**ACTIVITY #8: Subject Recruitment**

**8.1 Identify Prospective Subjects from EMR**

**Cohort Discovery Tool and Specific Patient Cohorts**
The cohort discovery tool provides researchers the ability to query several sources of patient data. Cohort discovery is a repository of patient information gathered from multiple sources, including electronic medical records, lab results, and demographic data. Register with Cohort Discovery and take training ([http://www.ucdmc.ucdavis.edu/ctsc/area/informatics/cohortdiscovery/](http://www.ucdmc.ucdavis.edu/ctsc/area/informatics/cohortdiscovery/)). In order to contact patients identified by EMR screening, provide the contact script (usually a paper letter) to the IRB for review. Describe the planned approach in HRP-503, Section 25 - Recruitment Methods.

**HIPAA Waiver of Authorization for Recruitment**
A HIPAA Waiver of Authorization can be obtained from the IRB if access to patient data is needed for recruitment purposes. Describe the need in the protocol template (HRP-503, Section 25 - Recruitment Methods). This section is reviewed by the IRB. If a full or partial waiver is granted, access to identifiable patient data to determine if a patient may be a potential research subject will be authorized. IRB approval is confirmed by issuance of the Form R (“Waiver of Research Participant’s Authorization for Use/Disclosure of PHI for Recruitment”).

**Disclosure Tracking Database**
Prior to a subject signing the HIPAA Authorization for Research form, any access to patient identifiable data for research purposes must be reported in the Disclosure Tracking Database, even if a Preparatory Research Application or HIPAA Waiver of Authorization has been approved. The database can be accessed at: [https://disclose.ucdmc.ucdavis.edu/disclose/index.dsc](https://disclose.ucdmc.ucdavis.edu/disclose/index.dsc). Check the box that says “Disclosures for Research (no authorization).” For high volume entries, a spreadsheet may be submitted to HIM for automatic upload. A spreadsheet template with “how-to” instructions is available on the CTSC Clinical Trial Resource Group website (tab “Tools for Study Management”).

At the time of this publication, Health Information Management is planning to launch **Quick Disclosure Activity** that can be accessed directly in the EMR. With the Quick Disclosure activity, EMR users can quickly and conveniently record what information they release, all from their clinical workspace. For example, after printing patient information from Chart Review and releasing it to their patients, clinicians can use the Quick Disclosure activity to record necessary information about what they released so that it can be included in disclosure reports.

To access the Quick Disclosure

1. Go to Hospital Chart or Chart;
2. Click “More Activities” and choose Quick Disclosure;
3. Quick Disclosure opens. Fill out the appropriate fields.
Decedent Research
To look at PHI for decedent research where there are no identifiers linked to living persons and no use of death records, submit a Decedent Research Application. The privacy officer may request proof of death.

If including identifiers linked to living persons or accessing death records maintained by the State Registrar, local registrars, or county recorders, the project must be approved by the IRB in advance.

Upon approval, authorization to access this data will be granted. The application can be found on the Compliance website: (http://www.ucdmc.ucdavis.edu/compliance/guidance/privacy/resdeced.html)

When does HIPAA apply?
When an established patient is being considered for participation in a research study by a clinician involved in the patient’s care, the HIPAA rules can be confusing. HIPAA applies when a provider is reviewing a patient’s medical record for both treatment and research purposes. In general, under the HIPAA privacy rules, a patient’s medical information may be accessed for a treatment, payment or operational purpose without obtaining prior written consent. Access to a patient’s record for any other purpose may require additional steps to be in compliance with privacy laws and rules. This means that when a provider looks at his or her patient’s medical record for research purposes, the research-related HIPAA rules apply.

When is access considered to be for a research purpose?
If a patient’s record is reviewed for a treatment purpose (e.g., to view lab results or consult with a referring provider) the research-related rules do not apply. However, once a patient’s medical information is viewed for a research-related activity (e.g., to screen for eligibility or review, to review a unique case for possible study, or to collect data) the research-related HIPAA rules apply. For example, if a provider is reviewing a patient’s lab report for regular care, this access would be for treatment purposes and the research-related rules would not apply. However, if during this review, the provider notices that the lab value may make them a potential research subject and wants to review the chart further for eligibility, the research-related rules would need to be considered.

