DEPARTMENT OF VETERANS AFFAIRS
WASHINGTON DC 20420

July 20, 2017

Mr. Adam Miles
Acting Special Counsel
U.S. Office of Special Counsel
1730 M Street, NW, Suite 300
Washington, DC 20036

RE: OSC File No. DI-16-1945/DI-17-1294

Dear Mr. Miles:

I am responding to the former Special Counsel's letter, dated March 8, 2017, regarding allegations made by whistleblowers at the Department of Veterans Affairs (VA) San Diego Healthcare System (the Medical Center), San Diego, California, that employees may have engaged in actions that constitute a violation of law, rule, or regulation; gross mismanagement; an abuse of authority; and a substantial and specific danger to public health. The Secretary has delegated to me the authority to sign the enclosed report and take any actions deemed necessary as referenced in 5 United States Code § 1213(d)(5).

The Under Secretary for Health directed the Office of the Medical Inspector to assemble and lead a VA team to conduct an investigation. The enclosed report substantiates none of the whistleblower's three allegations and makes ten recommendations to the Medical Center and two to the Veterans Health Administration.

Thank you for the opportunity to respond.

Sincerely,

Vivieca Wright Simpson
Chief of Staff

Enclosure

DEPARTMENT OF VETERANS AFFAIRS
Washington, DC

Report to the
Office of Special Counsel
OSC File Numbers DI-16-1945 and DI-17-1294

Department of Veterans Affairs (VA)
San Diego VA Medical Center
San Diego, California

Report Date: July 10, 2017

TRIM 2017-D-1219

Executive Summary

The Acting Under Secretary for Health requested that the Office of the Medical Inspector (OMI) assemble and lead a Department of Veterans Affairs (VA) team to investigate allegations lodged with the Office of Special Counsel (OSC) concerning the San Diego VA Medical Center (the Medical Center). whistleblower 1 whistleblower 1 at the Medical Center and whistleblower 2 alleged that Employee 1, at the Medical Center may have engaged in actions that constitute a violation of law, rule or regulation; gross mismanagement; an abuse of authority; and a substantial and specific danger to public health. The VA team conducted a site visit to the Medical Center on April 10–13, 2017.

Specific Allegations of the Whistleblower

1. Employee 1 is performing unapproved human liver research, without informed consent, that places patients at serious risk.

2. Employee 1 is not properly advising patients of their options, thereby delaying proper care.

3. Employee 1 directed the Medical Center staff to delete pending consults without proper medical review or follow up, in violation of VHA clinical policy and, in some cases, information security policy.

VA **substantiates allegations** when the facts and findings supported that the alleged events or actions took place. We **do not substantiate allegations** when the facts and findings showed the allegations were unfounded. We are **not able to substantiate allegations** when the available evidence is not sufficient to support conclusions with reasonable certainty about whether the alleged event or action took place.

After careful review of findings, VA makes the following conclusions and recommendations.

Conclusions for Allegation 1

- We **do not substantiate** that Employee 1 is performing unapproved human liver research, without informed consent, placing patients at serious risk.

- The Institutional Review Board (IRB) did not invite whistleblower 2 whistleblower 2 to the IRB meeting to discuss her concerns that the transjugular biopsies were not standard of care. However, her concerns were included in the approval process for the research protocol.

- The IRB did not initially utilize qualified clinical consultants to determine if transjugular biopsies were standard of care. However, the IRB did later consult with other providers with expertise in caring for patients with liver disease; these

providers offered information that transjugular biopsies are the standard of care for patients with, or suspected to have, alcoholic hepatitis.

- The InTeam Master Protocol (MP) provided by the coordinating center to the local study team did not include a study arm involving control subjects. However, the local study team added the use of control subjects to its protocol. It is not clear if this was appropriate based on the MP.

- Based on our review of the medical records, all transjugular biopsies were clinically indicated and subsequently used for research purposes in accordance with the approved IRB protocol and the subjects' informed consent.

- The Medical Center leadership did not document the process or findings from an investigation into whistleblower 1 concerns regarding the unethical conduct of research by Employee 1 They also did not refer the allegations for investigation to the IRB and Research and Development Committee.

- Current training for study coordinators is inadequate as evidenced by the study coordinator obtaining consent before she was approved by the IRB to be part of the protocol, the presence of poorly maintained and incomplete research records, and miscommunication between Principal Investigator, and the study coordinator.

- The Health Insurance Portability and Accountability Act (HIPAA) authorization and informed consent document did not inform the control subjects that personally identifiable information (PII) would be sent to the co-investigator's lab at the academic affiliate. Also, the IRB Protocol Application did not specify how the Primary Investigator planned to use information obtained from the "dietary questionnaire" or whether the PII from this document would be transferred for use in the co-investigator's lab.

- The approved research protocol included provisions for assessing decisional capacity, and the InTeam informed consent document reflects that the subject's legally authorized representative's consent would be used if indicated.

Recommendations to the Medical Center

1. The IRB needs to improve existing standard operating procedures and practices concerning the use of consultants for the purposes of facilitating the review of research beyond the Board's qualifications. This process should include inviting consultants or ad hoc reviewers to relevant meetings, as appropriate, to discuss their findings, and utilizing clinical providers with expertise in any of the research or standard of care procedures to be performed.

2. The IRB must review the amendment adding the control arm to this protocol, and determine whether this is an appropriate modification.

3. Medical Center leadership should develop a formalized plan for addressing complaints of research improprieties and communicate this plan to all staff. The plan should include a process for following up with individuals who have chosen not to remain anonymous.

4. Principal Investigator should provide more direct oversight of this study to ensure that research staff is adequately trained, that research records are appropriately maintained, that he has a clear understanding of where specimens are being shipped, and that protocol amendments adding new staff to the study are approved before any research procedures occur.

5. The IRB must also require an amendment to the informed consent document and HIPAA authorization to reflect that control subject specimens containing protected health information (PHI) will be disclosed to the academic affiliate. The IRB must address any instances of PHI and PII being disclosed to the academic affiliate without subjects' consent or HIPAA authorization.

Conclusions for Allegation 2

- We are **not able to substantiate** that Employee 1 is not properly advising patients of their treatment options, thereby delaying proper care.

- Because Employee 3 is no longer employed by VA and declined our interview request, we are **not able to substantiate** that Employee 1 routinely directed her to minimize the need for transplants when talking with patients and their families, directed her to assemble transplant requests to VA Central Office (VACO) in a "way to be rejected," or ordered her to stop all imaging for tumors for several months in 2014.

- Employee 1 has asked Employee 4 to submit transplant requests to VACO for patients who "clearly did not meet transplant criteria."

- The American Association for the Study of Liver Diseases (AASLD) strongly recommends surveillance of adults with cirrhosis using ultra sound, with or without Alpha-fetoprotein, every 6 months because it improves overall survival.

- Per AASLD, most patients require ongoing upper GI endoscopy (EGD) screening or surveillance for esophageal varices. The frequency of EGD evaluation depends on factors such as whether the patient has varices and whether the cause of the liver injury (continued infection or consumption of alcohol) is ongoing.

- Employee 5 denies that Employee 1 or anyone else instructed him not to schedule patients for endoscopies.

Recommendations to the Medical Center

6. When there is a difference of opinion in clinical management of this patient population, the Medical Center should use the Peer Review program to ensure that each patient's treatment plan meets the standard of care.

7. Establish internal practice guidelines for practitioners on acceptable standards of care, specifically in the management of patients diagnosed with hepatitis and the frequency of surveillance endoscopies.

Conclusions for Allegation 3

- We **do not substantiate** that Employee 1 directed Medical Center staff to delete pending consults without proper medical review or follow up in violation of the Veterans Health Administration (VHA) clinical policy.

- Employee 1 appropriately assigns administrative staff to close, administratively complete, and add comments to consults.

- We **do not substantiate** that Employee 1 directed Employee 5 to cancel all endoscopy procedures scheduled between July and September 2016, without a medical review, because there was "no space available" to complete the procedures and these patients were not rescheduled or referred to the VA Choice Program.

- VHA's official data source, VHA Support Service Center shows that in 2016 the Medical Center sent GI referrals for 55 Veterans to Non-VA Community Care; they sent 11 of the referrals between July and September 2016.

- We **substantiate** that Employee 1 directed Employee 10 and some research assistants to close consults while being logged on the computer under the Employee 1 network access, thereby violating VHA information security policy.

- Employee 1 currently logs in to multiple computers, while conducting procedures, to allow members of the procedure team to enter patient information.

