



Department of Health and Human Services
OFFICE OF INSPECTOR GENERAL



**OHRP SHOULD INFORM POTENTIAL
COMPLAINANTS OF HOW THEY CAN
SEEK WHISTLEBLOWER PROTECTIONS**

OEI-01-15-00351
September 2017

AT A GLANCE

- OHRP relies on information from complainants to identify noncompliance with protections for human subjects.
- However, fear of reprisals may prevent potential complainants from reporting suspected noncompliance with protections for human subjects.
- OHRP reported that it often gets requests from complainants for whistleblower protections, and sometimes complainants choose not to report suspected noncompliance because OHRP cannot offer such protections.
- We found evidence of a fear of reprisal in four of the five closed for-cause compliance evaluations that we reviewed.
- OHRP should inform potential complainants of how they can seek whistleblower protections.
- OHRP should request that HHS consider the adequacy of whistleblower protections for complainants who make disclosures to OHRP about human subjects protections.

THIS REPORT

This report highlights the implications of the Office for Human Research Protections' (OHRP's) not providing information on whistleblower protections to complainants who disclose alleged noncompliance with protections for human subjects.

BACKGROUND

OHRP receives and responds to alleged violations of protections for human subjects in research conducted or supported by the Department of Health and Human Services (HHS).¹ Sources of allegations can include human subjects (i.e., individuals who volunteer to participate in research), employees of research institutions, and advocates for human subjects. To address allegations of noncompliance, OHRP may conduct a for-cause compliance evaluation, or it may contact a research institution directly to resolve a dispute.² If OHRP identifies noncompliance with regulations protecting human subjects, it can take a variety of actions, including (1) requiring the institution to take corrective action, (2) restricting or suspending research at the institution, and (3) recommending that an institution or investigator be debarred from receiving Federal funds for research.

Information from complainants can be an invaluable resource in ensuring protections for human subject volunteers. Employees of research institutions (e.g., researchers or study coordinators) with insider knowledge of the circumstances can help identify noncompliance in human subjects research earlier than other complainants or OHRP oversight activities. Such information allows OHRP to address any noncompliance, hold institutions accountable, minimize risk to human subject volunteers, and ensure public confidence in federally funded research. However, when employees are considering whether to disclose information about potential noncompliance, they

may fear reprisal, such as demotion, suspension, or termination. For such complainants, information regarding whistleblower protections may encourage disclosures of noncompliance.

WHISTLEBLOWER PROTECTIONS

Under certain circumstances, employees at research institutions with HHS-funded grants or contracts may be entitled to relief commonly called "whistleblower protections."³ Such protections may be available if an HHS contractor, subcontractor, grantee, or subgrantee takes a prohibited employment

action (e.g., termination) against an employee for making a “protected disclosure.” For the employee’s disclosure to be considered protected, it must meet the following two criteria:

1. The disclosure is information that the employee reasonably believes is evidence of a substantial and specific danger to public health or safety, or a violation of law, rule, or regulation related to the HHS contract or grant.
2. The disclosure must be made to specific individuals and entities, such as the Office of Inspector General (OIG); the officials of the grant-awarding agency (e.g., the National Institutes of Health) who are responsible for grant oversight and management; or a relevant employee of the contractor, subcontractor, grantee, or subgrantee who has the responsibility to investigate employee misconduct.⁴

A disclosure to officials of a regulatory oversight agency such as OHRP does not qualify as a “protected disclosure” for the purposes of whistleblower protections.

Once an employee has made a protected disclosure, the research institution may not take a prohibited employment action because of the employee’s disclosure. If the employee believes that the research institution has taken a prohibited employment action as a result of the protected disclosure, the employee may submit a complaint to HHS OIG.⁵ Following an investigation, a whistleblower may be entitled to relief such as job restoration; reversal of suspension; back pay; and reasonable and foreseeable consequential damages, such as medical costs and attorney fees.⁶ Generally, for a complainant to receive whistleblower protections, (1) the complainant must make a protected disclosure; (2) the complainant’s employer must have knowledge of the complainant’s protected disclosure; (3) a specific prohibited action must have been taken against the complainant; and (4) the complainant must prove that the protected disclosure was a contributing factor in the action taken against the complainant.⁷ However, a complainant is not entitled to relief if the employer demonstrates by clear and convincing evidence that it would have taken the employment action in the absence of the disclosure—for instance, that it took the action because of the complainant’s poor performance.⁸

