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OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Review of Data Security and Oversight Processes of a Veterans Health Administration National Cancer Prevention, Treatment, and Research Program

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Brief Report

The VA Office of Inspector General (OIG) initiated an inspection on June 11, 2024, and conducted a site visit from June 26 through 27, 2024, and virtual interviews from June 27 through December 12, 2024, to assess allegations about patients' data security and related oversight practices within a Veterans Health Administration (VHA) national program associated with cancer prevention, treatment, and research, and the Office of Research & Development (ORD). During the review, the OIG learned of individuals, engaged in and responsible for research, whose conduct violated the Health Insurance Portability and Accountability Act (HIPAA) privacy and security rule regarding protected health information (PHI).

This inspection concerns VA's use and protection of PHI. To protect patients' privacy and the security of their information, the OIG protected the sensitive information and issued this brief report.

Background

VHA National Programs for Cancer Prevention, Treatment, and Research

VHA seeks to ensure high quality cancer care including prevention, molecular testing, and clinical research provided through the national cancer prevention, treatment, and research program, VHA's foundation for cancer care.[1] One of the many programs and services the national cancer prevention, treatment, and research program oversees is a national cancer testing program.[2] The national cancer testing program's use of advanced genomic sequencing analyzes the genetic structure of tumors to better understand cancer. The national cancer testing program collects genomic data to improve the diagnosis and treatment of cancer.[3]

Patient Data Use for Research and Operations Activities

The HIPAA of 1996, Pub. L. No. 104-191, 110 Stat.1936 (codified as amended in scattered sections of 26, 29, and 42 U.S.C.) authorized the US Department of Health and Human Services (HHS) to issue regulations governing the privacy and security of individually identifiable

[1] VHA Directive 1415, *VHA Oncology Program,* April 9, 2020; National Cancer Institute, "Molecular testing," accessed December 10, 2024, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/molecular-testing. The National Cancer Institute defines molecular testing as a lab process in which tissue samples are checked "for certain genes, proteins, or other molecules that may be a sign of a disease or condition, such as cancer."

[2] VHA Directive 1415.

[3] VA National Oncology Program, *Aiming For The Moonshot, VA National Oncology Program 2023 Program Guide,* version 2.0, 2023.

information.[4] HHS's HIPAA Privacy Rule set standards for the use and disclosure of PHI for covered entities and their business associates who transmit health information electronically. 45 C.F.R. §§ 160.103, 164.500-164.534 (2023). PHI is individually identifiable health information held or transmitted by a covered entity or its business associate. Covered entities such as VA must obtain individual authorization for any use or disclosure of PHI not otherwise permitted by the Privacy Rule, 45 C.F.R. § 164.508(a) (2023).[5]

Besides the Privacy Rule, the Security Rule is the second key component of HIPAA, 45 C.F.R. Part 160, 164, Subparts A and C, and establishes administrative safeguards, physical safeguards, and technical safeguards including audit and integrity controls for the transmission of electronic PHI. VA adopted these data security regulations by VA Directive 6500, *VA Cybersecurity Program*, and VA Handbook 6500, *Risk Management Framework for VA Information Systems VA Information Security Program*.[6]

VHA retains patient data, including PHI, for a variety of reasons, such as research and operations activities.[7] The Federal Policy for the Protection of Human Subjects, known as the Common Rule, defines research as a "systematic investigation … designed to develop or contribute to generalized knowledge" 38 C.F.R. § 16.101 et seq., 38 C.F.R. § 16.116(d) and 38 C.F.R. § 16.109 (2023).[8]

VHA researchers must follow federal regulations requirements, such as the Common Rule and HIPAA to protect patient's private information to conduct research.[9] Using protocols approved by a research and development committee and an institutional review board (IRB), researchers may request access to VHA data sources from VHA entities who specialize in accessing and

[4] Health Insurance Portability And Accountability Act of 1996, Pub. L. No. 104-191, § 261-264, https://www.congress.gov/104/plaws/publ191/PLAW-104publ191.pdf.

[5] 45 C.F.R. Public Welfare §164, (2023), https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-C/part-164/subpart-E/section-164.508.

[6] VA Directive 6500, *VA Cybersecurity Program*, February 24, 2021; VA Handbook 6500, *Risk Management Framework for VA Information Systems VA Information Security Program*, February 24, 2021.