Recommendations to the Medical Center

8. Provide immediate training to all clinic staff regarding the seriousness and inappropriateness of sharing VA staff members' passwords to gain access to VA computer systems. The VA Table of Penalties lists punishments ranging from admonishment to removal, depending on the stated offense.

9. Ensure all medical center staff members complete the required training regarding the use of, and access to, VA computer systems.

10. Take appropriate administrative action in response to Employee 1 persistent violation of VHA Privacy and HIPAA and Rules of Behavior Policies by allowing staff to use his password to gain access to VA computer systems.

Recommendations to VHA

1. Ensure scheduling and consult training is being provided, at least annually, to all affected Medical Center staff members according to appropriate VHA Policy and Directives, e.g., VHA Directives 1230, *Outpatient Scheduling Processes and Procedures* (July 2016), VHA Directive 1232, *Consult Processes and Procedures* (August 2016), and Medical Center memoranda.

2. Analyze and address the factors contributing to the delay in timely granting full computer access to residents and fellows.

Summary Statement

The VA team has developed this report in consultation with other VHA and VA offices to address OSC's concerns that the Medical Center may have violated law, rule or regulation, engaged in gross mismanagement, an abuse of authority, and a substantial and specific danger to public health. In particular, the Office of General Counsel has provided a legal review, VHA Human Resources has examined personnel issues to establish accountability, the Office of Accountability and Whistleblower Protection has reviewed the report and has or will address potential senior leadership accountability, and the National Center for Ethics in Health Care has provided a health care ethics review. We found instances where the Medical Center violated VHA policy; however, we found no substantial danger to public health at the Medical Center.

Table of Contents

I. Introduction

The Acting Under Secretary for Health requested that the Office of the Medical Inspector (OMI) assemble and lead a Department of Veterans Affairs (VA) team to investigate allegations lodged with the Office of Special Counsel (OSC) concerning the San Diego VA Medical Center (the Medical Center). whistleblower 1 whistleblower 1 at the Medical Center, and whistleblower 2, alleged that Employee 1 may have engaged in actions that constitute a violation of law, rule or regulation; gross mismanagement; an abuse of authority; and a substantial and specific danger to public health. The VA team conducted a site visit to the Medical Center on April 10–13, 2017.

II. Facility Profile

The Medical Center, part of Veterans Integrated Service Network (VISN) 22, is a level 1a, Joint Commission accredited facility that provides health care to more than 232,000 Veterans in the San Diego and Imperial Valley counties. It is an affiliated teaching hospital offering a wide range of inpatient and outpatient health services at the main facility, as well as at a medical center in La Jolla and six community clinics in Chula Vista, Escondido, Imperial Valley, Mission Valley, Oceanside, Sorrento Valley, and Rio. The Medical Center has 296 inpatient beds and provides medical, surgical, mental health, geriatric, spinal cord injury, and advanced rehabilitation services; its several regional referral programs include cardiovascular surgery and spinal cord injury. Affiliated with the University of California, San Diego School of Medicine, the Medical Center provides training for 1,440 interns, residents, and fellows, as well as 751 other clinical trainees, in areas such as nursing, pharmacy, dentistry, and dietetics. It has one of the largest research programs in the entire VA with a budget of over $41.3 million in fiscal year 2016, funding 210 principal investigators and 698 projects.

III. Specific Allegations of the Whistleblowers

1. Employee 1 is performing unapproved human liver research, without informed consent, that places patients at serious risk.

2. Employee 1 is not properly advising patients of their options, thereby delaying proper care.

3. Employee 1 directed the Medical Center staff to delete pending consults without proper medical review or follow up, in violation of VHA clinical policy and, in some cases, information security policy.

IV. Conduct of Investigation

The VA team conducting the investigation consisted of , M.D., FACP, FACHE, Interim Medical Inspector, , Registered Nurse (RN), Nurse Practitioner (NP), Clinical Program Manager (CPM), and , RN, MSN,

CPM, all of OMI; [redacted] and [redacted] both Health Science Specialists certified in Health Research Compliance, of VA's Office of Research Oversight; and [redacted], Human Resources (HR) Manager, VISN 6. We reviewed relevant policies, procedures, professional standards, reports, memorandums, and other documents listed in Attachment A. We toured the Medical Center's Research Lab, and held entrance and exit briefings with Medical Center and VISN leadership.

We interviewed the whistleblowers separately via teleconferences held on March 29, and March 31, 2017, and separately in person at the Medical Center on April 11, 2017.

The following employees participated in the Entrance Briefing:

- [redacted] Medical Center Director
- [redacted] M.D., Chief of Staff (CoS)
- [redacted], RN, Associate Director for Patient Care Services (ADPCS)/Chief Nurse Executive (CNE)
- [redacted], M.D., Associate CoS, Research and Development (ACoSR&D)
- [redacted], Chief of Performance Improvement Management Service (PIMS)
- [redacted], Director, Research Projects Division
- [redacted], Program Specialist, PIMS

We interviewed the following Medical Center Employees:

- [redacted] Director of Liver and Transplantation Clinics (Director, LTC)
- [redacted], Chair, Subcommittee on Research Safety (SRS)
- [redacted] Medical Center Director
- [redacted], M.D., CoS
- [redacted], M.D., ACoSR&D
- [redacted] M.D., Chief, GI
- [redacted], M.D., Chief, Medicine
- [redacted] M.D., Primary Care
- [redacted], Research Compliance Officer
- [redacted], Research Study Coordinator
- [redacted], M.D., GI Fellow
- [redacted], M.D., GI Fellow
- [redacted], M.D., GI Fellow
- [redacted], M.D., GI Fellow
- [redacted], M.D., Chair, Institutional Review Board (IRB)
- [redacted], RN, Nurse Manager, Outpatient Specialty Clinics
- [redacted], RN, GI Clinic
- [redacted], Advanced Medical Support Assistant (MSA), GI
- [redacted], Research Assistant (former employee)
- [redacted], Research Therapist (former employee)
- [redacted], Program Analyst, Medicine
- [redacted], Program Specialist

- [redacted], HR Assistant

The following employees participated in the Exit Briefing:

- [redacted], VISN 22 Quality Management Officer (phone)
- [redacted], Assistant Director
- [redacted], Acting Associate Director
- [redacted], M.D., Chief, Medicine
- [redacted] Medical Center Director (phone)
- [redacted], M.D., CoS
- [redacted], RN, ADPCS/CNE
- [redacted], M.D., ACoSR&D
- [redacted], Chief, PIMS
- [redacted], Director, Research Projects Division
- [redacted], Program Specialist, PIMS

We also interviewed the following Medical Center employees telephonically:

- [redacted], M.D., GI subspecialist, Interventional Endoscopy
- [redacted], RN, formerly in GI
- [redacted], M.D., GI Fellow
- [redacted], NP, GI

V. Findings, Conclusions, and Recommendations

Allegation 1

Employee 1 *is performing unapproved human liver research, without informed consent, that places patients at serious risk.*

The whistleblowers specifically alleged:

- Employee 1 intended to perform transjugular biopsies on patients' livers because he needed the biopsies to secure $150,000 in funding from the University of North Carolina Medical Center for a research study involving alcohol-related liver injuries and the presence of biomarkers.
- In the absence of archival biopsies, Employee 1 sought prospective liver biopsies without the approval of the IRB.
- Employee 1 has asked fellows, attending physicians, and residents to order the biopsies in their names in an attempt to conceal Employee 1 association with the requests.
- Employee 1 is improperly representing to patients that the taking of biopsies is consistent with the standard of care.
- Employee 1 is not informing patients that their biopsies will be included in a research project.

Background

The medical term for or relating to the liver is hepatic. The liver is a large, meaty organ that sits on the right side of the belly and works with the gallbladder and pancreas to digest, absorb, and process food. The capsule of the liver is a layer of connective tissue surrounding the liver and encloses the hepatic artery, portal vein, and bile ducts within the liver. The liver has two large sections, called the right and the left lobes, and its main job is to filter the blood coming from the digestive tract, before passing it to the rest of the body. The liver also detoxifies chemicals, metabolizes drugs, and makes proteins important for blood clotting and other functions.[1] Hepatic conditions include, but are not limited to:

1) Hepatitis is inflammation of the liver, usually caused by viruses like hepatitis A, B, and C. Hepatitis can have noninfectious causes too, including heavy drinking, drugs, allergic reactions, or obesity.
2) Cirrhosis is the long-term damage to the liver, usually as a result of alcohol abuse or chronic hepatitis leading to permanent scarring, and causes the liver not to function well.
3) Hepatocellular carcinoma is the most common type of liver cancer and almost always occurs after cirrhosis is present.
4) Liver failure has many causes, including infection, genetic diseases, and excessive alcohol use.
5) Ascites is a condition in which the liver leaks fluid into the belly causing the belly to become distended and heavy.

