities**
  - Patients in the hospital inpatient rooms may not be approached by research staff who are not part of the patients' care team unless the treatment care provider or attending obtained 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.
  - Yale New Haven Health System entities generally do not allow interaction with patients with the intent to enroll participants in research conducted by investigators who otherwise do not have privileges at the specific hospital.
  - **In all cases, researchers and study personnel <u>initiating contact</u> with potential participants must:**
    1. Have sufficient knowledge of the study to answer questions;
    2. Must be knowledgeable about where to refer a potential research participant should questions be raised about their research rights; and
    3. Must meet human subjects protection, Good Clinical Practice, and HIPAA training requirements.

# Recruitment Methods for Research involving Direct Interactions with Participants

Yale

- **Treatment Provider (Clinician) Researchers within Yale and Yale New Haven Health System**
  - Clinician-researchers conducting IRB approved studies may contact their own patients or patients of another Yale/YNHHS provider regarding a study unless the patients have opted out of being contacted about research opportunities.
    - In circumstances where the patient has opted out, but the research involves a therapeutic intervention of potential benefit to the patient, the patient may be contacted by the patient's primary treating physician to determine whether the patient might be interested in participating in the research protocol.
      - Please note, many patients have multiple physicians, and the Primary Care Provider (PCP) may not be the primary treating physician for a patient's primary problem. **It will be incumbent on Principal Investigators (PIs) to identify the primary treating physician from among several treating physicians.**
  - If a study involves investigational therapeutics for a condition of interest, the researcher must coordinate care with the primary treating physician before obtaining informed consent from the patient. **The process for identifying and coordinating with the treating physician must be described in the protocol or IRB application.**

Research Recruitment at Yale & YNHHS

# RECRUITMENT OF PARTICIPANTS USING REPOSITORIES, REGISTRIES, OR RECRUITMENT DATABASES

# Recruitment of Participants Using Repositories, Registries, or Recruitment Databases

Yale

- Investigators may create and maintain a list or registry 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.

- 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* provides investigators with a resource of persons who have voiced willingness to be contacted about participating in clinical trials at Yale through the registry.

**The development of a recruitment list or registry requires IRB approval. Similarly, 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.**

Research Recruitment at Yale & YNHHS

# USING A THIRD PARTY TO RECRUIT POTENTIAL PARTICIPANTS

# Using a Third Party to Recruit Potential Participants

Yale

- IRB review and approval is required when a third party is used for recruitment purposes such as to inform potential participants 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; and
    - Commercial entities hired to aid in recruiting research volunteers.

- Third party recruiters may provide the research contact information directly to the potential participant. <u>The collection of additional research-related information used to determine eligibility cannot be conducted by the third party.</u>

# Research Recruitment at Yale & YNHHS

## TARGETED RECRUITMENT OF STUDENTS, FELLOWS, TRAINEES, FACULTY, AND EMPLOYEES

# Targeted Recruitment of Students, Fellows, Trainees, Faculty, and Employees

Yale

- Researchers cannot directly recruit students, fellows, trainees, faculty, and employees 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.
  - 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 *(outlined in Section 8 of the 410 Recruitment Guidance)*

Research Recruitment at Yale & YNHHS

# STUDY-SPECIFIC RESEARCH ADVERTISEMENTS

# Study-Specific Research Advertisements

Yale

- **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.
  - 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.
  - The YCCI Recruitment and Marketing Unit is available to assist researchers with advertising material.

➢ **Note:** Online advertisements such as websites that are created for purposes of the specific study must follow Yale's policies and guidelines related to web publishing and use of social media. For more information, see Communications Policies, Procedures, and Guidelines.

# Research Recruitment at Yale & YNHHS

## METHODS OF CONTACT

# Methods of Contact

Yale

- Methods of acceptable patient contact (**with IRB approval first**) for recruitment include:
  - Phone
  - Text Message
  - Email
  - Mail
  - MyChart Recruitment

- Mailing content, email templates, text messages, and phone scripts that will be used for recruitment correspondences sent to prospective participants **must be approved by the IRB.**

- Investigators wishing to use phone, mail, email, or text messaging as the primary method to contact their patients must consider the timing of the correspondence, as the method of contact may seem intrusive, especially if they occur after regular business hours.

- The number of anticipated attempts to recruit participants via these methods and their timing should be described in the research protocol.
  - 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.

- When calling, mailing, emailing, or texting a recruitment message to the recipient, researchers and staff must be careful to not to relay any Protected Health Information (PHI) or any personal information where it could be reasonably expected that the individuals would not want others to know about them.

# Methods of Contact – MyChart Recruitment

Yale

- 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 aged 13 or younger).

- JDAT will build an Epic query to identify 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.

- The text used for MyChart messaging **must be approved by the IRB**. The investigator must take special care in drafting messages for research studying conditions that are considered sensitive such as research on mental health.
  - For example, instead of stating that the patient seems to be meeting eligibility criteria, the message can simply state that the study is in need of volunteers.
  - See **Appendix 2** of the 410 Recruitment Guidance Document for examples of message templates. Additional templates are provided in the Library section of the IRES IRB system.