This report is a companion to our report entitled *OHRP Generally Conducted Its Compliance Activities Independently, But Changes Would Strengthen Its Independence* (OEI-01-15-00350). In the evaluation that produced that report, we found that OHRP appeared to independently carry out compliance activities for protecting human subjects but that certain factors may have limited or appear to limit OHRP’s ability to operate independently.

METHODOLOGY

In our companion work, we analyzed a variety of data to understand how OHRP receives and responds to potential noncompliance with HHS regulations for protecting human subjects. For this review, we used data obtained through the same data-collection methodology as the companion report and took the following actions:

1. We analyzed data on OHRP’s activities from its Compliance Activity Tracking System for 2000 through 2015. Data included descriptions of the allegations that OHRP received, the dates when OHRP received the allegations, the sources of the allegations, the dates when OHRP opened and closed compliance activities, and the outcomes of those compliance activities.
2. We reviewed OHRP’s administrative files from eight closed compliance evaluations and an open incident report. Five of the eight compliance evaluations that we reviewed were for-cause evaluations and included documentation of the complaint reported to OHRP. If the

complainant explicitly requested whistleblower protections or reported concerns of retaliation or adverse effects on his or her career, we considered that to be evidence of fear of reprisal.

3. We conducted interviews with OHRP staff, HHS officials outside of OHRP, and individuals with expertise in protections for human subjects.

STANDARDS

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

FEAR OF REPRISAL MAY PREVENT POTENTIAL COMPLAINANTS FROM DISCLOSING ALLEGATIONS OF NONCOMPLIANCE TO OHRP

OHRP reported that it often gets requests from complainants for whistleblower protections and that some complainants have chosen not to report suspected noncompliance to OHRP because it does not have the statutory authority to offer such protections. OHRP relies primarily on allegations to learn about potential noncompliance with human subjects protections, and employees of research institutions are valuable sources of allegations. Between 2007 and 2015, allegations from researchers, study coordinators, and other research institution staff were the source for about one-quarter of OHRP's closed for-cause evaluations.

In addition, of the five closed OHRP compliance evaluations we reviewed that were prompted by complaints, four had evidence of a fear of reprisal. In one instance, the documentation noted that the complainant indicated she was worried about raising the concern with the research institution's Institutional Review Board because other employees had been reassigned after doing so. In another instance, documents showed that the complainant reported that she feared for her job and requested whistleblower protections. In all instances, the complainants made their allegations despite their reported fears. In two of these four compliance evaluations, OHRP found noncompliance and issued corrective actions.

CONCLUSION AND RECOMMENDATIONS

OHRP's effectiveness may be hampered if potential complainants at research institutions that conduct HHS-funded studies are unaware of whistleblower protections that may be available to them. Fear of reprisal may prevent some individuals from coming forward with knowledge of noncompliance in protecting human subjects. This raises concerns that some instances of noncompliance may go unreported and unresolved. Although whistleblower protections are not available for complainants who make disclosures of noncompliance only to OHRP, protections may be available if complainants disclose such noncompliance to other entities, such as OIG or the HHS grant-awarding agency. Providing information about these available whistleblower protections could encourage complainants to come forward and thus help OHRP identify actual or potential problems.

Therefore, we recommend that OHRP:

- **Inform potential complainants of how they can seek whistleblower protections**

OHRP should inform complainants of how they can potentially obtain whistleblower protections by reporting their allegations of noncompliance with human subject protections to entities such as OIG or the HHS awarding agency. OHRP should post this information

prominently on its website and include it in routine outreach to research institutions. OIG will provide technical assistance to OHRP via its Whistleblower Ombudsman on how potential complainants can make a protected disclosure. Furthermore, OHRP should coordinate with the HHS grant-awarding agencies to ensure that they relay to OHRP any allegations they receive.