Alcoholic Hepatitis

Excessive alcohol consumption is associated with a range of hepatic symptoms and takes a significant toll on human health throughout the world. In the United States, the burden of alcoholic hepatitis, including alcoholic fatty liver disease, alcoholic hepatitis, and cirrhosis, is increasing. While some health care providers may refer to asymptomatic fatty liver disease due to alcohol as "alcoholic hepatitis," the term is typically used to describe the acute onset of symptomatic hepatitis. The amount of alcohol intake that puts an individual at risk for alcoholic hepatitis is not known, but the majority of patients have a history of heavy alcohol use (more than 100 grams per day) for two or more decades. One drink is considered to be 12 ounces of beer, 5 ounces of wine, or 1.5 ounces of spirits (hard liquor). Each drink contains 12 to 14 grams of ethanol, a molecule that directly affects the stomach, brain, heart, gall bladder, and liver.[2,3]

Liver biopsy

A diagnostic test is any approach used to gather clinical information for the purpose of making a clinical decision, i.e., diagnosis. The goal of a diagnostic test is to rule out or

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[1] http://www.webmd.com/digestive-disorders/picture-of-the-liver#1.

[2] https://www.uptodate.com/contents/management-and-prognosis-of-alcoholic-hepatitis?source=preview&search=Management%20and%20Prognosis%20of%20Alcoholic%20Hepatitis&language=en-US&anchor=H234083145#H234083145. Accessed March 15, 2017.

[3] http://www.webmd.com/mental-health/addiction/understanding-alcohol-abuse-symptoms#1 Accessed April 27, 2017.

confirm disease. Some examples of diagnostic tests include x-rays, results from physical examinations, and biopsies. A biopsy is the removal and examination of tissue, cells, or fluids from the living body. Liver biopsy provides useful information that health care providers use for the diagnosis, prognosis, staging, and management of patients with acute or chronic liver diseases. Indications for biopsy include characterization of liver diseases, evaluation of abnormal liver function studies, characterization of abnormalities seen on imaging studies, detection and staging of adverse effects of drug treatment, evaluation of liver status following transplantation, evaluation of acute liver failure, and evaluation of fever of unknown origin.

Despite the progress and advances in clinical medicine, biological chemical analysis, and diagnostic imaging, examination of hepatic tissue still has an important role in the management of patients with liver diseases. Providers can obtain liver biopsies using a percutaneous or transjugular method. Percutaneous liver biopsy entails inserting a long needle through the skin over the right lower ribs to remove a sample of liver tissue. In the transjugular approach, a radiologist inserts a thin tube (catheter) into a large neck vein (jugular), and guides it to the liver. The radiologist then takes a sample of tissue through the catheter. Percutaneous liver biopsy has proven to be fast, safe, and efficient, to the point of becoming the gold standard for liver tissue sampling. However, percutaneous liver biopsy involves cutting across the liver capsule, and patients taking blood thinners or who have blood-clotting problems are at an increased risk for severe bleeding in the area surrounding the liver. Other factors such as morbid obesity and high-volume ascites also represent a challenge for the percutaneous approach, increasing the risks associated with the procedure. Consequently, health care researchers developed alternative techniques such as transjugular liver biopsy to permit harvesting of liver tissue in patients with contraindications to the percutaneous procedure.

Unlike a percutaneous biopsy, the transjugular approach accesses the liver through the major blood vessels, the superior vena cava, and the hepatic vein. The superior and inferior vena cava are large veins that carry oxygen-depleted blood respectively from the upper and lower body to the heart. The hepatic veins originate from the core vein of the liver and carry oxygen-depleted blood from the liver to the inferior vena cava.[4] Using the transjugular approach, the provider can obtain hepatic tissue through the major blood vessels, unlike the percutaneous approach, which requires puncturing of the liver capsule resulting in possible heavy bleeding into the abdominal cavity. Bleeding from the transjugular biopsy site is contained within the accessed blood vessel, minimizing the risk of heavy bleeding into the abdominal cavity. Although the provider accesses major blood vessels when the transjugular approach is used, this approach is considered safe and well tolerated, and is generally the first-line option for patients in whom the percutaneous approach is suboptimal, contraindicated, or has previously failed.[5]

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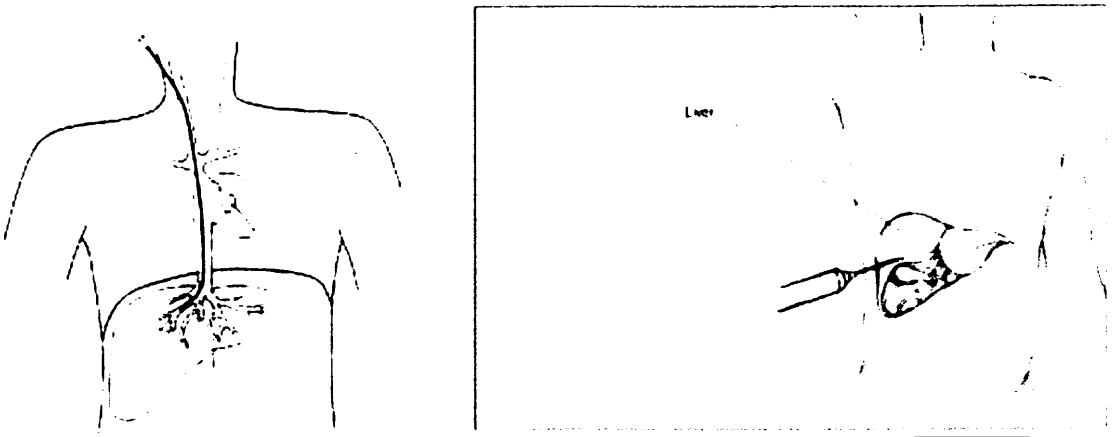
[4] http://www.healthline.com/human-body-maps/hepatic-veins.

[5] https://www.uptodate.com/contents/transjugular-liver-biopsy?source=preview&search=transjugular%20liver%20biopsy&language=en-US&anchor=H1#H1. Accessed March 15, 2017.



Transjugular approach | Percutaneous approach

Human Subjects In Research

Human subjects research is a systematic investigation designed to yield generalizable knowledge. The subject of that investigation must be a living individual about whom an investigator obtains data through intervention or interaction with the individual, or obtains identifiable private information. Research often produces evidence for approaches to making health care safer, of higher quality, or more accessible. VA researchers refer to Veterans who participate in research as "subjects." Per VHA Handbook 1200.05, "A research protocol details the aims and objectives of a research study, scientific rationale, the methods used to carry out the research, and how data will be analyzed. For human subject research, it also entails how subjects will be accessed/recruited, any foreseeable risks, and how these risks will be mitigated."[6] The Code of Federal Regulations (CFR) defines minimal risk as the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.[7] For human subject research, as set out in the CFR, there are separate informed consent requirements that we discuss in detail below.[8]

Findings

Research

The National Institute on Alcohol Abuse and Alcoholism (NIAAA), a division within the National Institutes of Health, funded a research protocol entitled, "Integrated Approaches for Identifying Molecular Targets in Alcoholic Hepatitis (InTeam)." The InTeam protocol, known as the master protocol (MP), is a prospective data and specimen collection study where "[t]he objective of this study is to develop a patient and specimen biorepository to help investigations into the natural history and pathogenesis

[6] VHA Handbook 1200.05, *Requirements for the Protection of Human Subjects in Research* (1) §4.dd.
[7] *Protection of Human Subjects* 38 CFR 16.102
[8] *General Requirements For Informed Consent.* 38 CFR 16.116

of alcoholic hepatitis."[9] This MP does not include the provision for specimen and data collection from a control group of subjects (patients without alcoholic hepatitis). Prospective research involves collection of materials (data, documents, records, or specimens) from subjects during the study period. Prospective research may include materials collected solely for nonresearch purposes (such as medical treatment or diagnosis), materials collected exclusively for research purposes, as well as materials collected for both nonresearch and research purposes. A biorepository collects, processes, stores, and distributes specimens of biological material (e.g., urine, blood, tissue, cells) to support future scientific investigation. The NIAAA coordinating center for the MP is overseen by a researcher at the University of North Carolina (UNC) at Chapel Hill.[10] The Medical Center was one of 10 sub-award sites conducting the study under the leadership of Principal Investigator, who was the local Principal Investigator. The allegations raised by the whistleblowers reference the InTeam research protocol and alleged that Employee 1 is conducting unapproved research under this protocol.

