UC San Diego Senior Associate Vice Chancellor for Health Sciences Office of Clinical Research	SOP Number	OCR:006 Page 1 of 2
	Date:	04/23/2025
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SOP TITLE: STUDY PARTICIPANT REGISTRATION		

1 PURPOSE

1.1 This procedure establishes the process for Principal Investigators (PIs) and study personnel under the PI's supervision to accurately document a patient's participation in clinical research within the electronic medical record (EMR) to ensure data integrity, participant safety and privacy, and compliance with regulatory requirements.

1.2 The process begins when a study is opened to accrual.

1.3 The process ends when all participants have been enrolled and no further participants will undergo the informed consent process, or it is determined that registration in the EMR is not required for the study.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Add clarification of requirements (Section 3.1). Add provision for requesting exception (Section 3.1.1)

3 REQUIREMENTS

3.1 UC San Diego Health policy 340.1 requires that all research participants who participate in a research study involving investigational drugs, devices, biologics, or procedures or where a billable moment occurs will have a medical record created to ensure participant safety.

3.1.1 The PI may request an exception to the provisions of USDHP 340.1 by submitting the exception request via the IRB electronic submission system.

3.2 For study participants to which 3.1 applies, the PI or designee must place a copy of the signed informed consent/assent/parent permission form, as applicable, and HIPAA Research Authorization into the participant's (patient's) EMR.

4 RESPONSIBILITIES

4.1 The PI is responsible for ensuring these procedures are completed.

5 PROCEDURE

5.1 Before the first study participant is enrolled, determine whether the study meets the requirement for participant registration in the EMR by reviewing UCSDH policy 340.1.

5.2 When a study participant is ready for enrollment in the study, or if the participant is signing a new version of the informed consent, confirm whether the participant already has an EMR number at UC San Diego Health or requires new patient registration in the EMR.

5.2.1 If the participant already has an EMR number at UC San Diego Health, confirm the participant's information in the EMR by searching for the record using at least two identifiers.

5.2.2 If the participant does not have an EMR number at UC San Diego Health, the investigator or designee will complete OCR-103 MRN Request Checklist, or equivalent, for transmission to the EMR (EPIC) registration staff to provide identifying information and request for medical record generation.

5.2.2.1 Provide the registration desk team the participant's name, date of birth, and telephone number to ensure that a duplicate record is not generated in the EMR.

5.3 After the informed consent process is completed, scan and upload the signed informed consent documents, including assent and parental permission forms, as applicable, along with the HIPAA authorization document, into the EMR.

5.3.1 The recommended scanning method is described in Health Information Management (HIM) training.

5.3.2 In lieu of scanning by study personnel, a copy of the informed consent may be sent to HIM for centralized scanning into the medical records.

5.3.2.1 Complete OCR-113 Consent Upload Cover Page, or equivalent, for consents sent to HIM for scanning.

6 MATERIALS

6.1 OCR-103 MRN Request Checklist

6.2 OCR-113 Consent Upload Cover Page

7 REFERENCES

7.1 UC San Diego Health Policy (UCSDHP) 340.1