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IRB Essentials:

Research Recruitment at Yale & Yale New Haven Health System

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Learning Objectives

- This session will provide investigators under the purview of the Yale Human Research Protection Program (HRPP) (including Yale and Yale New Haven Health System [YNHHS]) with an overview of the requirements regarding research recruitment (biomedical and social behavioral research), best practices for ethical recruitment, and tips for enhancing study enrollment through thoughtful recruitment.

- Upon completion of this session, attendees will be also be informed of the IRB review process for proposed recruitment.

Training Agenda

Agenda Item	SLIDE #s
The Importance of Well-Developed Research Recruitment	4-6
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Overview of Research Recruitment Requirements at Yale/YNHHS	9-18
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The Importance of Well-Developed Research Recruitment

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The Importance of Recruitment

- "Participant recruitment is one of the most challenging aspects of a clinical trial, directly impacting both the study's duration and the quality of its results."
  - Hung, M., et al., (2024). Successes and Challenges in Clinical Trial Recruitment: The Experience of a New Study Team. *Medical Sciences*, 12(3), 39. https://doi.org/10.3390/medsci12030039

- "A robust recruitment plan enhances trustworthiness and overall research success."
  - Negrin, K. A., et al. (2022). Successful Recruitment to Qualitative Research: A Critical Reflection. *International Journal of Qualitative Methods*, *21*. https://doi.org/10.1177/16094069221119576

The Importance of Recruitment

- Participant recruitment (and proper recruitment planning) is crucial to the success of research studies.

- When recruitment is delayed, studies can be affected in several ways:
  - Budget overspending;
  - Extended study timelines;
  - Inability to properly analyze the investigational drug or device;
  - In some cases, the failure of the clinical trial.

- An analysis of registered RCTs showed that 19% of the studies were closed or terminated early because of failure to recruit enough participants
  - Carlisle B, Kimmelman J, Ramsay T, MacKinnon N. Unsuccessful trial accrual and human subjects protections: an empirical analysis of recently closed trials. Clin Trials 2015;12:77-83.

- Global data analysis of all terminated trials within Clinical Trials Database reported 55% of trials were terminated due to the single highest reason of low accrual rate
  - Desai M. Recruitment and retention of participants in clinical studies: Critical issues and challenges. Perspect Clin Res. 2020 Apr-Jun;11(2):51-53.

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Types of Recruitment Practices

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Types of Recruitment Practices

"Print"/Visual Recruitment

- Print materials
  - ✓ *flyers, letters, pamphlets*
- Online recruitment
  - ✓ *social media, websites, search engine advertising*

In-Person Recruitment

- Community outreach
  - ✓ schools, community events, town halls, targeted study sessions
- In-person recruitment via professional relationships
  - ✓ clinical team/patient
- In-person recruitment via personal relationships
  - ✓ community groups, referrals

Other Types of Recruitment

- MyChart recruitment
- Secondary Data Research (no direct interaction)
  - ✓ Medical records, repositories, publicly available data
- Third party recruitment
- Snowball Sampling

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Overview of Research Recruitment Requirements at Yale/YNHHS

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410 Recruitment Guidance

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 <u>without</u> participant interaction, including use of medical records for research

Procedures for research recruitment through <u>direct participant interaction</u>, 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

Recruitment Methods for Secondary Data Research

- **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.

  - Investigators **from HIPAA covered Yale/YNHHS entities** should submit an exemption request (category 4iii) to the Yale HRPP Office for review.

  - **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.**

Recruitment Methods for Research involving Direct Interactions with Participants

- **Approaching Patients at Care Facilities**
  - Patients in 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, research 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 (as applicable), and HIPAA training requirements.