Federal regulations and VHA policy require that a formally designated IRB "review, approve, require modification, disapprove, and conduct continuing oversight of human subject research in accordance with the Common Rule (38 CFR Part 16) and other applicable regulations."[11] The Medical Center's IRB initially approved the InTeam protocol on March 6, 2013, and determined the research involved no more than minimal risk. According to the relevant InTeam research protocol, which is discussed in greater detail below, the VA research team could recruit active subjects, that is, patients with alcoholic hepatitis, from the emergency room, intermediate care areas, and the hospital wards, and recruit control subjects, patients without alcoholic hepatitis, from outpatient GI clinics and Alcohol Drug Treatment Programs.

The Medical Center's IRB Protocol Application, Version 1.17 (10/20/2014) §10, Inclusion criteria for Alcoholic Hepatitis patients states:

> ... (8)Liver biopsy is not required for this protocol. The protocol assures that archival liver biopsy tissue from patients is only used if published guidelines are followed as specified in the American Association for the Study of Liver Diseases (AASLD) and European Association for the Study of the Liver (EASL) Practice Guidelines. Specifically, these guidelines state that liver biopsies are done to assist clinical decision making for severe alcoholic hepatitis and that liver biopsies are not done for investigational purposes only, and liver biopsies are not considered clinically indicated if no treatment for ALD or AH is contemplated. The diagnosis of alcoholic hepatitis is made by the medical team and the consulting gastroenterology team using standard medical practice. This diagnosis is made on clinical grounds as per the current guidelines by both the AASLD and EASL. These guidelines allow for the use of liver biopsy to assist in making a diagnosis when the clinical picture or

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[9] Medical Center's R&D Project Abstract, Protocol #H120108, Integrated Approaches for Identifying Molecular Targets in Alcoholic Hepatitis; 2014.

[10] 1U01AA021908-01, Molecular Subtypes for Targeted Therapies in Alcoholic Hepatitis

[11] VHA Handbook 1200.05(1) §4.o

therapeutic path is unclear. If the medical and consulting GI physicians make a clinical diagnosis of alcoholic hepatitis, without a liver biopsy, then the patient is a candidate to be enrolled in the study.

The IRB's minutes for the sessions leading to its initial approval of the InTeam protocol show that multiple protocol modifications were undertaken to secure approval. The IRB's initial concerns involved the proposed requirement that all enrolled subjects receive a transjugular biopsy as a standard of care procedure to enable investigators to confirm that a subject had alcoholic hepatitis.[12] One of the whistleblowers had concerns about the InTeam research protocol. In her role as whistleblower 2 whistleblower 2 '. She expressed her concern in a letter to the IRB that transjugular biopsies were not clinically indicated for the diagnosis of alcoholic hepatitis.[13] The IRB responded by requesting that the requirement for these biopsies be removed, and Principal Investigator, agreed to the request. The IRB approved only the use of specimens from transjugular biopsies obtained for clinical indications; however, subjects could still participate even if a transjugular biopsy was not obtained. Following initial approval, the IRB conducted annual continuing reviews, with the last one occurring on February 6, 2017.[14,15]

We reviewed the backgrounds of the clinicians listed on the IRB membership roster at the time of the initial approval, and found that they did not appear to be sufficiently qualified to evaluate whether transjugular biopsies were a standard of care procedure for the particular subject group or cohort. Although whistleblower 2 had research experience with alcoholic hepatitis, she does not have any medical training or credentials, is not a practicing clinician, and therefore, is not a clinical expert. Furthermore, she is not trained to perform transjugular biopsies and has not received education to determine when liver biopsies are indicated. Nonetheless, the IRB relied heavily on her written evaluation during its initial reviews of the protocol and agreed with her concerns that transjugular biopsies were not a standard of care procedure at the Medical Center, but the IRB did not invite her to any meetings to discuss her concerns. Additionally, during the course of its initial reviews, the IRB did not seek consultation from any independent clinical providers with experience in treating this particular subject cohort, namely, patients with alcoholic hepatitis. Instead, they depended on the clinical care input from Employee 1

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[12] Medical Center IRB Meeting Minutes, February 14, 2013, §3.1, "The IRB discussed the biopsy procedures at length and debated whether or not this may be considered standard of care. The issue remained unresolved after discussion..."

[13] Medical Center IRB Meeting Minutes, February 21, 2013, §2.1.1, "whistleblower 2 wished to share whistleblower 2 comments with the IRB and submitted documents for review. The IRB members reviewed these documents but concluded that there was no current action pending before the Board on the agenda, the protocol was not yet approved, and there has been no research activity. Therefore, IRB will review the protocol, and consider whistleblower 2 comments, when a response to the prior deferral is submitted."

[14] VHA Handbook 1200.05(1) §9.b, "In the expedited review process, the IRB Chair may carry out the review or delegate the review to one or more experienced reviewers from among voting IRB members."

[15] The IRB determined that protocol met Expedited Review Category #9 "Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified."

At initial approval in March 2013, the IRB requested a progress report within 90 days on subject accrual and specimens collected. However, Principal Investigator, did not provide this information by the due date because he had not enrolled any subjects. Principal Investigator eventually provided this information on March 27, 2014, and the IRB reviewed it on April 10, 2014, although it did not appear that the IRB itself had anyone with clinical expertise included in the review process to evaluate the information provided. The IRB record does not show any consultations with clinicians who had expertise in this area of care until a full year after initial approval; its reliance was solely on the comments of the whistleblower 2 with Employee 1 subsequent input. The IRB minutes from April 10, 2014, reflect clinical consultation from other providers with expertise in caring for patients with liver disease. These providers provided information that the transjugular biopsies were indeed a standard of care in this cohort of patients.

The InTeam MP provided by the coordinating center to the local study team did not include a study arm involving control subjects. Principal Investigator submitted a request to the IRB to amend the local protocol by adding a control arm. Although the information provided by Principal Investigator did not detail the aims and objectives for use of a control arm, and did not describe how the control subject data would be analyzed or by whom, the IRB approved this amendment on April 10, 2014.

The MP required the active subjects to provide a small amount of freely passed stool and blood samples on the initial day of enrollment and periodically until study interventions ended on day 90. If the subjects had a liver biopsy in the course of their routine care, the study team requested access to these "archival" tissue samples for further studies only. While the protocol described these biopsies as "archival," meaning researchers could only obtain the specimen from biopsies already performed, the biopsies themselves could in fact be obtained prospectively for clinical purposes. At the time of this review, nine active subjects had received such biopsies, of which the study team obtained a portion for use in this study. All samples collected from active subjects were processed and shipped to the coordinating center.

We reviewed the medical records for all Veterans enrolled in the InTeam research protocol, both active and control subjects, as well as those deemed ineligible (45 patients). There were no concerns about the clinical care rendered to any of these patients. For the 20 subjects in the active subject arm, the clinical care was thoughtful and appropriate in each case: 9 had transjugular liver biopsies that their provider requested in serious clinical situations where a tissue diagnosis was imperative. There were no concerns about the care provided, or the 45 percent rate of transjugular biopsies completed in the active subject study arm. Based on our review of the medical records, all transjugular biopsies were clinically indicated based on the subjects' clinical conditions.

The local protocol for the research study included two arms of enrolled subjects: those with alcoholic hepatitis (active subjects) who met the inclusion criteria, and those without alcoholic hepatitis (control subjects) who met those criteria. The protocol intended to enroll 200 subjects at the Medical Center; however, at the time of this

review, only 38 had been enrolled (20 active and 18 controls). For control subjects, the protocol required the collection of a small amount of freely passed stool on the initial day of enrollment or within a week of enrollment, and a single blood sample on the day of enrollment.[16] These blood and stool samples were stored at the Medical Center: the co-investigator for this research protocol is on staff at the Medical Center's academic affiliate, and he analyzed the stool samples in the affiliate's laboratory space.[17]

The whistleblower 1 raised concerns in June 2013 and September 2016 about "unethical" aspects of the research protocol. Employee 8 Employee 8 acknowledged that the whistleblower 1, had made him aware of the concerns, and an email provided by him corroborated this acknowledgment. A fact-finding team assembled in response to allegations of a hostile work environment also captured the whistleblower 1, concerns related to the research protocol. The newly appointed CoS also acknowledged her awareness of the allegations raised during her tenure as Deputy CoS.

Notwithstanding the acknowledged awareness, the Medical Center provided no documentation that Employee 8, the fact-finding team, or the past or present CoS followed up on these allegations or reported them to the IRB or to the Research and Development Committee (R&DC). Instead, Employee 8 and the CoS both stated that they referred the allegations to Employee 2 Employee 2 for follow up. However, Employee 2 did not conduct inquires or investigations concerning the allegations of unethical conduct of research by Employee 1 Employee 1 The Medical Center leadership did not document the process or findings from an investigation into the whistleblower 1, concerns regarding the unethical conduct of research by Employee 1. They also did not refer the allegations for investigation to the IRB and R&DC.

