<u>Multisite Participant Recruitment using EHR-Derived Cohorts</u>
Guidelines and Best Practices for Researchers

<u>Introduction</u>

Multisite participant recruitment using EHR-derived cohorts (hereafter referred to as "EHR recruitment") requires special planning and consideration due to complexities around patient privacy, data limitations and security, and variance in local administrative practices. These guidelines and best practices are intended to aid researchers in creating a multisite EHR recruitment plan that is respectful to patients, minimizes the risk of loss of patient confidentiality, and helps researchers anticipate and prepare for patient feedback. This document was developed as a collaborative effort by the UC BRAID Participant Recruitment workgroup, comprised of representatives of University of California campuses at Davis, Irvine, Los Angeles, Riverside, San Diego, and San Francisco, with input from Stanford University.

Note: For the purposes of this document, "EHR recruitment" is defined as**:**
>   Recruitment of patients who are identified via a systematic query of the electronic health record. The query generates a list of patients who may meet basic study eligibility criteria; providers may span multiple clinics and disease areas and initial contact is conducted outside of the clinic setting.

Characteristics of EHR recruitment:	**Characteristics of non-EHR recruitment:**
- PI may be unknown to the patient. - Lists of potentially eligible patients are derived via an EHR data extraction, typically by a certified EHR programmer. - Initial contact is conducted outside of the clinic, typically by letter, email, or a patient portal.	- Data is derived from any source other than the EHR (e.g., clinic administrative data, registries, publicly available mailing lists). - Initial Patient eligibility is determined by a chart review. - Initial recruitment approach is in a clinic setting.

IRB approval for any recruitment method is granted on a case-by-case basis; EHR recruitment may not always be appropriate or practical, depending on the context of the study design, patient population, availability of data, and research infrastructure at recruitment sites. Some patient populations may not be suitable for EHR recruitment, such as when eligibility is based on sensitive or rare diagnoses. In these cases, PIs may wish to establish additional collaborations

with clinicians working in the disease area to determine appropriate and effective methods for recruiting these patients.

Collaboration and Feasibility tools

Researchers interested in exploring new collaborations can use the [UC Health Profiles tool](#) to search for potential partners.

UC Researchers can conduct feasibility searches prior to IRB approval using cohort discovery tools such as [Accrual to Clinical Trials (ACT)](#). The ACT tool allows researchers to independently execute simple queries to obtain counts of potentially eligible patients across the UC system and a national network of academic medical centers.

The Role of Local Partners

All sites obtaining EHR recruitment data must identify a site PI. The site PI is responsible for following local processes to obtain and use the data. Identified data is managed locally within each system, and must be obtained from each site by the site PI. Processes vary by institution; site PIs should contact their local CTSA for guidance and to confirm availability of resources (see Table 2, below).

 The site PI will be accountable for addressing any patient feedback or complaints and ensuring they are appropriately handled according to local guidance.

Table 2: Recruitment Contacts at UC academic medical centers

Campus	Contact	Email
UC Davis	CTSC Clinical Trials Office	hs-clinicaltrials@ucdavis.edu
UC Irvine	Accrual and Retention Consult Service	icts@uci.edu
UC Los Angeles	CTSI Informatics Program	patientdata@mednet.ucla.edu
UC San Diego	Community Engagement	ctri-community@ucsd.edu
UC San Francisco	Participant Recruitment Program	PRP@ucsf.edu

Process and Getting Started

Any study conducting multisite EHR-based recruitment within the five UC Academic Medical Center campuses can use this guidance to guide their recruitment plan.

Steps to get started

1. Local partners: confirm availability of data extraction resources at each site.
2. Coordinating center:
   a. Develop the recruitment strategy, including recruitment messages that follow the recruitment guidance in Section 1. Creating the Recruitment Message
   b. Submit for IRB approval using the guidance in Section 2. IRB Approval and Processes
3. Coordinating center: Following IRB approval, work with institutional programmers to develop your query. See Section 3. Requesting and Sharing Identified Data
4. Local partners: Follow local guidelines to request data extraction from local partners.
5. All sites: recruitment can proceed as data is obtained. If data will be shared between campuses, or if interested patients will contact a study team at a site other than that at which they will receive care, refer to the section on Section 4. Special Considerations for Cross-Campus Data Sharing and Communication

Recruitment maintenance

There are a few points to keep in mind while recruitment is ongoing.

1. Recruitment data should be periodically refreshed for updated vital status and contact preferences. Every three 3 months, work with programming resources to refresh the list to update vital status, contact preferences (if applicable at site), and eligibility.
2. Depending on the study design, it is possible that patients may contact a study team member at another campus with complaints or request not to be contacted. In such cases, study team members at all sites should report this information to the PI at the patient's home institution for appropriate follow-up.

Guidelines and Best Practices

Section 1. Creating the Recruitment Message

In the context of EHR recruitment, the *protection* of patient privacy refers to ways in which researchers can make patients feel that their privacy is respected when their health information is used for recruitment to research studies. Following are guidelines recommended by UC IRB and Privacy officers to use in your recruitment message.

Selecting a Contact Method

For initial contact, choose a communication method that limits the spread of PHI.

EHR Recruitment contact methods should follow a "closed envelope" methodology, meaning the recruitment message is not visible until opened. Possible "closed envelope" recruitment methods include: letters enclosed in sealed envelopes; email; or messages sent via an EHR patient portal. Policies and availability of services vary by institution.