Recruitment Methods for Research involving Direct Interactions with Participants

- **Treatment Provider (Clinician) Researchers within Yale and Yale New Haven Health System**
  - Clinician-researchers conducting IRB approved studies (and/or their delegated staff, such as coordinators) 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 interest in the study.
  - If a study involves investigational therapeutics for a condition of interest, the researcher must coordinate care with the primary treating physician in case standard of care is affected or participation is precluded due to prohibited medications. **The process for identifying and coordinating with the treating physician must be described in the protocol or IRB application.**

MyChart Recruitment

- The IRB may approve a recruitment method using messaging to potential participants to their MyChart account.
- 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.

MyChart Recruitment

- What is NOT allowed when it comes to EPIC or MyChart recruitment?
  - Using EPIC's "Patients like mine" functionality, which searches records from other participating health systems (even if only deidentified data is accessed) and communicating with providers at those health systems asking for referrals, etc.
  - CareEverywhere cannot be used strictly for recruitment purposes (but can be used to screen participants who come to the clinic/site who are interested in participation in therapeutic trials).

Recruitment of Participants Using Repositories, Registries, or Recruitment Databases

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

- 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.
  - E.g., 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

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 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.

  - **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 (e.g., **ResearchMatch**, a national registry funded by the Clinical and Translational Science Award program that links potential participants with researchers.).

- 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.
  - However, third party recruitment services that maintain their own pool of potential participants can determine study eligibility amongst their populations and can then refer those individuals to the PI/study team for additional screening/potential enrollment.

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

- Researchers cannot directly recruit students, fellows, trainees, faculty, and employees to be research participants 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)*

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IRB Review and Approval of Recruitment Procedures

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IRB Review and Approval of Recruitment Procedures

- Recruitment **materials** and **methods** must be approved by the IRB and must be consistent with the policies and practices of the recruitment site before recruitment may begin:
  - **Materials** include printed material, newsletters, social media posts, Internet advertisements, telephone/email/verbal scripts, videos, MyChart messages, etc.
  - **Methods** of recruitment include reviewing medical or research records to identify potential participants for a research project, direct interaction with patients, etc.
  - 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.

IRB Policies Surrounding Research Advertisements & Recruitment Materials

- The IRB must review and approve all advertisements and recruitment materials prior to posting, use, or distribution. Recruitment materials should be limited to the information prospective participants need to determine their eligibility and interest:

  - Name and contact information for the PI;
  - The condition being studied and/or the purpose of the research;
  - In summary form, the criteria that will be used to determine eligibility for the study;
  - The time or other commitment required of the participants;
  - The location of the research and the person or office to contact for further information;
  - A clear statement that the activity is research and not treatment;
  - A brief list of potential benefits (e.g., no-cost health exam).

IRB Policies Surrounding Research Advertisements & Recruitment Materials

- The IRB reviews the material to assure the material is accurate and is not coercive or unduly optimistic, creating undue influence on potential participants to participate. **Inappropriate content includes, but is not limited to the following (as applicable):**
    1. Statements implying a certainty of favorable outcome or other benefits beyond what was outlined in the consent form and the research plan;
    2. Claims that the test article (drug, biologic or device) or intervention is safe or effective for the purposes under investigation;
    3. Claims that the test article or intervention is known to be equivalent or superior to any other drug, biologic, device, or intervention;
    4. Using terms like "new treatment," "new medication," or "new drug" without explaining that the test article or intervention is investigational;
    5. Promising "free medical treatment" when the intent is only to say participants will not be charged for taking part in the investigation;
    6. Emphasis on payment or the amount to be paid, such as bold type or larger font on printed media;
    7. Offers for a coupon good for a discount on the purchase price of an investigational product once it has been approved for marketing; and
    8. The inclusion of exculpatory language.

Crafting Your Research Recruitment Plan

★ The IRB Submission Form is available in the IRES IRB Library HERE

FOR EXTERNAL IRB STUDIES:

Recruitment must be described **even when the study is using an external IRB.** It is the Yale HRPP's responsibility to ensure the proposed recruitment matches our institution's guidelines.

- The Yale HRPP does not need to see changes to recruitment materials for external studies, as this is the reviewing IRB's responsibility.
- The Yale HRPP does need to be notified of any changes to the recruitment plan.
- The recruitment plan must be described within the "Request to Use External IRB" form.