Research protocols also often have research study coordinators (study coordinators). Study coordinators act as agents of the listed primary investigator who is authorized to conduct research with the responsibilities outlined in his scope of practice. Principal Investigator Principal Investiga was the primary investigator in this case.

We discovered apparent weaknesses in the management of the InTeam study at the Medical Center. Based on our document review and interviews with different research team members, we found that Principal Investigator delegated many of his research oversight responsibilities to his study coordinators. This may be appropriate if the study coordinators are appropriately trained and qualified. However, the current study coordinator indicated she had received only 1 hour of direct training from the former

[16] The Medical Center IRB Protocol Application, Version 1.17 (10/20/2014) §9, "...For control patients, the protocol for stool samples is to collect a small amount of freely passed stool (1-2ml) on the initial day of enrollment if possible, or else within a week of enrollment. Blood samples will be collected on the day of enrollment (23 ml) only."

[17] The Medical Center IRB Protocol Application, Version 1.17 (10/20/2014) §9, "Stool specimens will be stored frozen at -80 C without preservatives or chemical additives in the Chair, GI's laboratory at the VA with the other biologic specimens. One de-identified aliquot of 0.2 g will be taken by for bacterial DNA extraction and sequencing, which will consume the specimen. He will do this work in his laboratory

coordinator before assuming substantive study responsibilities that included obtaining informed consent from subjects and performing numerous laboratory activities in preparing bio-specimens. We noted that on one occasion a study coordinator, not yet approved by the IRB to participate in the study, obtained the consent of a Veteran for the study. We also noted that research records were poorly maintained or missing for some subjects. Also, Principal Investigator believed that the study coordinator had sent all control subjects' data and specimens to the coordinating center, although the current study coordinator indicated they had not. Current training for study coordinators is inadequate as evidenced by the study coordinator obtaining consent before she was approved by the IRB to be part of the protocol, the presence of poorly maintained and incomplete research records, and miscommunication between Principal Investigator and the study coordinator.

Informed Consent

The IRB-approved informed consent document includes several statements that collections of liver biopsies were not a required part of the research process, such as "If a liver biopsy is done, this will be part of your routine care to make sure of the diagnosis and not part of the research process.[18] However, if available, a portion of this sample may be collected for research purposes." Employee 1 and the current study coordinator both stated that they explained to subjects that the liver biopsy would be obtained for clinical purposes and not research, but could be used for research purposes if obtained. Study records reflect that in most instances informed consent was obtained by the study coordinator, a practice permitted by Federal and VHA policy.[19] However, both stated that although Employee 1 explained the study to active subjects, he did not provide the same information to control subjects.

We also noted that the Health Insurance Portability and Accountability Act (HIPAA) authorization approved for use with the study disclosed the fact that specimens and protected health information (PHI) for the active subjects would be sent to the coordinating center, UNC at Chapel Hill.[20,21] However, the HIPAA authorization and informed consent document did not inform the control subjects that fecal specimens and identifiable PII would be sent to the co-investigator's lab at the academic affiliate. We reviewed a sample of specimens awaiting transportation to that lab, and found that they contained the dates the samples were collected, which, under the HIPAA Privacy Rule, is considered PII. The protocol also included a dietary questionnaire that each subject

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[18] Research Informed Consent, Integrated Approaches for Identifying Molecular Targets in Alcoholic Hepatitis (InTeam), Approved June 2, 2014.

[19] VHA Handbook 1200.05 (1) §15.a, "Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence."

[20] The regulations implementing the Health Insurance Portability and Accountability Act (HIPAA) of 1996, the HIPAA Privacy and Security Rules, includes provisions to protect the privacy of a patient's health information and contains security procedures that must be followed to protect the confidentiality, integrity, and availability of a patient's health information.

[21] Authorization for Release of Protected Health Information for Research Purposes: VA San Diego Healthcare System, IRB Protocol number: H120108

was expected to complete. However, the IRB Protocol Application did not specify how Principal Investigator planned to use information obtained from the "dietary questionnaire" or whether the PHI from this document would be transferred for use in the co-investigator's lab.

One of the whistleblowers expressed concern that the InTeam protocol included subjects who, due to disease progression, lacked the ability to give informed consent. The approved research protocol included provisions for assessing decisional capacity, and the InTeam informed consent document reflects that consent of the subject's legally authorized representative would be used if indicated.[22]

Conclusions for Allegation 1

- We **do not substantiate** that Employee 1 is performing unapproved human liver research, without informed consent, placing patients at serious risk.

- The IRB did not invite whistleblower 2 to the IRB meeting to discuss her concerns that the transjugular biopsies were not standard of care. However, her concerns were included in the approval process for the research protocol.

- The IRB did not initially utilize qualified clinical consultants to determine if transjugular biopsies were standard of care. However, the IRB did later consult with other providers with expertise in caring for patients with liver disease; these providers offered information that transjugular biopsies are the standard of care for patients with, or suspected to have, alcoholic hepatitis.

- The InTeam MP provided by the coordinating center to the local study team did not include a study arm involving control subjects. However, the local study team added the use of control subjects to its protocol. It is not clear if this was appropriate based on the MP.

- Based on our review of the medical records, all transjugular biopsies were clinically indicated and subsequently used for research purposes in accordance with the approved IRB protocol and the subjects' informed consent.

- The Medical Center leadership did not document the process or findings from an investigation into the whistleblower 1 , concerns regarding the unethical conduct of

[22] The Medical Center IRB Protocol Application, Version 1.17 (10/20/2017) §10.5 Individuals with Cognitive/Decisional Impairment. Section 10.5 question: "Provide the rationale and additional study procedures that will be required for including individuals with known cognitive impairment or institutionalized individuals. (Address Decisional Capacity Assessment and Surrogate Consent Sections 12.5 and 12.6)." InTeam investigator response: "Many patients suffering from acute alcoholic hepatitis have very poor health, and the research team does not wish for these subjects to feel forced to participate because of their failing health. Because some patients with alcoholic hepatitis may have encephalopathy, we will use a decisional capacity assessment to determine ability to obtain informed consent. If it appears that this capacity is impaired, we will obtain surrogate consent. This is added to the consent form and Protocol Application."

research by Employee 1 . They also did not refer the allegations for investigation to the IRB and R&DC.

- Current training for study coordinators is inadequate as evidenced by the study coordinator obtaining consent before she was approved by the IRB to be part of the protocol, the presence of poorly maintained and incomplete research records, and miscommunication between Principal Investigator and the study coordinator.

- The HIPAA authorization and informed consent document did not inform the control subjects that PII would be sent to the co-investigator's lab at the academic affiliate. Also, the IRB Protocol Application did not specify how the primary investigator planned to use information obtained from the "dietary questionnaire" or whether the PII from this document would be transferred for use in the co-investigator's lab.

- The approved research protocol included provisions for assessing decisional capacity, and the InTeam informed consent document reflects that the subject's legally authorized representative's consent would be used if indicated.

Recommendations to the Medical Center

1. The IRB needs to improve existing standard operating procedures and practices concerning the use of consultants for the purposes of facilitating the review of research beyond the Board's qualifications. This process should include inviting consultants or ad hoc reviewers to relevant meetings, as appropriate, to discuss their findings, and utilizing clinical providers with expertise in any of the research or standard of care procedures to be performed.

2. The IRB must review the amendment adding the control arm to this protocol, and determine whether this is an appropriate modification.

3. Medical Center leadership should develop a formalized plan for addressing complaints of research improprieties and communicate this plan to all staff. The plan should include a process for following up with individuals who have chosen not to remain anonymous.

4. Principal Investigator should provide more direct oversight of this study to ensure that research staff is adequately trained, that research records are appropriately maintained, that he has a clear understanding of where specimens are being shipped, and that protocol amendments adding new staff to the study are approved before any research procedures occur.

5. The IRB must also require an amendment to the informed consent document and HIPAA authorization to reflect that control subject specimens containing PHI will be disclosed to the academic affiliate. The IRB must address any instances of PHI and private identifiable information being disclosed to the academic affiliate without subjects' consent or HIPAA authorization.