➤ **Request that HHS consider the adequacy of whistleblower protections for complainants who make disclosures to OHRP about human subjects protections**

Our work raises questions about the adequacy of current whistleblower protections for complainants who make disclosures of noncompliance with protections for human subjects. Elevating this issue would prompt HHS to consider whether a broad review of whistleblower protections is appropriate. Furthermore, it could help HHS determine whether it should seek a legislative change that enables OHRP and other HHS entities that are not responsible for contract or grant oversight management to receive protected disclosures.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

The Office of the Assistant Secretary for Health (OASH) concurred with our recommendations. Regarding our first recommendation, it stated that OHRP will inform potential complainants of how they can seek whistleblower protections by concurrently reporting their allegations of noncompliance with human subject protections to entities such as OIG or the HHS awarding agency. OHRP will post this information on its website and notify HHS grant-awarding agencies of how they can relay any allegations they receive to OHRP.

Regarding our second recommendation, OASH will ask HHS leadership to consider the adequacy of whistleblower protections for complainants who make disclosures to OHRP about human subject protections. OASH agrees that elevating this issue could help HHS determine whether it should seek a legislative change.

OIG requests details on the efforts to implement these recommendations in OASH's final management decision. We will monitor these efforts through our recommendations tracking process.

For the full text of the agency comments received, see Appendix A.

APPENDIX A: AGENCY COMMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Office of the Assistant Secretary for Health
Washington, D.C. 20201

AUG 28 2017

TO: Daniel R. Levinson
Inspector General

FROM: Acting Assistant Secretary for Health

SUBJECT: OIG Draft Report: *OHRP Should Inform Potential Complainants of How They Can Seek Whistleblower Protections*, OEI-01-15-00351

Thank you for the opportunity to respond to the above-referenced report of the Department of Health and Human Services (HHS) Office of Inspector General (OIG) regarding whistleblower protections for complainants submitting allegations or complaints to the Office for Human Research Protections (OHRP).

We concur with the recommendations in the report.

OHRP will inform complainants of how they can potentially obtain whistleblower protections by concurrently reporting their allegations of noncompliance with human subject protections to entities such as OIG or the HHS-awarding agency. This information will be posted on OHRP's website for complainants to potentially obtain whistleblower protections.

We appreciate OIG's offer to provide technical assistance to us via its Whistleblower Ombudsman on how potential complainants can make a protected disclosure. Furthermore, we will notify HHS grant-awarding agencies of this process and request that they relay to OHRP any allegations of non-compliance with HHS regulations at 45 CFR Part 46.

Regarding your recommendation on this matter, we will ask HHS leadership to consider the adequacy of the proposed whistleblower protections for complainants making disclosures about human subject protections to OHRP. We agree that elevating this issue could help HHS determine whether it should seek a legislative change that enables OHRP and other HHS entities that are not responsible for contract or grant oversight management to receive protected disclosures.

If you have any questions, please contact Lisa Buchanan, Division of Compliance Oversight, OHRP at lisa.buchanan@hhs.gov.

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cc: Suzanne Murrin
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U.S. Public Health Service

ENDNOTES

¹ 42 U.S.C. § 289(b).

² OHRP, *OHRP's Compliance Oversight Procedures for Evaluating Institutions* (October 14, 2009).

³ 41 U.S.C. § 4712(a). P.L. No. 114-261 (December 14, 2016) made the pilot program permanent.

⁴ *Ibid.* Other eligible entities and individuals to which potential complainants may make disclosures include the Government Accountability Office; a Member of Congress or a representative of a committee of Congress; an authorized official of the U.S. Department of Justice or other law enforcement agency; and a court or grand jury.

⁵ 41 U.S.C. 4712(b)(1).

⁶ 41 U.S.C. 4712(c).

⁷ 41 U.S.C. 4712(c)(6).

⁸ *Ibid.*

ACKNOWLEDGMENTS

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This report was prepared under the direction of Joyce Greenleaf, Regional Inspector General for Evaluation and Inspections in the Boston regional office, and Kenneth Price, Deputy Regional Inspector General.