Section 2. Recruitment

This section asks about recruitment methods. Please review "**Guidance 410, Research Recruitment at Yale and Yale New Haven Hospital**" at https://your.yale.edu/policies-procedures/guides/410-guidance-recruitment-patients-or-use-data-patients-research for detailed guidance related to recruiting or using data from Yale and YNHHS patients for research.

Answer the questions below **OR** provide the section and/or page numbers in the protocol where you addressed all of the questions.

1. Indicate general recruitment methods below:

☐ Approaching patients at care facilities/clinics
☐ Medical Record Review of Yale investigator's patients followed by direct contact
☐ JDAT services, specify:

☐	Chart reviews
☐	EPIC/MyChart Direct-to-Patient Messaging
☐	Mailing
☐	Other:

☐ YCCI Recruitment Services, specify:

☐	Advertisement
☐	Call Center
☐	Flyer/Brochure
☐	Recruitment Database ('Help Us Discover' volunteer registry)
☐	Social Media
☐	Valpak Mailing
☐	YCCI website (yalestudies.org)
☐	Other:

☐ Registry Protocol, specify IRES IRB#:_____
☐ Referrals from centralized recruitment or referring physician
☐ Letter
☐ Telephone
☐ Text message
☐ Email
☐ Mass email solicitation
☐ Flyers/brochures
☐ Posters
☐ Internet/web postings
☐ Web-based clinical trial registries
☐ Clinicaltrials.gov
☐ Social Media
☐ ResearchMatch

☐ Doctor to Doctor Letter
☐ Departmental/Center website
☐ Departmental/Center research boards
☐ Departmental/Center newsletters
☐ Valpak mailing
☐ Newspaper
☐ Radio
☐ Television
☐ Other: _____

Crafting Your Research Recruitment Plan

General Recruitment Questions – IRB Submission Form

2.	**Describe how you will identify potential participants:** *(i.e., the PI will seek permission from the Chair of the hospital unit to recruit patients on the premises of their hospital floor; on the day of the research activities, the nurse and/or attendings will identify potential participants and will obtain their permission to be approached by the research team, etc.);*
3.	**Describe how potential participants will be contacted and by whom:** *(i.e., describe when and where/how the initial contact will take place and who will be in contact with the potential participant (clinicians, non-clinician researchers, student researchers, other). Phone scripts, email templates, text message templates, etc. used to contact potential participants must be submitted to the IRB for approval.)*
4.	**If applicable, describe the use of YCCI's Recruitment and Marketing Unit:** *(e.g., YCCI's role in pre-screening, contacting potential participants, and/or other recruitment efforts through YCCI)*

Crafting Your Research Recruitment Plan

Additional Recruitment Questions For Interventional Research – IRB Submission Form

(e.g., treatment studies, social-behavioral and biomedical clinical trials, etc.)

5.	**What steps have you taken to ensure you have sufficient eligible participants to reach your recruitment goals? What were the results of your analysis?** *(e.g., describe use of Slicer/Dicer in EPIC to ensure there is population available in the YNHHS catchment area when applicable; sponsor uses a centralized recruitment and will provide contact information for potential participants; follow-up study on previously enrolled participants who agreed to be contacted for other studies)*
6.	**What barriers or seasonal factors that could impact the recruitment rate do you expect? Address any potential barriers to accrual and plans for addressing unanticipated delays, including a mitigation plan for slow or low enrollment or poor retention.** *(If you have experience with recruitment challenges and successes in similar previous studies, please, describe them).*
7.	**Are there any stakeholders or community leaders involved in the recruitment process? If so, describe.**
8.	**If the study involves multiple visits, what strategies will be implemented to retain participants throughout the study?** *(E.g., Providing regular updates on the study's progress and reminders to the participants of upcoming activities or appointments, etc.)*

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Recruitment Resources:

Yale Center for Clinical Investigation (YCCI)

& Yale Cancer Center (YCC)

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What can the Yale Center for Clinical Investigation (YCCI) do to help you with community engagement and participant recruitment?

