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OHRP GENERALLY CONDUCTED ITS COMPLIANCE ACTIVITIES INDEPENDENTLY, BUT CHANGES WOULD STRENGTHEN ITS INDEPENDENCE



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Why OIG Did This Review

Protecting the rights of human subjects—individuals who volunteer to participate in research—is critical to ensuring the safety of these volunteers and public confidence in research conducted or supported by the Department of Health and Human Services (HHS). The Office for Human Research Protections (OHRP) enforces compliance with HHS regulations for protecting human subjects. Congress and others have raised questions about OHRP’s independence, and Congress requested that the Office of Inspector General (OIG) review OHRP procedures and make recommendations to strengthen protections for human subjects and ensure OHRP’s independence.

How OIG Did This Review

We analyzed data on OHRP’s compliance activities for 2000 through 2015. We administered a survey to research institutions that were the primary subjects of OHRP compliance evaluations about their experiences with OHRP. We also reviewed documents from eight compliance evaluations that had been closed. Finally, we interviewed OHRP staff, other HHS officials, and individuals with expertise in protections for human subjects.

OHRP Generally Conducted Its Compliance Activities Independently, But Changes Would Strengthen Its Independence

What OIG Found

According to our review, OHRP appeared to carry out its compliance activities for protecting human subjects while maintaining its independence from the HHS agencies that fund the research and the institutions conducting the research. OHRP decided how to use its resources and, over time, initiated fewer compliance evaluations while increasing its use of other mechanisms in response to allegations. OHRP determined the scope of its evaluations and what methods to employ. Furthermore, OHRP was able—with some delays—to access the information it needed to conduct its compliance evaluations. Lastly, OHRP maintained its determinations, changing only 1 finding in 492 evaluations since 2000, a record consistent with operating independently.

However, certain factors may limit or appear to limit OHRP’s ability to operate independently. For instance, stakeholders have varying interpretations as to whether OHRP’s role is oriented more toward enforcing compliance or toward setting broader policy. In addition, OHRP is under the Assistant Secretary for Health while the research agencies it oversees are directly under the Secretary, and OHRP’s budget is set by HHS, rather than by the Office of Management and Budget or by Congress. Lastly, OHRP’s practice of not reporting publicly on all of its compliance activities may give the appearance of limited oversight and independence.

What OIG Recommends

We recommend that HHS address factors that may limit OHRP’s ability to operate independently. To accomplish this, HHS could (1) issue guidance that clarifies OHRP’s role, (2) evaluate OHRP’s position within HHS, and (3) evaluate the sufficiency of OHRP’s resources and consider ways to elevate the prominence of its budget, such as including OHRP’s budget as a line item in the President’s budget. HHS should also foster a shared understanding for OHRP’s independence by considering seeking statutory authority for OHRP’s independence. We also recommend that OHRP post the following on its website: (a) a description of its approach to oversight and (b) data (in aggregate) regarding its compliance activities. The Office of the Assistant Secretary for Health provided HHS’s response and said it would consider our recommendation to address factors that may limit OHRP’s ability to act independently as part of a comprehensive review of HHS’s structures and functions that is underway. OHRP concurred with our recommendation to make information about its oversight activities available on its website.

Key Takeaway

According to our review, OHRP appeared to independently carry out its compliance activities for protecting human subjects. However, varying interpretations of OHRP’s role, its placement within HHS, and the way its budget is set may limit its ability to operate independently. In addition, OHRP’s practice of not reporting publicly on all of its compliance activities may give the appearance of limited oversight and independence. We recommend that HHS address factors that may limit OHRP’s ability to operate independently.

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OBJECTIVE

To determine the extent to which the Office for Human Research Protections (OHRP) independently initiates, conducts, and makes determinations about compliance evaluations.