Allegation 2

Employee 1 *is not properly advising patients of their options, thereby delaying proper care.*

The whistleblowers specifically alleged that Employee 1

- Is reluctant to perform liver transplants on patients who are in need of the procedure.
- Routinely directed Employee 3 , to minimize the need for transplants when talking with patients and their families.
- Routinely directed Employee 3 to assemble transplant requests to VA Central Office (VACO) in a "way to be rejected," regardless of the patient's level of need or likely outcome and ordered her to stop all imaging requests [ultrasound] for tumors for several months in 2014.
- Asked Employee 4 , to submit a transplant request to VACO for a patient who has irrefutable exclusionary criteria for liver transplantation and directed her not to schedule endoscopy appointments for patients with liver cirrhosis and hepatitis because the facility lacked appropriate resources.
- Instructed Employee 5 not to schedule patients for an endoscopy between July and September 2016; and these patients were not referred to an outside provider under the VA Choice Program.

Background:

Solid Organ Transplantation

Solid organ transplantation is a technically complex therapy in which the functioning organ of one person is implanted in a patient whose organ has failed or is failing. This procedure is often lifesaving and VA has provided Veterans with this therapy since 1961. VHA's National Surgery Office is responsible for clinical and operational oversight of the 13 VA Transplant Centers (VATC) currently performing solid organ and bone marrow transplantation procedures, and for policy development of the Transplant Program. Of these 13 VATCs, 6 perform solid organ transplantations of the liver. The Medical Center refers potential candidates for liver transplants to one of the six VATCs or local affiliates for evaluation and treatment.

Endoscopy

An upper GI endoscopy (EGD) includes visualization of the oropharynx, esophagus, stomach, and proximal duodenum, with real-time assessment and interpretation of the

findings encountered.[23] An EGD is indicated in the diagnostic evaluation of signs and symptoms of a wide variety of GI disorders; one example is screening patients with portal hypertension for the presence of esophageal varices.[24] In 2012, the American Society of Gastrointestinal Endoscopy (ASGE) issued guidelines regarding the performance of EGD which they recommend if the results are likely to influence management of the patient, if empiric treatment for a suspected benign disorder has been unsuccessful, if the procedure can be used as an alternative to radiographic evaluation, or if a therapeutic maneuver may be needed.

Patients with cirrhosis are susceptible to a variety of complications, and their life expectancy can be markedly reduced. Cirrhosis accounted for approximately 49,500 deaths and was the eighth leading cause of death in the United States in 2010. In addition, an estimated 19,500 deaths were due to liver cancer, which often occurs in the setting of cirrhosis. Patients with cirrhosis should be monitored for the development of complications, and, when possible, steps should be taken to prevent that development. In particular, patients should be screened for esophageal varices and hepatocellular carcinoma (HCC) by EGD. If varices are present, prophylactic treatment is indicated.

Patients infected with hepatitis C virus (HCV) who also have advanced fibrosis should be monitored for the development of complications. This includes evaluating for clinical signs of liver failure such as ascites and bleeding from gastroesophageal varices, as well as laboratory testing to identify hepatic dysfunction. Patients with advanced liver fibrosis or cirrhosis should undergo surveillance for HCC; these patients develop this malignancy at a rate of 1 to 4 percent per year. Liver ultrasonography (US) every 6 months is the recommended method for HCC surveillance.[25]

Child-Pugh classification is established from a set of measurements used to determine the likelihood of developing complications of cirrhosis, generating a score ranging from 5 to 15, with 15 being the worst condition. Patients with a score of 5 or 6 have Child-Pugh class A cirrhosis (well-compensated cirrhosis), those with a score of 7 to 9 have Child-Pugh class B (significant functional compromise), and those with a score of 10 to 15 have Child-Pugh class C cirrhosis (decompensated, heralding a progressive breakdown of bodily functions). Child-Pugh class C patients are much more likely to develop variceal hemorrhage and other life-threatening conditions than those with Child-Pugh class A cirrhosis.

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[23] Endoscopy typically refers to looking inside the body for medical reasons using an endoscope, an instrument used to examine the interior of a hollow organ or cavity of the body. Unlike most other medical imaging devices, endoscopes are inserted directly into the organ.

[24] In people who have cirrhosis, high blood pressure in the veins that carry blood from the intestines to the liver (portal hypertension) causes many problems. One serious complication of portal hypertension is variceal bleeding. When blood pressure increases in the portal vein system, veins in the esophagus, stomach, and rectum enlarge to accommodate blocked blood flow through the liver. The presence of enlarged veins (varices) usually causes no symptoms. (They may be found during an endoscopy exam of the esophagus.) About 50 to 60 out of 100 people who have cirrhosis develop varices in the esophagus. As the blood pressure in the portal vein system continues to increase, the walls of these expanded veins become thinner, causing the veins to rupture and bleed. This is called variceal bleeding.

[25] https://www.uptodate.com/contents/overview-of-the-management-of-chronic-hepatitis-c-virus-infection?source=see_link&sectionName=MONITORING%20DURING%20ANTIVIRAL%20THERAPY&anchor=H2369791832. Accessed April 28, 2017.

Findings:

Transplantation

Employee 8 stated that Employee 1 told him he has not referred patients who were actively drinking for liver transplants because they would not be accepted. Employee 1 told us that "active alcoholics are not approved for transplants." However, he went on to say "I prefer that we refer patients and let VACO make the decision [if they're eligible or not]; they're the experts, not me."

Employee 4 has coordinated liver transplant referrals at the Medical Center for the last 18 months. Normally, the liver clinic is the referral source for liver transplantation candidates; however, other providers also make referrals that the Director, LTC or the Chief, GI, must approve before Employee 4 can proceed to prepare the Veteran and the referral packet for approval by VACO, a process that can take 2 to 3 months. She gave us examples where Employee 1 had asked her to submit a request for patients who "clearly did not meet transplant criteria" but in the interest of efficient resource utilization she chose not to work up those patients, telling us "it's a waste of resources and time knowing they won't qualify." Examples of VATC exclusion criteria are Veterans who are actively drinking or using illicit drugs, noncompliant with their current care plan or lack care support. Employee 4 says she works closely with the Medical Center's referral VATC, discussing and reviewing cases, and the physician at the VATC supports her decisions regarding which patients to refer for transplantation.

Since 2013, Medical Center providers have referred 43 patients to the transplant coordinator for work up and possible referral to a VATC for liver transplantation. Of these, 19 were determined ineligible, 16 are in various stages of work up, 4 are awaiting transplantation, 1 successfully underwent a transplant, and 3 have died. Of the 3 who died, none met VATC's criteria for transplant consideration. Forty of the 43 Veterans were referred during Employee 4 employment as transplant coordinator: the Chief, GI, referred 13, the Director, LTC, 21, and other physicians the remaining 6.

Employee 3 is no longer employed by VA and declined our interview request. Others we interviewed had no knowledge of how Employee 1, managed or instructed Employee 3 work, so we cannot confirm that he ordered her to stop all imaging requests for tumors for several months in 2014; routinely directed her to minimize the need for transplants when talking with patients and their families; or directed her to assemble transplant requests to VACO in a "way to be rejected."

Endoscopy

Employee 4 stated that according to the AASLD, a patient referred to and successfully treated in the liver clinic for HCV no longer requires follow up in that clinic. She therefore refers the patients back to their primary care providers. However, patients with HCV and cirrhosis require follow up with an EGD every 6 months. Employee 4 stated when she questioned Employee 1 about EGDs for Child-Pugh A patients, he became upset and sent an email in December 2015 to the providers in primary care and the HCV clinic that read, "If a patient has [Child-Pugh class] A cirrhosis, [is] asymptomatic and has been cured from [HCV], I do not recommend [esophageal

varices] screening. All [Child-Pugh class] B and C patients should follow up in Liver clinic after [sustained virologic response]."[26] However, Employee 4 did not agree with these instructions, sought the opinion of another provider, and attended a national meeting in October 2015 where she learned that EGDs should be done for all HCV patients regardless of their Child-Pugh classification, voicing her concerns in an email to her supervisor, manager , Outpatient Specialty Clinics, around December 2015. During her interview, that manager told us she verbally advised Employee 4 to continue to follow the clinical guidelines. She then verbally conveyed Employee 4 concerns to the Associate Chief Nurse, who agreed that the guidance to Employee 4 was appropriate. As a result, Employee 4 continued to order the EGDs for her patients.

We reviewed the AASLD Guidelines for the management of patients following successful treatment for HCV. It states that patients who have undetectable HCV 12 or more weeks after completing treatment, are unlikely to experience a return of the virus.[27] In these patients, HCV-related liver injury stops, although the patients remain at risk for non-HCV-related liver disease, such as fatty or alcoholic liver disease. Patients with cirrhosis remain at risk for developing HCC.