What are the research-related privacy rules that should be considered?
In general, before any patient information can be used for a research purpose, the patient must sign a study-specific Authorization which recites the patient’s privacy rights. This is true whether or not the patient is seen by the researcher/physician for medical care. Patient information can be used for research-related purposes without a signed patient authorization under two limited exceptions: if the IRS has granted a study a “Form R” or a “Preparatory Research Authorization.” If access to a patient’s medical information is pursuant to one of these exceptions, then any access must be documented and tracking the Disclosure Tracking Database.
IMPORTANT

Any study data obtained without the proper authorizations cited above may not be used for publication (i.e. journals, abstracts, etc.) or any other purpose and can be subject to notification requirements under state and/or federal laws.

See Clinical Trials Resource Group’s November 2012 Newsletter for additional information http://intranet.ucdmc.ucdavis.edu/ctsc/area/ctnewsletters/

8.2 Advertise

The UC Davis IRB must review and approve all materials for human subject recruitment before recruitment efforts begin. An advertisement to recruit subjects is any form of materials whose main purpose is to inform and invite the potential subjects to participate in a research study, including:

- Flyers and handouts
- Bulletin boards/Billboards
- Letters and e-mails
- Newspapers/magazine Ads
- Posters
- Radio, TV and Cable
- Website/Internet postings
- Phone scripts
- Facebook

The advertisement should be limited to the information prospective subjects need to determine their eligibility and interest, such as:

- Name and address of the investigator or research facility
- The condition under study or purpose of the research
- In summary form, the criteria that will be used to determine eligibility for the study
- A brief list of participation benefits, if any
- The time or other commitment required of all subjects
- The location of the research and the phone number of the person or office to contact for further information

For FDA-regulated research, the advertisement should not:

- Make claims, either explicitly or implicitly, that the drug, biologic or device is safe or effective for the purposes under investigation.
- Make claims, either explicitly or implicitly, that the test article is known to be equivalent of superior to any other drug, biologic or device.
- Use terms, such as “new treatment,” “new medication” or “new drug” without explaining that the test article is investigational.
- Include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.
- State or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.
- Promise “free treatment,” when the intent is only to say subjects will not be charged for taking part in the research.
• Include exculpatory language.
• Emphasize the payment or the amount to be paid, by such means as larger or bold type.

8.3 Screen Research Participants

Screening is the term used to describe research activities performed on participants after obtaining their informed consent. Usually screening activities are performed to ensure subjects are eligible to be enrolled in the study, i.e., that the participant meets the inclusion and exclusion criteria for the study. Screening activities include interactions with potential subjects to determine eligibility that would not otherwise have been performed if not for the study. Note that a screen failure is the term used to describe the circumstance in which a subject who has provided consent has subsequently failed to meet eligibility criteria for participation in the study based on screening procedures performed after informed consent was obtained. UC Davis does not have a separate informed consent just for screening. The screening script (i.e. by telephone) has to be approved by the IRB.

8.4 Obtain Informed Consent

Please reference Appendix “Informed Consent”

8.5 Submit a Copy of Consent Form to HIM

Consent Forms for research are required to be in the Legal Medical Record for drug and device studies. Policy & Procedure 2306 (Legal Medical Record Content/ Core Elements) requires that the Informed Consent Form must be part of the Legal Medical Record. Under Section VI.E.2.f, (Consents for Care, Treatment and Research/Human Subjects Research involving investigational use of a drug or device), the policy requires that a “signed copy of the consent form is filed in the medical record.” Place these documents in the Health Information Management (HIM) mail baskets located in all patient care areas. Couriers routinely pick these up and all documents are promptly scanned by health information management (HIM) into the medical record. It is important to send the signed ICF’s to HIM as soon as possible since they are held to time standards for scanning documents. The scanned documents can be found under the “Media” tab in the EMR. The ICF needs to be scanned and uploaded even if the patient does not pass screening criteria.


8.6 Maintain Participant Research Records

Please refer to Activity #11