SOP 505: RESEARCH MATERIALS IN PARTICIPANTS' MEDICAL RECORDS

POLICY

The IRB allows the placement of research materials—including informed consents; case report forms; laboratory, radiology, or other clinical reports; psychiatric records; surveys or questionnaires; or any other records generated from human subjects research—in research participants' medical records for research conducted under a covered entity.

If an investigator does not want to include research materials in medical records, a request to exclude data from the electronic medical record (EMR) must be approved by the covered entity where the research is conducted. Investigators should inform the IRB if a request to exclude data from the EMR has been approved and research materials are allowed to be excluded from the medical record.

The IRB model HIPAA authorization language that is provided on the IRB website states that research materials will be included in the participant's medical record. If an request to exclude data from the EMR is granted, the IRB may approve modified HIPAA authorization language in the consent document.