1. PURPOSE

1.1 This procedure establishes the process to conduct recruitment outreach to potential study participants utilizing data derived from UCD Electronic Health Records or student records.

2. REVISIONS FROM PREVIOUS VERSION

2.1 None

3. POLICY

3.1 To use or disclose a patient's protected health information (PHI) for research purposes, a covered entity (UCD Health) is generally required to obtain a written HIPAA research authorization from a subject, or a Waiver of HIPAA Authorization from the Institutional Review Board (IRB) that meets the requirements of the regulations [45 CFR 164.512(i)]. Accessing PHI for the purposes Preparatory to Research, or decedent research or recruitment of participants in an IRB approved protocol clinical trial must follow UCDH Policy and Procedure 2410 "Allowable Uses and Disclosures for Protected Health Information (PHI)."

3.2 An Accounting of Disclosure is required for all access to PHI for research unless a written HIPAA research authorization signed by the subject is on file with the study." An Accounting of Disclosure must be documented in accordance with UCDH Policy 2446 "Tracking Disclosures of Protected Health Information (PHI).

3.3 UC Davis IRB is responsible for issuing a waiver or alteration of the HIPAA authorization requirement for the purposes of subject recruitment using the criteria set forth by 45 CFR § 164.512(i)(1)(i)(A) or (B), "Uses and disclosures for which an authorization or opportunity to agree or object is not required."

3.4 Deriving information from UCD Health Records must adhere to the standardized processes established by the Data Provisioning Core enterprise program.

3.5 All recruitment methods must be described in the narrative of the IRB protocol and recruitment materials reviewed and approved by the IRB. Opt-out provisions must be clearly addressed in all direct contact recruitment methods. Study teams are responsible for following through on opt-out requests by maintaining study specific do not call databases and sharing that information with platform managers. Alternatively, study teams may provide directions to individuals as to research opt-out functions within the platform used for recruiting, e.g. Epic MyChart.

3.6 The HIPAA Privacy Rule specifically excludes from its coverage those student records that are protected by FERPA by excluding such records from the definition of "protected health information." When deriving student health information defined as treatment or education records for recruitment subject to FERPA protections must also be in compliance with 34 CFR 99.30 and or 34 CFR 99.31, and the California Information Practices Act, Civ. Code Section 1798-1798.78.

4. RESPONSIBILITIES

4.1.1 Investigators are responsible for ensuring compliance with this standard operating procedure.

5. PROCEDURE

5.1 Investigators seeking a Waiver of HIPAA Authorization for research recruitment must present evidence in the narrative with sufficient details for the IRB to be able to ascertain:

- The PHI being used and disclosed presents no more than a minimal risk to the privacy of the subject, based on, at least, the presence of: (a) an adequate plan to protect PHI from improper utilization; (b) an adequate plan to destroy PHI at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the PHI or such retention is otherwise required by law; and (c) adequate written assurance that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which use of the PHI would be permitted by HIPAA;

- The research could not practicably be conducted without waiver; and
- The research could not practicably be conducted without access to and utilization of the PHI.

5.2 The documented approval by the IRB shall include:

- The name of the IRB committee and the date on which the alteration or waiver of authorization was approved;
- Statement that the IRB has determined that the alteration or waiver of authorization satisfies the criteria set forth above;
- Statement that a description of the PHI, for which use or access has been determined to be necessary by the IRB, is retained in the IRB's file for the study;
- Statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures; and
- The signature of the IRB committee chair, or other member designated by the chair.

5.3. It is recommended that patients identified through data provision/chart review be approached by someone already involved in their care (e.g., treating physician, administrative and research staff working with the physician). While recruitment may occur, written informed consent and HIPAA authorization is required before additional information is gathered and/or research procedures are initiated.

5.3.1 Patient Communication Portal in Electronic Health Record – Patient Portal provides patients an additional opt-out feature. Researchers may not use this method for any patient who has opted not to be contacted about research through Electronic Health Record. This method is the most appropriate for recruitment when prospective subjects are UCDMC patients, likely have established Electronic Health Record accounts, and/or PHI needs to be included in the initial recruitment messages.