Advertising

Advertising services offer customized digital and print strategies to promote research studies, including social media campaigns, email outreach, flyer design, and poster placement. These services help boost visibility and attract potential participants.

Community Project-Specific Consultation

Provides expert guidance to Principal Investigators (PIs) from trained community leaders, offering insights on research partnerships, priority research areas, and recruitment strategies to ensure cultural sensitivity and effective community engagement.

Outreach & Recruitment

Outreach and recruitment services support participant engagement through community events, call center outreach, pre-screening, and promotional material placement to increase awareness and study enrollment.

Translation Coordination Support

Coordination to ensure research materials are accessible and culturally relevant by managing translation services for informed consent forms, recruitment materials, and educational documents. This includes reviewing materials for cultural relevance, coordinating translation requests, and obtaining necessary approvals.

[Click Here for YCCI Service Information, including Recruitment Resources Details]

Or email YCCI's **Community Engagement & Participant Recruitment team** at:

yccicommunity@yale.edu

How to Submit a YCCI Research Service Request for Community Engagement & Participant Recruitment Services

Scan the QR code to submit a YCCI Service Request or visit

https://yale-medicine.my.site.com/ticketingycci/s/

You will be automatically logged in through CAS with your Yale University NetID and password.

Click Here for Submission Guidance & Training Materials

Yale Cancer Center
Community Outreach and Engagement (COE)

Mission of COE Component under the NCI Cancer Support Grant:

- Conduct research relevant to state of CT
- Establish community advisory board and partnerships
- Seek input to prioritize, facilitate and expand cancer research
- Communicate community needs to researchers
- Catalyze research with communities/partners to decrease cancer burden

New Leadership:

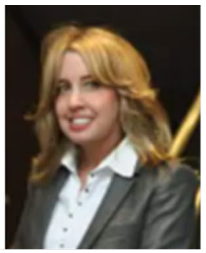
Associate Director of COE at YCC: Tracy Battaglia, MD, MPH

Assistant Director of COE at YCC: Melissa Hughes, MSc

YCC COE Community Advisory Board

- Includes **community voices** (e.g., survivors, caregivers) from CT cities to communicate local priorities & concerns
- Provides **feedback** to research studies at any stage to incorporate community perspectives
- Participates in **designing community-facing** materials; community education, outreach activities, grant reviews
- **Monthly** CAB meetings; meets with **YCC Director** 2-3 times per year & key partner in realizing **YCC Strategic Plan**
- CAB members serve on **YCC External Scientific** & **Internal Advisory Boards**


Alycia Santilli (Co-Chair)


Melissa Lang (Co-Chair)


Shantana Hazel


Noor Al Zoubabi


Teretha Brooks


Jamie Lenese Belton


Eileen Esdaile


Sean Reeves


Teri Carson


Natasha Ray


Kisha Annette Hull


Zarghona Sadat


Victoria Dancy

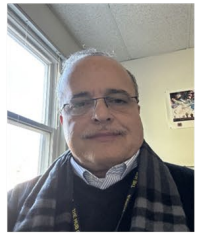

James Rawlins


Grisel Aguilar-Cobos


Rynasia Baldwin


Leslie Brown


Dawn White-Bracey


Alvin Perez


Brienne Simmonds

YaleNewHavenHealth
Smilow Cancer Hospital

Yale CANCER CENTER
A Comprehensive Cancer Center Designated by the National Cancer Institute

Yale Cancer Center
Community Outreach and Engagement (COE)

How can the YCC COE team support investigators?

Consultations with our YCC COE team and/or with our Community Advisory Board (CAB) for investigators on recruitment and dissemination strategies for oncology-specific studies.

