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, an exception must be approved by the covered entity where the research is conducted. Investigators should inform the IRB if an exception has been approved and research materials are allowed to be excluded from the medical record.

The standard HIPAA authorization language in the Consent Template states that research materials will be included in medical records. If an exception is granted, the IRB may approve modified HIPAA authorization language in the consent document.