5.3.2 Email – This method is the most appropriate for research recruiting where PHI does not need to be included in the initial message. If PHI is to be disclosed using this method, it shall only be in relation to the individual's Email address where the prospective subject's Email address contains elements of their name. No other PHI shall be divulged, nor shall the title of the study. The use of specific diseases or conditions should be limited to convey the subject of the study only.

5.3.3 SMS – SMS technology solutions may be utilized when reviewed through the vendor risk assessment process by the UC Davis CISO or CISO delegated reviewer. PHI, PII and RHI may not to be sent via this method without appropriate protection level classification evaluation and approval in consultation with the Privacy Office. Further, all recruiting efforts must be in compliance with applicable law or University policy. IRB review is required for all instances of SMS recruiting utilization. No information may be disclosed that would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation. Specific review for potential participants that are subject to FERPA protections or employees of the University must be considered during IRB review. Utilization of linked information through SMS must include an authentication process unique to the recipient. All recruiting activities employing SMS must include an opt-out mechanism in the initial solicitation.

5.3.4 Printed letters - PHI may be disclosed on the letters sent via USPS mail. It is not required that letters be sent certified unless it is desired by the researcher. Certified mail imposes an additional burden on the recipient to either be home or go to a post office to collect the letter.

5.3.5 Phone calls – PHI may be disclosed using this method after verifying the prospective subject's identity. Many people will not answer calls from people they do not know, so a voicemail script should also be included if utilizing this method. PHI (e.g. diagnosis, date of birth, MRN) should not be left in a voicemail message.

5.4. The method utilized should be described to the IRB in the protocol narrative. The IRB will determine if the method(s) described is/are appropriate based on several factors including but not limited to: study population, risk level, nature of information to be disclosed. In all cases, any material meant to be seen or heard by prospective subjects (e.g. flyers, letters, phone scripts) should be submitted to the IRB for review.

5.5 If a prospective subject refuses to participate, no identifiable information may be kept about the individual unless they consent to allow retention of this information. The protocol narrative should include a description of this consent process. With IRB approval, non-identifying information about those who refuse to participate may be retained/collected; otherwise all information obtained from charts, records, registries must be destroyed.

5.6 Opt-out options must be included in each message and subsequently reflected in a subject's Electronic Health or Student Record. For study specific opt-outs the research team is responsible for annotating individual research records to reflect a no contact order. If a subject requests an opt-out for all research the study team may provide instruction to the individual to self-designate no contact for research or may provide the subject information to the system administration office of record to designate the individual as a no-contact for research.

6. MATERIALS

6.1 WORKSHEET: Advertisements (HRP 315)

6.2 Health Research Advisory: Sharing UC Protected Health Information Across UC for Research Purposes. UC Office of General Counsel

7. REFERENCES

7.1 45 CFR Part 46 (Common Rule)

7.2 45 CFR Part 160 (HIPAA Security Rule)

7.3 45 CFR Part 164 "Uses and disclosures for which an authorization or opportunity to agree or object is not required"

7.4 20 U.S.C. § 1232g; 34 CFR Part 99 (FERPA)

7.5 California Code, Civil Code – CIV 1798.3

7.6 California Code, Civil Code – CIV 56.10

7.7 University of California Policy BFB-IS-3: Electronic Information Security

7.8 UC Policies Applying to Campus Activities, Organizations and Students (PACAOS)

7.9 130.00 Policies Applying to the Disclosure of Information from Student Records

7.10 Policy and Procedure Manual (PPM), Section 310-24, Electronic Communications Privacy and Access

7.11 PPM 310-18 Mass Electronic Messaging

7.12 PPM 320-20 Privacy and Access to Personal Information.

7.13 UCD PPM 320-21 Privacy and Disclosure of Information from Student Records (FERPA)

7.14 UCD PPM 320-35 Privacy of Health Information (health information in a non-HIPAA context)

7.15 UCDH Policy 2446 "Tracking Disclosures of Protected Health Information (PHI)

7.16 UCDH Policy 2410 "Allowable Uses and Disclosures for Protected Health Information (PHI)

7.17 UC Davis IRB HRP-092 "Clinical Trials Recruitment Websites"