# Research Recruitment at Yale & YNHHS

## RECRUITMENT TEMPLATES

# Recruitment Templates - MyChart

Yale



**Appendix 2**

**MyChart Messaging Templates**

**Suggested Language to describe MyChart recruitment in the Protocol:**

For additional recruitment, we will utilize the services provide by Yale's Joint Data Analytics Team to leverage the Direct-to-Patient Messaging capability using the Yale New Haven Health System's electronic health record system (Epic) patient portal MyChart to help identify potential participants. After the study receives IRB approval to use MyChart recruitment, in collaboration with the JDAT team, we will develop an Epic based query which aims to identify high-level matches based on eligibility criteria, such as diagnosis codes or other administrative codes stored in the health record and will send an automated message to potential participants through the participant's MyChart portal account (Please see content below: for MyChart message language templates). The MyChart message provides information about our research study and information on how to express interest in the study. Interested participants will self-identify through their MyChart portal, phone, or email. Researchers will receive identifying information of only those individuals who indicate interest. After a potentially eligible participant has self-identified themselves as being interested in this research study, then the study team will contact the potentially eligible participant directly, to discuss the study further and answer any questions about the study that the potentially eligible participant may have.

*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.

**Helpful tips in Drafting Your MyChart Invitation Language:**

The purpose of a MyChart Invitation is to notify recipients and share information that they may be eligible for a study and encourage them to join a study – by clicking on "I'm interested" button or clicking on survey link.

1. Use the following principles for your MyChart invite:
    - Use lay language.
    - Use person-centered, person first language, e.g. people who have elevated blood sugar, people living with diabetes.
    - Use 5th grade literacy level.
    - Use developmentally appropriate language.
    - Content: reminder this is an invitation to learn more about your study.
        - Keep the volume of information to the minimum to engage.
        - Do not include all eligibility criteria.
        - Do not put in the consent language.
2. Answer the following *header questions* as you draft your invitation:
    - Why are we doing this study?
    - What will happen in this study?
    - What the potential participant should do to learn more about the study.
        - Standard language as determined by YNHHS/Yale.
    - Links
        - It is possible to provide hyperlinks to locations to which you wish to direct recipients (websites, pre-screening forms, etc.).
        - Hyperlinks can be included in the body of the invitation or incorporated at the bottom of the message for additional accessibility.
    - Additional Features that are part of the standard language:
        - *I'm Interested Button - **Important**: There is limited flexibility in the MyChart Invitation format.*

**a. General Template**

| **MyChart Study Title**<br>***(will be displayed in the MyChart Portal, at top of message)*** |
|---|
| **Why are we doing this study?**<br>We are doing this study for [select target population] who are [select age range], who may be living with [enter X condition(s)] affecting their school, home, or work life.<br><br>We want to [enter general statement about what you hope to gain].<br><br>[Enter optional information]<br><br>**What happens in this study?**<br>If [select person] decide(s) to join, [select pronoun] will be in the study for [enter study time period, e.g. x months].<br><br>The study involves [enter general descriptions, e.g. answering surveys].<br>[Enter compensation/compensation range information]<br><br>**Want to learn more? [Standard Language]:**<br>If you are interested in learning more about this research study, please click the "I'm Interested" button. *Saying you are interested* simply means you would like to learn more and that someone can reach out to talk with you about the research study and answer any questions.<br><br>Please call the 'Help us Discover' recruitment call center at 1-877-978-8343 and select #3, if you want to opt-out of future recruitment communications.<br><br>**LINKS**<br>[Add relevant links, e.g. survey link] |

**Appendix 2** of the 410 Recruitment Guidance includes helpful tips for drafting MyChart invitations, and also includes MyChart recruitment templates for:

- **General recruitment;**
- **Children and adolescents;**
- **People living with cognitive decline, consideration of proxy access; and**
- **People living with mental health conditions.**

# Recruitment Templates – Phone, Mail, & Text Scripts

Yale

**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 [recruitment specialist, nurse, physician, study coordinator] at [Yale, Yale Medicine, Yale New Haven Health System, 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, from a direct to patient message, 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, Yale Medicine, or Yale New Haven Health System]. 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 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 or QR codes, if applicable).



**Appendix 2** of the 410 Recruitment Guidance includes templates/scripts for:

- **Phone recruitment;**
- **Mail recruitment; and**
- **Text message recruitment.**

Research Recruitment at Yale & YNHHS

# LEARNING EXERCISES: IS RECRUITMENT APPROPRIATE OR NOT?

You are a clinician at Yale New Haven Hospital (YNHH) who has received approval from Yale IRB to conduct research on heart disease prevention through exercise and diet intervention. You will review medical records at YNHH to screen for patient eligibility, specifically looking for elevated blood pressure and lipid panel levels. You will then contact the eligible patients to assess interest in research participation.