[7] VA Office of Research & Development Program Guide 1200.21, *VHA Operations Activities that May Constitute Research*, January 9, 2019.

[8] Common Rule, 38 C.F.R. §16, Definitions for purposes of this policy; Health Insurance Portability And Accountability Act of 1996, Pub. L. No. 104-191, § 261-264; VHA Program Guide 1200.21.

[9] "Safeguarding Veterans' Information," VHA Office of Research & Development, Safeguarding Veterans' Information, accessed April 24, 2024, https://www.research.va.gov/for_veterans/safeguarding_vets.cfm; VHA Program Guide 1200.21; Common Rule 38 C.F.R. § 16; "Federal Policy for the Protection of Human Subjects (Common Rule)," US Department of Health and Human Services, accessed April 24, 2024, https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html; Health Insurance Portability and Accountability Act § 261-264; "Summary of the HIPAA Privacy Rule," US Department of Health and Human Services, accessed April 24, 2024, https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html.

analyzing data.[10] An IRB "is the [c]ommittee responsible for the review, approval, and continuing oversight of research involving human subjects."[11]

Allegations and Related Concern

The OIG opened the inspection to review allegations that (1) the national cancer prevention, treatment, and research program Executive Director categorized projects as operational versus research to bypass the VHA IRB requirement; (2) VA and contracted non-VA staff assigned to national cancer prevention, treatment, and research program projects were not compliant with rules requiring correct, secure management of patient data and PHI; and (3) VHA program offices did not review concerns of a breach of PHI.[12] During the inspection, the OIG identified additional concerns related to a VHA project not submitted to a VHA IRB and the process for reviewing a breach of PHI.

Scope

The OIG did not independently verify VHA data for accuracy or completeness.

In the absence of current VA or VHA policy, the OIG considered previous guidance to be in effect until superseded by an updated or recertified directive, handbook, or other policy document on the same or similar issue(s).

The OIG substantiates an allegation when the available evidence indicates that the alleged event or action more likely than not took place. The OIG does not substantiate an allegation when the available evidence indicates that the alleged event or action more likely than not did not take place. The OIG is unable to determine whether an alleged event or action took place when there is insufficient evidence.

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, as amended, 5 U.S.C. §§ 401–424. The OIG reviews available evidence to determine whether reported concerns or allegations are valid within a specified scope and methodology of a healthcare inspection and, if so, to make recommendations to VA leaders on patient care issues. Findings and recommendations do not define a standard of care or establish legal liability.

[10] Good Data Practices Cyber Seminar Series, March 28, 2022.

[11] VHA Handbook 1200.12, *Use of Data and Data Repositories in VHA Research*, March 9, 2009.

[12] VA Handbook 6500.2, *Management of Breaches Involving Sensitive Personal Information*, June 30, 2023. A breach is an unauthorized access of information, including data containing PHI, that results in "the potential compromise of the confidentiality or integrity of the data." PHI is any information about individuals maintained by an agency to include names, social security numbers, and dates of birth.

The OIG conducted the inspection/review in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Inspection Results

Categorization of National Cancer Prevention, Treatment, and Research Program Projects

The OIG did not substantiate that the national cancer prevention, treatment, and research program Executive Director categorized projects as operational to bypass IRB review. The OIG found that the national cancer prevention, treatment, and research program had a process in place involving other experts to categorize projects as operational or research and categorized some projects as research that required IRB approval.

Project Not Submitted to a VHA IRB

The OIG found that national cancer prevention, treatment, and research program investigators and staff did not submit a collaborative project between VHA researchers and non-VHA investigators (the project) to a VHA IRB for approval after the pilot phase, as required by VHA Directive 1200.01(1). In May 2022, a VHA research director created a data file with electronic health record (EHR) reports and PHI to be used for the project. In September, VHA staff and non-VHA investigators established a collaborative agreement that included VHA sharing data with non-VHA investigators.[13]

While project team members discussed IRB review of the project and the national cancer prevention, treatment, and research program, Executive Director indicated that a VHA project lead investigator was responsible for submission of the project for IRB review, the OIG found no evidence the project was submitted for VHA IRB review.