The AASLD strongly recommends surveillance of adults with cirrhosis. They recommend using US every 6 months because it improves overall survival. The AASLD suggests not performing surveillance of patients with cirrhosis with Child-Pugh C unless they are on the transplant waiting list, given the low anticipated survival for these patients.

On UpToDate, the evidenced-based recommendations for patient follow up were:

> Most patients require ongoing endoscopic screening or surveillance for esophageal varices. The frequency of endoscopic evaluation depends on factors such as whether the patient has varices and if the cause of the patient's liver injury is ongoing (e.g., ongoing alcohol consumption in a patient with alcoholic liver disease).
> Patients with ongoing liver injury should undergo endoscopy every one to two years:
> - Compensated cirrhosis, no varices: Repeat screening every 2 years
> - Compensated cirrhosis, small varices: Repeat surveillance every year
>
> Patients who do not have ongoing liver injury (e.g., following cure of HCV) should undergo endoscopic evaluation every two to three years, provided there are no other cofactors that increase the risk of liver injury (e.g., obesity):
> - Compensated cirrhosis, no varices: Repeat screening every 3 years
> - Compensated cirrhosis, small varices: Repeat screening every 2 years.[28]

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[26] SVR is defined as the presence of the virus in the blood 24 weeks after completion of antiviral therapy for chronic HCV infection. In analyses of SVR durability, the incidence of late relapse is extremely low (<1%).

[27] http://www.bing.com/search?q=sustained+SVR+in+hepatitis&src=IE-SearchBox&FORM=IENTTR&conversationid Accessed May 22, 2017.

[28] http://www.uptodate.com/contents/primary-and-pre-primary-prophylaxis-against-variceal-hemorrhage-in-patients-with-cirrhosis?source=search_result&search=Primary+prophylaxis+against+variceal+hemorrhage+in+patients+with+cirrhosis&selectedTitle=1~150. Accessed April 28, 2017.

The optimal approach to the prevention of recurrent variceal hemorrhage in patients with cirrhosis is uncertain and warrants an individualized approach.

Employee 5, works collaboratively in an interdisciplinary coordinated care delivery model with the patient care team to review the clinic utilization by using various reports. They ensure that the clinic setup is closely monitored to effectively support the needs of the clinic and make necessary adjustments. They also maintain effective communication with the patient, interdisciplinary team, VA medical centers, and other agencies. Employee 5 denies that Employee 1 or anyone else had ever instructed him not to schedule patients for endoscopies. He explained the consults for GI are reviewed by the GI Fellows or Attending Physicians and then given to him for scheduling.

Conclusions for Allegation 2

- We are **not able to substantiate** that Employee 1, is not properly advising patients of their treatment options, thereby delaying proper care.

- Because Employee 3 is no longer employed by the VA and declined our interview request, we are **not able to substantiate** that Employee 1 routinely directed her to minimize the need for transplants when talking with patients and their families, directed her to assemble transplant requests to VACO in a "way to be rejected," or ordered her to stop all imaging for tumors for several months in 2014.

- Employee 1 has asked Employee 4 to submit transplant requests to VACO for patients who "clearly did not meet transplant criteria."

- The AASLD strongly recommends surveillance of adults with cirrhosis using ultra sound, with or without Alpha-fetoprotein, every 6 months because it improves overall survival.

- Per AASLD, most patients require ongoing EGD screening or surveillance for esophageal varices. The frequency of EGD evaluation depends on factors such as whether the patient has varices and whether the cause of the liver injury (continued infection or consumption of alcohol) is ongoing.

- Employee 5 denies that Employee 1 or anyone else instructed him not to schedule patients for endoscopies.

Recommendations to the Medical Center

6. When there is a difference of opinion in clinical management of this patient population, the Medical Center should use the Peer Review program to ensure that each patient's treatment plan meets the standard of care.

7. Establish internal practice guidelines for practitioners on acceptable standards of care, specifically in the management of patients diagnosed with hepatitis and the frequency of surveillance endoscopies.

Allegation 3

Employee 1 *directed the Medical Center staff to delete pending consults without proper medical review or follow up, in violation of VHA clinical policy and, in some cases, information security policy.*

The whistleblowers specifically alleged that Employee 1 directed:

- Employee 5 to cancel all endoscopy procedures scheduled between July and September 2016, without a medical review, because there was "no space available" to complete the procedures and these patients were not rescheduled or referred elsewhere despite the requirement to do so under the VA Choice Program.
- Employee 5 and his administrative assistant (AA) to close inactive patient consults without a clinical review.
- The AA and research assistants , , , , and to close the consults under his name and in some cases, this occurred simultaneously on several computers, with all employees using the Employee 1 login information.

Background

Consultations

A consultation is a request for clinical services for a patient. In VHA, providers request all consultations by submitting an electronic request in VA's Computerized Patient Record System (CPRS). Of the numerous types of consultations, the three most common are administrative, clinical, and Care in the Community (CITC), the latter of which was previously known as Non-VA Care Coordination (NVCC). An administrative consultation is a one-way request to transfer care or communicate orders. A clinical consultation is a two-way communication from one provider seeking the opinion, advice, or services from a second provider; the service sending the consultation is responsible for reviewing and acting on the results of completed consultations. A CITC consultation is a request for hospital care and/or medical services to be purchased in the community when the requirements of VA's CITC authorities are met.

The current VHA scheduling directives, 1230 and 1232, were in place at the time of the whistleblowers' allegations.[29,30] Together they provide the guidelines for appointment scheduling and the disposition and scheduling of consultations. VHA Directive 1230 also provides guidance to employees on the importance of reducing delays, ensuring timely access to care, and scheduling of appointments. In addition to other specified services, Home-Based Primary Care and community care programs such as Purchased Skilled Care, Homemaker Home Health Aide, Outpatient Home Respite, and Purchased Home Hospice, are exempt from the requirements of VHA Directive 1230 due to their unique scheduling requirements.[31]

[29] VHA Directive 1230, *Outpatient Scheduling Processes and Procedures*, July 15, 2016
[30] VHA Directive 1232, *Consult Processes and Procedures*, August 24, 2016.
[31] VHA Directive 1230, *Outpatient Scheduling Processes and Procedures*, July 15, 2016

Consistent with VHA Directive 1232, the status of a consult request is indicated in CPRS as follows:

- **Pending (p):** the referring service has sent a request for consultation, but the receiving service not yet acted on the request. The receiving service must update the status to reflect the appropriate action in no more than 7 calendar days from receiving the request. Merely adding a comment without changing the status from pending is not acceptable.
- **Active (a):** A consult has been "received" and efforts are underway to fulfill a consult. A consult may also revert to "active" in other scenarios such as when an appointment is canceled or the patient fails to show.
- **Scheduled (s):** An appointment has been made and linked to the consult request. Scheduled status automatically sends an alert to the sending provider. The consult status should not be manually changed to "scheduled" in the consult package, but should be linked to appointments so that the consult status changes when the appointment status is changed.
- **Partial Result (pr):** The consult request has been partially, but not completely, resolved.
- **Complete (c):** The requested service has been completed.
- **Administrative Complete:** Administrative or clinical staff may complete a consult without a consult-titled progress note. This function, which triggers an alert to the sending provider, must be used with extreme care in order to avoid compromising treatment.
- **Add Comments:** Enables and documents communication, including instructions to the scheduling clerk; it may trigger an alert to the sending provider depending on the consult notification setup.[32]

Findings

Consult Scheduling

Employee 5 came to the GI clinic in Date and his assignment was to schedule patients for GI procedures. He denies that Employee 1 or anyone instructed him not to schedule or cancel patients for endoscopies at any time, and he continues scheduling patients referred to GI for procedures. whistleblower 1 sent us an email with an attachment: "an example for cancelled GI endoscopies for July – Sep 2016." The email attachment contained a list of 285 GI procedures that were allegedly cancelled without medical review; these procedures included EGD, colonoscopies, and flexible sigmoidoscopies. We reviewed a random sample of 73 of these consults and found that the GI staff had appropriately discontinued all the consults included in our sampling in accordance with VHA Directive 1232. We also found evidence in VHA's official data source, VHA Support Service Center (VSSC), that in 2016 the Medical Center sent GI referrals for 55 Veterans to NVCC; they sent 11 of the referrals between July and September 2016.

[32] VHA Directive 1232, *Consult Processes and Procedures*, August 23, 2016.

A nurse who previously worked in the GI clinic stated that during her tenure she was responsible for scheduling most of the GI consult requests for advanced procedures. She told us she scheduled procedures for the GI fellow who then performed the procedure and completed the consult by attaching her procedure note. The nurse explained that Employee 1, often asked her to manage a "batch of colonoscopy and EGD consults" but she never agreed to do so. She did not know if a clinician had medically reviewed the consults prior to Employee 1 asking her to close them. She informed her manager of the request and her manager informed Employee 1, that the nurse would not be closing the batch of open consults. Employee 1 then directed Employee 6 and Employee 7 to close the consults.