**Question: What special considerations must this clinician-researcher be cognizant of prior to contacting the potential participants?**

# Case Study #1

Yale

**Points to Consider:**

1. Did any of the eligible patients identified during the screening process opt out of being contacted about research opportunities? If so, can the clinician-researcher still contact the patient about participation in this specific research?

    - **Answer:** No. If patients have opted out of research, they must not be contacted. In circumstances where the patient has opted out, but the research involves a therapeutic intervention of potential benefit to the patient, the patient may be contacted by the patient's primary treating physician to determine whether the patient might be interested in participating in the research protocol.

2. Is the clinician-researcher contacting their own patients or the patients of another Yale/YNHHS provider? If these are not the clinician-researcher's patients, but they still want to contact the patients to assess interest in the research, must the clinician-researcher receive approval from the patients' primary treating physician?

    - **Answer:** In this case, no. The clinician-researcher's privileges at YNHH and IRB approval indicate it is acceptable to contact the patients directly.
        - However, If the study involves a therapeutic intervention that has potential clinical impact, the researcher must coordinate care with the patient's primary treating physician before enrolling the patient in the study. The process for identifying and coordinating with the treating physician must be described in the protocol or IRB application.

## Points to Consider (continued):

3. What methods of recruitment are acceptable to contact potential participants for this research study (if first approved by the IRB)?

**Answer:**

- MyChart Recruitment
- Phone
- Text Message
- Email
- Mail

4. What specifically should the clinician-researcher consider when contacting participants via the methods above?

**Answer:**

- Consider the timing of the correspondence, as the method of contact may seem intrusive, especially if it occurs after regular business hours.
- The number of anticipated attempts to recruit participants (generally no more than 3 attempts).
- Do not relay any PHI or any personal information where it could be reasonably expected that the individuals would not want others to know that information about them.
- All recruitment scripts/templates must be approved by the IRB.

A YNHHS PI wants to contact a potential study participant identified via Epic, but the patient is from another federally qualified health center in New Haven.

**Question: What steps or policies must the PI follow when seeking to contact the potential participant to recruit them into the study?**

**Points to Consider:**

1. If recruitment is proposed at another institution, outside of the Yale HRPP's purview, the HRPP will ask for letters of support and/or confirmation that the recruitment is acceptable at that institution.

2. Yale and YNHHS-based researchers seeking to recruit participants from institutions such as the VA Healthcare system or federally qualified health centers must recognize those institutions may have more (or less) restrictive participant recruitment policies.
   - Institutions may also impose additional restrictions regarding the patient populations, contact methods, and approved technologies that may be used for recruiting study patients.

# Resources & Contacts

Yale

- **HRPP Policy and Standard Operating Procedure Manual**
  - The "**Guidance 410 - Research Recruitment at Yale and Yale New Haven Health System**" document can be found in Part II of the SOP Manual, or as a standalone document on this webpage.

POLICIES, PROCEDURES, GUIDANCE, AND RELATED DOCUMENTS

HRPP Policy and Standard Operating Procedure Manual

HRPP Investigator Manual

IRB Members and Chairs Manual

HRPP Supplemental Guidance Manual

IRB Submission Documents (Protocol Templates, Submission Forms, Consent Templates)

IRB Checklists and Worksheets

Forms & Templates

Protocol Builder

HRPP Policy and Standard Operating Procedure Manual

HRPP Policy and Standard Operating Procedure Manual
Revision Date: July 24, 2023

This document serves as the Yale HRPP Policy and Standard Operating Procedure Manual which serves as a guide for all components of the Human Research Protection Program, including the Institutional Review Board, Investigators and their Research Teams, and other members of the Research Community. This document includes links to the following HRPP Standalone Policies, Procedures, and Guidelines cited in Part II of the Manual:

- Yale University Policy 1360, Human Research Protection
  Revision Date: March 22, 2022
- HRPP Policy 501, Institutional Conflicts of Interest In Human Research
  Revision Date: April 1, 2013
- Policy 1000, Clinical Trial Registration and Reporting Requirements
  Revision Date: April 18, 2017
- HRPP Policy 1200 Oversight of Yale Sponsor-Investigator held Investigational New Drug (IND) Applications, Investigational Device Exemptions (IDE) or Emergency Use or Emergency Use Authorizations(EUA)
  Revision Date: September 17, 2021
- Guidance 410, Research Recruitment at Yale and Yale New Haven Hospital
  Revision Date: December 2, 2022

- **Epic Data Requests for Researchers**
- **Yale HRPP/IRB Contact Information & Resources:**
  - For general questions on the 410 Recruitment Guidance document, or any questions related to HRPP/IRB policies, procedures, or oversight, please contact hrpp@yale.edu
  - **Yale HRPP Website:** http://www.yale.edu/hrpp/
  - **Yale IRB Submission Process Overview:** CLICK HERE
  - **IRES IRB Login:** CLICK HERE

# Questions?

Yale

**Thank you for your dedication to protecting the rights and welfare of research participants!**