Privacy and Data Security Requirements Not Met

The OIG substantiated that the Executive Director of Operations for a national cancer testing program and project staff did not ensure that VA and non-VA project staff complied with PHI

[13] VHA Directive 1200.01(1), *Research and Development Committee,* January 24, 2019, amended January 8, 2021, amended April 1, 2025. A material transfer agreement or other agreement must be executed for the transfer of biospecimens from VA; The OIG uses the term *collaboration agreement* to refer to the agreement VHA initiated with non-VHA investigators to transfer tumor samples and data.

security and confidentiality requirements.[14] By sharing the data file with non-VHA investigators without deidentification or authorization, VA did not follow the requirements of the Privacy Rule or the requirements of HIPAA. In addition, data audit logs used to validate the secure management of electronic PHI were not maintained, as required.[15]

VHA Program Offices' Actions Following Disclosure of PHI

The OIG did not substantiate that the Executive Director of Operations for a national cancer testing program and ORD privacy officer did not take action to review concerns of a potential breach of PHI (privacy event).

The OIG found that on December 5, 2023, one day after learning that non-VHA investigators had access to the data file, the ORD privacy officer corresponded with national cancer prevention, treatment, and research program leaders to obtain information about the privacy event. However, the ORD privacy officer did not enter the privacy concern in a VA tracking system within one hour of discovery, as required by VHA Directive 1605.01, and did not report the privacy event to a VHA privacy officer until December 19, 2023.[16] The VA Data Breach Response Service Director evaluated the privacy event and concluded that while the sharing of the data file was an unauthorized disclosure of PHI, it was not a breach and there was no need to provide written notification of the breach to individuals.

According to VHA, health information cannot be considered deidentified without meeting the requirements of expert determination or Safe Harbor provisions.[17] Expert determination occurs when a qualified biostatistician with expertise in methods for deidentification determines whether PHI is at risk of being used to identify an individual.[18]

The OIG determined that the Executive Director of Operations for a national cancer testing program, did not use subject matter experts to review the information that was disclosed in the

[14] For the purposes of this report, project staff include non-VA project management consultants. Covered entities such as VA must obtain individual authorization for any use or disclosure of PHI not otherwise permitted by the Privacy Rule. 45 C.F.R. § 164.512(a) (2023). Common Rule 38 C.F.R. § 16; "Federal Policy for the Protection of Human Subjects (Common Rule)," US Department of Health and Human Services, accessed April 24, 2024, https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html. 45 C.F.R. Public Welfare §164, (2023), https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-C/part-164/subpart-E/section-164.512. VHA Directive 1605.01, *Privacy and Release of Information*, July 24, 2023.

[15] VHA Directive 1200.01(1); VA Directive 6500; VA Handbook 6500.2.

[16] VHA Directive 1605.01, *Privacy and Release of Information*, August 31, 2016, rescinded and replaced by VHA Directive 1605.01, *Privacy and Release of Information*, July 24, 2023. Privacy officers record reported actual or suspected privacy breaches in VA's Privacy and Security Event Tracking System.

[17] VHA Directive 1605.01. VHA Safe Harbor refers to procedures in place to deidentify an individual who is the subject of the information.

[18] VHA Directive 1605.01.

data file for deidentification. Additionally, the Executive Director of Operations for a national cancer testing program did not recognize the extent of PHI disclosed.

In August 2024, the OIG conducted a review of the data file and found the file contained a significant amount of unprotected PHI. The OIG spoke with the Executive Director of Operations for a national cancer testing program, to discuss the extent of the data disclosed. The Executive Director of Operations reported being unaware of this information.

The OIG found initial mitigation plans drafted by the Executive Director of Operations for a national cancer testing program did not address national cancer testing program processes, including privacy issues, with the disclosure. In late October 2024, the Executive Director of Operations for a national cancer testing program provided the OIG with a final mitigation plan to include determining when projects move from operations to research, removing PHI from projects, and ensuring staff complete training.[19]

Recommendations 1–6

1. The Executive Director of Operations for a national cancer testing program ensures the project has met the requirements for Institutional Review Board review for research with human subjects and takes action as needed.
2. The Executive Director of Operations for a national cancer testing program ensures national cancer prevention, treatment, and research program staff are trained on Institutional Review Board project submission and privacy requirements.
3. The National Specialty Care Program Office Chief Officer ensures the national cancer prevention, treatment, and research program staff reviews and provides required approvals before the release of protected health information for research.
4. The National Specialty Care Program Office Chief Officer, in conjunction with the Office of Research & Development ensures that VA privacy officers report privacy incidents involving data obtained from or for national cancer prevention, treatment, and research program activities timely and monitors for compliance.
5. The Office of Research Oversight Executive Director in conjunction with the Chief Research and Development Officer, VHA Office of Research & Development, reviews the national