Key point: *Avoid language that may make a patient feel singled out.*

Avoid using language that may be alarming to a patient, such as "a review of your medical records indicates you may be eligible for this study." Instead, begin your letter by introducing the importance of research and research participation opportunities. For example:

> *We are writing to you with information on a new research study being conducted at <<institution>> that may interest you. Research plays an important role in advancing our understanding of clinical care and helps lead to improvements in health. To facilitate research, <<institution>> invites patients to participate in these research studies.*

(Critical) Key Point *Avoid including diagnosis information in the letter.*

To limit the spread of protected health information (PHI), do not include information that may indicate the patient's medical condition. In some cases, this will require obscuring certain details, such as the study title, the PI's department, the return address, study website, study email address, inclusion/exclusion criteria, or PI practice or research area. Patients can learn more about the research and details of participation when they contact the study team or visit the study website. Take care to limit PHI in these elements in the recruitment message:
- Return address: Omit the name of the research institute or clinic if it indicates a condition which the patient may have
- Title: It is not necessary to use the official study title if it indicates a diagnosis; use a study nickname, or omit the study title altogether in favor of a general study description.

- Study information: Describe this in general terms.
- Study website: If the study website contains information about a condition, use a URL-shortener such as bit.ly or tinyurl.com to create a custom link that will redirect to your study website.
- Study email: If the study email address contains information about a condition, use an alternate email address such as a staff email address
- **EXCEPTION**: If the condition that you are studying is prevalent in the general population and not sensitive or potentially stigmatizing, it may be appropriate to include it in the letter.
- **NOTE**: An [example letter](#) is available in the [Appendices](#)

If the recruitment message will reference multiple institutions: *Ensure that the recruitment message prominently references the home institution where the patient receives care.*

Patients should be able to easily understand that the institution where they receive care is participating in the research study for which they are being contacted. This can be accomplished in several ways, such as:
- The recruitment message is signed or co-signed by the site PI or representative of the institution where the patient receives care
- The body of the recruitment message explains the research partnership between the coordinating center and the institution where the patient receives care; or
- If feasible and practical, the recruitment message can reference or be cosigned by a provider, department, or clinic associated with the patient's care; or
- In the letterhead, feature the logo of the institution where the patient receives care.

NOTE: A Multi-Campus Patient Letter [template](#) and [example](#) are available in the Appendices.

Section 2. IRB Approval and Processes

IRB applications may vary in how information is collected; if you have questions about how to implement this guidance in your specific application please contact the IRB of record. Studies should follow local standards of obtaining and providing IRB approval documentation to facilitate service requests related to obtaining and transferring data.

Your IRB application will need the following components:

- Request for a partial Waiver of HIPAA Authorization
- Copies of the recruitment materials that will be sent to patients for all sites
- Description of the recruitment method, including
  - Justification for need of identifiable data elements, limited to the minimum necessary amount of identifiers

- Who will receive the data/Collaborators at other sites
- Basic criteria used to identify patients
- Method for securing identifiable information

Use this boilerplate language as a starting point:

The email/letter (attached) will be sent to individuals identified from the [HEALTH SYSTEM] record systems via a data extraction by [*Data Service Site*] of patients with a diagnosis of [XXX]. These patients [are/are not] known to be under the care of the researcher team. Interested subjects will contact the study staff at [CAMPUS] as described in the message. The data extract will be delivered to the research team's [*data sharing platform*] account at [LIST CAMPUS] and the message will be sent by the research team.

Studies should customize and add more details to this boilerplate text as relevant to their specific recruitment workflow.

Required: *Coordinating center should provide documentation of IRB approval to local sites to support local data requests.*

Full documentation of IRB approval is only accessible by personnel at the coordinating center associated with the IRB of Record. The coordinating center should provide IRB approval documentation to the sub-sites in order to meet local administrative requirements, including data extraction.

Data Extraction Landscape

The landscape of EHR data for multisite recruitment varies depending on the stage and form of research design and existence of IRB approval for requesting identified data. Recruitment via EHR derived cohorts works best for cohorts that have inclusion/exclusion criteria that correspond to coded variables in the electronic medical record; clinic notes, images, and insurance data are generally not able to be effectively queried for eligibility at present.

Section 3. Requesting and Sharing Identified Data

Best practice: *To increase efficiency, develop the query at the coordinating center and share the example code with local sites.*

Best practice*: If identifiable data is shared with another campus, the collaboration site PI should ensure data is transmitted in accordance with local data security policies.*

Section 4. Special Considerations for Cross-Campus Data Sharing and Communication

Best practice: *Establish an IRB-approved communication plan to ensure that all recruitment intake teams respond appropriately to patient feedback and funnel any follow-up requests to the patient's home institution.*

The communication plan should include:
- A description of the types of feedback and/or information that should be referred for additional follow up.
- A sample script detailing how to respond to common patient concerns including information privacy, reason for contact, request to be removed from contact lists, and request to speak to Institutional official or Researcher in charge of the study. This may take the form of a document which answers "Frequently Asked Questions." (Please see our template example.)
- A report form that collects information required for follow-up (e.g., patient's name, preferred contact method, and institution where they receive health care.)
- A list of the appropriate contacts at each Institution who are designated to receive patient feedback and who will be responsible for follow-up, both on the local study team and the compliance office to manage concerns.
- Approved procedure for transmitting information that includes PHI between Institutions (e.g., via secure email.)

Section 5. Appendices and Templates
1. Multi-Campus Patient Letter template
2. Multi-Campus Patient Letter example
3. Patient PHI Removal template
4. Multi-site Research at UC - Frequently Asked Questions
5. UC BRAID Multi-site EHR Recruiting Workflow