BACKGROUND

Protecting the rights of human subjects—individuals who volunteer to participate in research—is critical to ensuring the safety of these volunteers and public confidence in research conducted or supported by the Department of Health and Human Services (HHS). Federal agencies that fund research help to ensure human subjects are protected, and OHRP provides guidance and enforces compliance with HHS regulations for protecting human subjects.¹ Congress and others have raised questions about OHRP’s independence, and Congress requested that the Office of Inspector General (OIG) review OHRP procedures and make recommendations to strengthen protections for human subjects and ensure its independence.² For purposes of this study, we consider independence for OHRP to be characterized by the ability to decide how to fulfill its mission to protect human subjects independently from the HHS agencies that fund the research and the institutions that conduct the research.

Regulations to Protect Human Subjects

A human subject is a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.³ Biomedical and behavioral research activities that involve human subjects range from (for example) ingesting an experimental drug to providing a blood sample, participating in a focus group, or completing a survey. Research involving human subjects has provided substantial benefits, but it has not been

¹ 42 U.S.C. 289(b); 65 Fed. Reg. 37136 (June 13, 2000).

² “Explanatory Statement submitted by Mr. Rogers of Kentucky, Chairman of the House Committee on Appropriations regarding the House Amendment to the Senate Amendment on H.R. 83.” Congressional Record 160:151 (Dec. 11, 2014) p. H9839 accompanying the Consolidated and Further Continuing Appropriations Act, 2015, P.L. No. 113-235 (Dec. 16, 2014).

³ 45 CFR § 46.102(f). The Food and Drug Administration (FDA) defines a “human subject” as an individual (who may be healthy or a patient) who is or becomes a participant in research, either as a recipient of the test article or as a control, 21 CFR § 56.102(e).

without cases of abuse. A few highly publicized cases of such abuse led to the development of a regulatory framework to protect human subjects.⁴

The Federal Policy for the Protection of Human Research Subjects—also known as the Common Rule—establishes the basic regulatory provisions for assurance of compliance, Institutional Review Boards (IRBs), and informed consent.⁵ The Common Rule was published in 1991 and is followed by 18 Federal departments and agencies. A Federalwide Assurance (FWA) is a written statement that commits a research institution to comply with all Common Rule requirements for protecting human subjects. To receive an FWA, research institutions must use an IRB that protects human subjects by approving proposed research, disapproving it, or recommending modifications to it.⁶ In addition, informed consent must generally be obtained from human subjects under circumstances that give subjects the opportunity to decide whether to participate in the research and that minimize the possibility of coercion or undue influence.⁷ Federal agencies are responsible for reviewing research proposals that involve human subjects and awarding Federal funds only to research that meets these requirements for protecting human subjects.⁸

In 2015, HHS published a Notice of Proposed Rulemaking proposing the first substantial revision to the Common Rule in 25 years.⁹ HHS published the final rule on January 19, 2017.¹⁰ Revisions to the Common Rule include new requirements for informed consent, new categories of research that are exempt from IRB review, and a requirement for the use of a single IRB in research conducted by multiple institutions.

The Office for Human Research Protections

OHRP provides leadership and maintains regulatory oversight of human subjects research supported or conducted by HHS.¹¹ OHRP also develops guidance and educates researchers, IRBs, and research institutions on complying with HHS regulations.

⁴ P.L. No. 93-348 (July 12, 1974) created the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research. This commission was charged with identifying the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects.

⁵ The Common Rule is codified at 45 CFR pt. 46, subpart A.

⁶ 45 CFR § 46.109(a).

⁷ 45 CFR § 46.116. HHS regulations have additional protections for vulnerable populations, such as pregnant women and prisoners, and require the registration of IRBs.

⁸ 45 CFR §§ 46.120, 46.122.

⁹ 76 Fed. Reg. 44512 (July 26, 2011); 80 Fed. Reg. 53933 (Sept. 8, 2015).

¹⁰ 82 Fed. Reg. 7273 (Jan. 19, 2017).

