OFFICE OF RESEARCH AND DEVELOPMENT
VETERANS HEALTH ADMINISTRATION

FAQ Topic: Revocation of HIPAA Authorization for Research

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Questions: Can a research team continue to collect, use and disclose individual subject information on receipt of a revocation? Must the revocation be in writing or can the research team accept an oral revocation from the subject? If a subject withdraws informed consent, is that the same as a HIPAA revocation?

Answer: A research subject may revoke his/her Authorization at any time. The revocation must be in writing. An oral discussion between the subject and member of the research team does not revoke a HIPAA authorization. If the intent of the subject is to revoke, the principle investigator must provide a revocation form to the subject or request the subject's revocation in writing. A revocation can be on any document. VHA researchers may use VAF 10-10116, *Revocation of Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research*. The revocation is effective as soon as it is received, in writing, by the study's Principal Investigator. A revocation of the HIPAA authorization is not the same as withdrawing from the Study.

As permitted by HIPAA, VHA may continue to use and disclose protected health information (PHI) that was obtained before the individual revoked his or her Authorization to the extent necessary to preserve the integrity of the research study. This permits VHA, as the HIPAA covered entity, to continue using the PHI as necessary to maintain the integrity of the research; for example, to account for a subject's withdrawal from the research study, to conduct investigations of scientific misconduct, or to report adverse events. For example, a VA Investigator has IRB approval and VA R&D Committee approval to conduct a clinical trial at a VA Facility that recruits Veteran patients with asthma. Each study subject's participation in the study is approximately 2 years. One of the Veteran subjects who has participated in the study for 6 months informs the VA Investigator in writing that he or she is revoking the Authorization and withdrawing from the study. The VA Investigator is permitted to retain and analyze all study that was obtained and collected up to the date the Veteran subject revoked his or her authorization, provided such analysis falls within the scope of the analysis described in the IRB-approved protocol.

However, it would not permit VHA to continue allowing a researcher to collect new or additional protected health information from any source for the approved study. In the above example, a Veteran subject revoked his or her Authorization before completing the study. The VA Investigator wishes to obtain additional information regarding the number of the Veteran subject's hospitalizations for asthma exacerbations for the 18 months following the revocation of the HIPAA authorization since no direct contact with

the Veteran subject is necessary. The information will be obtained through review of the VHA Health Record. This is not permitted once the Veteran subject revokes Authorization because there is no legal authority for the VA Investigator to access the Veteran subject's VHA Health Record for research purposes. There is also no Authorization to collect and use this new additional protected health information.

VHA may only continue to disclose the PHI as necessary to maintain the integrity of the research, when legal authority exists under all applicable federal privacy laws and regulations, including the Privacy Act, 38 USC 7332 and 38 USC 5701. Consult with the facility Privacy Officer prior to making any disclosure of PHI for the study once the individual has revoked authorization.

Additional human research protection regulations apply to retaining and analyzing already collected data when a subject withdraws from the research or his or her participation is terminated by the Investigator of the research. The human research protection regulations applying to informed consent in the VA are found in the Common Rule (38 CFR Part 16). **Unlike HIPAA, the Common Rule does not require a human subject consented to participate in a human subjects study to withdraw his or her informed consent in writing.** VA follows OHRP's interpretation of the Common Rule as allowing investigators to retain and analyze already collected data relating to any subject who chooses to withdraw from a research study or whose participation is terminated by an investigator without regard to the subject's consent, provided such analysis falls within the scope of the analysis described in the IRB-approved protocol. This is the case even if the data includes identifiable private information about the subject. As long as a non-exempt human subjects research study continues to involve the use, study, or analysis of identifiable private information by the investigators, the research continues to involve human subjects and must undergo continuing review by an IRB at least annually (38 CFR 16.109(e)).

If the subject withdraws informed consent or is terminated from the study by the investigator, the investigator can no longer collect any additional data on the subject even if the subject has not revoked his/her authorization in writing.

FDA has also issued guidance regarding data retention when subjects withdraw from FDA-Regulated Clinical Trials: Guidance for Sponsors, Clinical Investigators, and IRBs: Data Retention when Subjects Withdraw from FDA-Regulated Clinical Trials. That guidance can be found at http://www.fda.gov/downloads/regulatoryinforamtion/guidances/ucm126489.pdf.

References: **Authorization Required Statements** (45 C.F.R. § 164.508(c)(2) and (c)(5))
https://privacyruleandresearch.nih.gov/authorization.asp and
http://www.hipaasurvivalguide.com/hipaa-regulations/164-508.php

Withdrawal of Subjects from Research Guidance (2010):
http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-withdrawal-of-subject/index.html

HHS FAQ: **http://www.hhs.gov/hipaa/for-professionals/faq/316/if-a-research-subject-revokes-authorization-can-a-researcher-continue-using-information-obtained/index.html**

FDA Guidance: Guidance for Sponsors, Clinical Investigators, and IRBs: Data Retention when Subjects Withdraw from FDA-Regulated Clinical Trials (2008):
http://www.fda.gov/downloads/regulatoryinforamtion/guidances/ucm126489.pdf