[19] The OIG did not determine whether the issues associated with the disclosure constituted research impropriety; however, the OIG would expect, in accordance with VHA requirements, the Office of Research Oversight to review the unauthorized disclosure of PHI and the mitigation plan to address the disclosure. Per 48 C.F.R. 835.001-70, "research impropriety refers to non-compliance with the laws, regulations, and policies regarding human subject protections."; VHA Directive 1058.01, *Research Compliance Reporting Requirements*, "oversight of … remediation efforts to resolve noncompliance reported to [Office of Research Oversight]," October 22, 2020, rescinded and replaced by VHA Directive 1058, November 8, 2024. The updated directive contains similar language to the previous Directive.

cancer prevention, treatment, and research program final mitigation plan and ensures corrective actions address system-wide issues for determining whether a national cancer prevention, treatment, and research program project constitutes research, safeguarding privacy when data is shared for projects, and ensuring data security requirements are met.

6. The National Specialty Care Program Office Chief Officer ensures the national cancer prevention, treatment, and research program has safeguards in place including biostatistician expertise to ensure that data containing sensitive patient information and protected health information is deidentified before sharing outside of VA as required.

VA Comments and OIG Response

On September 10, 2025, the Acting Under Secretary for Health concurred with recommendations to ensure national cancer prevention, treatment, and research program staff are trained on IRB project submission and privacy requirements; review required approvals before release of PHI; review the national cancer prevention, treatment, and research program's final mitigation plan and ensure corrective actions address system-wide issues; and ensure data containing PHI is deidentified before sharing outside of VA. VHA concurred in principle with recommendations to ensure projects has met the requirements for IRB review and VA facility privacy officers report privacy incidents involving data obtained from national cancer prevention, treatment, and research program activities timely. Acceptable action plans were provided (see appendix A). The OIG will follow up on the planned and recently implemented actions to ensure that they have been effective and sustained.

JULIE KROVIAK, MD
Principal Deputy Assistant Inspector General,
in the role of Acting Assistant Inspector General,
for Healthcare Inspections

Appendix A: Office of the Under Secretary for Health Memorandum

Department of Veterans Affairs Memorandum

Date: September 10, 2025

From: Acting Under Secretary for Health (10)

Subj: Office of Inspector General (OIG) Draft Report, Review of Data Security and Oversight Processes of a Veterans Health Administration [redacted]

To: Director, Office of Healthcare Inspections (54HL09)

1. Thank you for the opportunity to review and comment on OIG's draft report on Review of Data Security and Oversight Processes of a Veterans Health Administration [redacted]. The Veterans Health Administration (VHA) concurs with recommendations 2, 3, 5, and 6, and concurs in principle with recommendations 1 and 4. An action plan is provided in the attachment.

2. The VHA greatly values OIG's assistance in ensuring that all stakeholders are unified in supporting VHA's vision of providing all Veterans with access to the highest quality care. Your collaboration is instrumental in helping us achieve our commitment to excellence in health care services for Veterans.

3. Comments regarding the contents of this memorandum may be directed to the GAO OIG Accountability Liaison Office at vacovha10oicoig@va.gov.

(Original signed by:)

Steven L. Lieberman, M.D., MBA, FACHE

[OIG comment: The OIG received the above memorandum from VHA on September 11, 2025. The OIG redacted information in the memorandum and response for the security of data and private protected health information.]

Office of the Under Secretary for Health Response

VETERANS HEALTH ADMINISTRATION (VHA)

Action Plan

OIG Draft Report - Review of Data Security and Oversight Processes of a Veterans Health Administration [redacted]

(Project # 2024-00568-HI-1378)

Recommendation 1: The Executive Director of Operations [redacted] in conjunction with the [redacted] VA Medical Center Director ensures the project has met the requirements for Institutional Review Board review for research with human subjects and takes action as needed.