Employee 6 referred to by the whistleblowers as Employee 6 informed us that for the past 5 years Employee 1 instructed her to close consults. He gave her and others in the GI section a list of consults telling them to be sure they are administratively closed. Despite the training provided by the Medical Center, she has "grave concern over her lack of clinical experience which she believes is necessary to close consults." She is also concerned that once she closes the consult, the patient will not get the appropriate GI follow up and the referring provider will not be aware of the outcome of the referral. Employee 6 voiced her concerns to her supervisor, the administrative officer for the medicine service, who stated that the administrative staff is responsible for managing consults as part of their assigned duties. Employee 1 stated that he had reviewed these consults and determined they simply required administrative closure because the patients had received care already or the consults were no longer appropriate.

In response to our questions regarding any training the Medical Center provided to Employee 6 on managing consults, the Medical Center provided us with two emails and a certificate of completion. On October 4, 2012, the CoS drafted the first email that the Employee 8 forwarded to Employee 6 and others. The subject line of the email is Consult Backlog Information; recipients are instructed to access a SharePoint site "for information relevant to the consult backlog." On April 22, 2016, the CoS drafted an email that Employee 6 supervisor forwarded to Employee 6 and others with the subject "changes to consult/clinically indicated date/earliest appropriate date;" and highlights changes to how the clinically indicated date is entered on consults. On Date, Employee 6 received a certificate of completion for the training "What Every VA Clinician & Resident Needs to Know About Consults."

We reviewed Medical Center Memorandum 11-48, *Consultation Process*, July 20, 2016, which includes responsibilities of the Service/Section Chief with oversight of the area being consulted. The service/section chief is expected to ensure that their service provides an appropriate response to the consultation requests by:

> Identifying individuals within their service (Service Users) who are responsible for responding to consult requests and who will receive CPRS alerts when appropriate.

Reviewing performance data on a regular basis to assure that pending consults are being received, consults are being completed, and the interval between receipt and initial action is within five business days, and between receipt and closure is appropriate.

Assigning administrative consult managers to track consult completion and provide reports to periodically assess timeliness and completeness of responses.[33]

Employee 1 assigned his staff to administratively close, complete, and add comments to open consults in accordance with VHA policy and the Medical Center Memorandum.

System Access

Employee 5, the research assistants, and the GI fellows all denied that the Employee 1 logged them into the network using his own network or electronic health record (EHR) account. However, Employee 9 told us that she personally witnessed one research assistant and several volunteers signed on the computer under Employee 1 Employee 1 login information. Also, Employee 10 informed us that when she started closing consults approximately 5 years ago, Employee 1 would use his log in information to give her access to the EHR. This went on for approximately 6 months, at which time the Medical Center provided her with access to scheduling and consult management menu, and for over 4 years, she has logged in using her own access to administratively close consults.

Employee 1 admitted that he would log on to the network and into the EHR for his GI fellows and research assistants, because it would take months for the Medical Center to provide them with computer access. Because he allowed others to work under his network account, Employee 1 is aware of the rules of behavior and has consented not to violate the VHA Privacy and Information Security Awareness Rules of Behavior (Rules of Behavior) policy in the future.[34]

The Medical Center provided evidence that Employee 1 had completed mandatory training for Privacy, HIPAA, and Rules of Behavior in Date and Date Date respectively. The Medical Center provided a training module titled *"What Every VA Clinician & Resident Needs to Know About Consults"* developed by the VA Consult Steering Committee. However, Employee 1 admitted that while conducting procedures, he currently logs in to multiple computers to allow members of the procedure team to enter patient information. He explained that one computer allows them to enter orders for the patient and the other to capture images of the procedure. He insists that this process is necessary in order for the providers to successfully perform procedures. We explained to Employee 1 that this was against VHA policy and he needed to consult his information security officer for guidance on how to conduct procedures in GI while complying with VHA policies.

[33] Medical Center Memorandum 11-48, *Consultation Process*, July 20, 2016.
[34] VHA Handbook 1907.01, *Health Information Management and Health Records*. March 19, 2015

Conclusions for Allegation 3

- We **do not substantiate** that Employee 1 directed the Medical Center staff to delete pending consults without proper medical review or follow up in violation of VHA clinical policy.

- Employee 1 appropriately assigns administrative staff to close, administratively complete, and add comments to consults.

- We **do not substantiate** that Employee 1 directed Employee 5 to cancel all endoscopy procedures scheduled between July and September 2016, without a medical review, because there was "no space available" to complete the procedures and these patients were not rescheduled or referred to the VA Choice Program.

- VSSC shows that in 2016 the Medical Center sent GI referrals for 55 Veterans to NVCC; they sent 11 of the referrals between July and September 2016.

- We **substantiate** that Employee 1 directed Employee 10 and some research assistants to close consults while being logged on the computer under the Employee 1 network access, thereby violating VHA information security policy.

- Employee 1 currently logs in to multiple computers, while conducting procedures, to allow members of the procedure team to enter patient information.

Recommendations to the Medical Center

8. Provide immediate training to all clinic staff members regarding the seriousness and inappropriateness of sharing VA staff members' passwords to gain access to VA computer systems. The VA Table of Penalties lists punishments ranging from admonishment to removal, depending on the stated offense.

9. Ensure all medical center staff members complete the required training regarding the use of, and access to, VA computer systems.

10. Take appropriate administrative action in response to Employee 1 persistent violation of VHA Privacy and HIPAA and Rules of Behavior Policies by allowing staff members to use his password to gain access to VA computer systems.

Recommendation to VHA

1. Ensure scheduling and consult training is being provided, at least annually, to all affected Medical Center staff according to appropriate VHA Policy and Directives, e.g., VHA Directives 1230, *Outpatient Scheduling Processes and Procedures* (July 2016), VHA Directive 1232 *Consult Processes and Procedures* (August 2016), and medical center memoranda.

2. Analyze and address the factors contributing to the delay in timely granting full computer access to residents and fellows.

VI. Summary Statement

OMI has developed this report in consultation with other VHA and VA offices to address OSC's concerns that the Medical Center may have violated law, rule or regulation, engaged in gross mismanagement and abuse of authority, or created a substantial and specific danger to public health. In particular, the Office of General Counsel has provided a legal review, VHA HR has examined personnel issues to establish accountability, the Office of Accountability and Whistleblower Protection has reviewed the report and has or will address potential senior leadership accountability, and the National Center for Ethics in Health Care has provided a health care ethics review. We found violations of VHA policy; however, we found no substantial danger to public health at the Medical Center.

Attachment A

Documents in addition to emails and Electronic Medical Records reviewed.

VHA Directive 1230, *Outpatient Scheduling Processes and Procedures*. July 15, 2016

VHA Directive 1232, *Consult Processes and Procedures*. August 24, 2016.

VHA Handbook 1200.05, *Requirements for the Protection of Human Subjects in Research*. November 12, 2014. Amended February 22, 2017.

VHA Handbook 1907.01, *Health Information Management and Health Records*. March 19, 2015

Medical Center R&D Project Abstract, Protocol #H120108, *Integrated Approaches for Identifying Molecular Targets in Alcoholic Hepatitis*; 2014.

Medical Center Memorandum 11-48, *Consultation Proc*ess. July 20, 2016

Medical Center Memorandum 11-43, *Informed Consent*, September 7, 2016

Medical Center's R&D Committee Records (May 2013 – April 2017)

Medical Center's Organizational Charts for Research, Surgery and Medicine

Medical Center Fact Finding Report, November 23, 2016.

Medical Center Institutional Review Board Meeting Minutes (May 2013 – April 2017)

Medical Center Scope of Practice for Research Assistants named

Medical Center Peer Reviews of Employee 1 (May 2013 – April 2017)

Research Informed Consent, Integrated Approaches for Identifying Molecular Targets in Alcoholic Hepatitis (InTeam), Approved June 2, 2014

https://www.uptodate.com/contents/overview-of-the-management-of-chronic-hepatitis-c-virus-infection?source=see_link&sectionName=MONITORING%20DURING%20ANTIVIRAL%20THERAPY&anchor=H2369791832. Accessed April 28, 2017.

http://www.uptodate.com/contents/primary-and-pre-primary-prophylaxis-against-variceal-hemorrhage-in-patients-with-cirrhosis?source=search_result&search=Primary+prophylaxis+against+variceal+hemorrhage+in+patients+with+cirrhosis&selectedTitle=1~150.