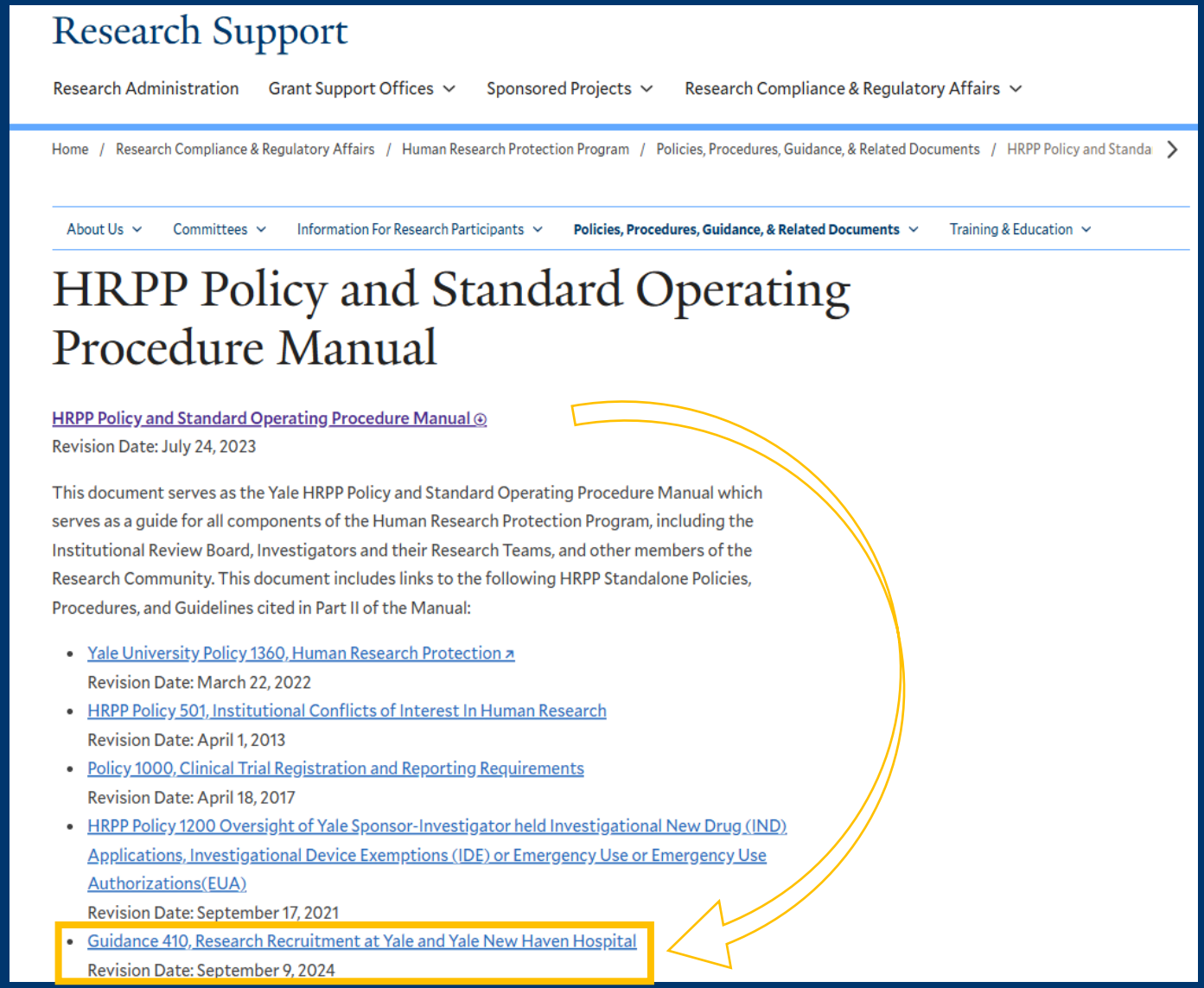
Reach out to: ycc.coe@yale.edu if interested in office hours.

Additional Resources

- **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.

- **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?

Questions? Contact HRPP@yale.edu
Yale HRPP Website

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