

SOP: 505	RESEARCH MATERIALS IN PARTICIPANTS' MEDICAL RECORDS
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POLICY

The IRB may allow the placement of any 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 the medical record. The IRB may require that research materials be excluded from the medical record in cases where it is necessary for protection of the participants' privacy. For VA research, the IRB will determine whether the patient's medical record is flagged (by indicating his/her participation in the study and the source of more information on the study) to protect the participant's safety.