VHA Comments: Concur in Principle. The research will be conducted outside of the [redacted] VA Medical Center (VAMC); therefore, it does not fall under the jurisdiction of the [redacted] VAMC Director. The Executive Director of Operations [redacted] will ensure that this project meets the requirements for an Institutional Review Board (IRB) review for research with human subjects prior to any research beginning. This will be done in conjunction with the home facility or central IRB based on the determination by the principal investigator once they prepare the necessary documentation for IRB review. To date no research has been conducted as part of this project since the original planned investigator left prior to being able to prepare a protocol for IRB review.

Status: In Progress **Target Completion Date: June 2026**

Recommendation 2: The Executive Director for Operations [redacted] ensures [redacted] staff are trained on Institutional Review Board project submission and privacy requirements.

VHA Comments: Concur. The Executive Director of Operations [redacted] will develop an action plan to ensure that [redacted] staff are trained to identify projects that need to be submitted to the IRB and trained in privacy requirements.

Status: In Progress **Target Completion Date: December 2025**

Recommendation 3: The National Specialty Care Program Office Chief Officer ensures the [redacted] staff reviews and approves required approvals before the release of personal health information for research.

VHA Comments: Concur. The [redacted] reviews and approves processes for obtaining and documenting required approvals before the release of personal health information for research. The Specialty Care Program Office and the [redacted] will implement improvements to address concerns identified in this investigation as well as the [redacted] review. Additionally, the [redacted] will supplement existing processes with regular summary

reports for the National Specialty Care Program Office Chief Officer regarding data requests and decisions.

Status: In Progress **Target Completion Date: December 2025**

Recommendation 4: The National Specialty Care Program Office Chief Officer in conjunction with the Office of Research & Development ensures that VA facility privacy officers report privacy incidents involving data obtained from or for [redacted] activities timely and monitor related compliance.

VHA Comments: Concur in Principle. The VHA Digital Health Office provides oversight of privacy officers and associated policies related to privacy incident reporting. For this reason, the National Specialty Care Program Office Chief Officer in conjunction with the VHA Privacy Compliance and Accountability (PCA) Office will ensure that VA facility privacy officers report privacy incidents involving data obtained from or for [redacted] activities timely and monitor related compliance.

VA Directive 6500.2 and VHA Directive 1605.01 require field Privacy Officers to report all incidents, regardless of the data type involved, in the Privacy and Security Event Tracking System (PSETS) within one hour of being notified of the incident. The facility Medical Center Director is responsible for ensuring that this process is being completed according to these policies. VHA PCA Office also audits a sample of health care facilities each year to evaluate privacy programs to include the reporting of privacy incidents according to policy.

The [redacted] will supplement existing processes so that when any staff member reports an incident to the Privacy Officer for entry in VA's PSETS, they obtain the report number and provide the number to [redacted], who in turn will provide the privacy incident report number to Specialty Care Program Office.

Status: In Progress **Target Completion Date: December 2025**

Recommendation 5: The Office of Research Oversight Executive Director in conjunction with the Chief Research and Development Officer, Office of Research & Development, reviews the [redacted] final mitigation plan and ensures corrective actions address system-wide issues for determining whether a [redacted] project constitutes research and safeguarding privacy when data is shared for [redacted] projects.

VHA Comments: Concur. The Office of Research Oversight Executive Director in consultation with the Chief Research and Development Officer, VHA Office of Research & Development Director, will review the [redacted] final mitigation plan and ensure corrective actions in the plan address system-wide issues for determining whether a [redacted] project constitutes research and safeguarding privacy when data is disclosed for [redacted] research projects as required.

Status: In Progress **Target Completion Date: December 2025**

Recommendation 6: The National Specialty Care Program Office Chief Officer ensures the [redacted] has safeguards in place including

biostatistician expertise to ensure that data containing sensitive patient information and personal health information is deidentified before sharing outside of VA as required.

VHA Comments: Concur. The [redacted] reviews and improves processes for deidentifying data containing sensitive patient information and personal health information before sharing outside of VA. Specialty Care Program Office and the [redacted] will implement improvements to address concerns identified in this investigation including greater awareness amongst all staff of the requirements and expertise required to ensure data is properly deidentified. This review will include identifying an expert to assist the [redacted] on any future needs within VHA.

Status: In Progress **Target Completion Date: December 2025**

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