¹¹ OHRP, *About OHRP: Mission*. Accessed at www.hhs.gov/ohrp on March 28, 2017.

History and Organizational Structure. In 2000, the Secretary of HHS moved OHRP from the National Institutes of Health (NIH), where it was part of the Office of the Director, to the Office of the Assistant Secretary for Health (OASH), which is within HHS's Office of the Secretary.¹² HHS made this change to minimize the appearance of a conflict of interest between an agency that funds research and the office that ensures the protections of human subjects in that research.¹³ No law mandates that OHRP be independent from other components of HHS or limits OHRP from receiving input from them.¹⁴

In 2017, OHRP consisted of the Office of the Director and 3 divisions with a total of 22 staff.¹⁵ Four staff in the Division of Compliance Oversight are responsible for responding to allegations of noncompliance with HHS regulations and other compliance activities.¹⁶

Jurisdiction. OHRP oversees research involving human subjects that is supported by HHS or covered by an applicable FWA.^{17, 18} Research is covered by an applicable FWA when an institution voluntarily applies HHS regulations to all its research, regardless of funding source.¹⁹ Most research that OHRP oversees is funded by NIH.²⁰ OHRP shares oversight of human subjects protections with FDA when HHS-funded research is associated with an application for approval of a product such as a drug or medical device.²¹ If OHRP receives allegations regarding research that is conducted or supported solely by a non-HHS Federal agency—for example, the Veterans Health Administration—OHRP may refer those allegations to that agency.

¹² 65 Fed. Reg. 37136 (June 13, 2000).

¹³ OIG, *Report of OIG Review of Allegations of Interference in OHRP Compliance Determination for SUPPORT* (OIG-12-14-04), September 2014.

¹⁴ *Ibid.*

¹⁵ OHRP, *About OHRP: Staff Listing*. Accessed at <http://www.hhs.gov/ohrp/about-ohrp/staff/index.html> on March 28, 2017.

¹⁶ One of the four staff members is a temporary fellow until June 2018.

¹⁷ OHRP, *OHRP's Compliance Oversight Procedures for Evaluating Institutions*, October 14, 2009.

¹⁸ Research may be exempt from HHS regulations if it is determined to meet the criteria for an exemption category (e.g., research conducted in educational settings involving normal educational activities).

¹⁹ Federal regulations for protecting human subjects also apply to research that is conducted outside the United States but is funded or supported by a department or agency covered by the Common Rule.

²⁰ Presidential Commission for the Study of Bioethical Issues, *Moral Science: Protecting Participants in Human Subjects Research*, June 2012.

²¹ FDA has its own requirements for protecting human subjects in clinical trials associated with an application for product approval. FDA's regulations can be found at 21 CFR pts. 50 and 56.

OHRP's Compliance Oversight Procedures

OHRP has procedures in place to evaluate potential noncompliance with HHS regulations for protecting human subjects.²² OHRP has considerable discretion in this process, allowing it to prioritize and shape its evaluations.²³ In addition, OHRP may use mechanisms other than compliance evaluations to address allegations of noncompliance, such as contacting a research institution directly to resolve a dispute regarding reimbursement to a study participant. As part of its compliance activities, OHRP also receives and reviews mandatory incident reports from research institutions.

For-Cause Compliance Evaluations. OHRP may conduct for-cause compliance evaluations upon receipt of a complaint or allegation of noncompliance. In such an evaluation, OHRP requests that the institution conduct its own investigation of the potential noncompliance, provide a written response with supporting documentation, and develop a corrective action plan if any noncompliance is revealed. OHRP reviews the institution's investigation and may request additional information, conduct interviews or site visits, or consult experts.

Not-For-Cause Compliance Evaluations. In the absence of a complaint, OHRP may also conduct a not-for-cause compliance evaluation at an institution. OHRP selects institutions for these evaluations on the basis of various factors, such as an institution's volume of HHS-supported research. OHRP reviews documents and may conduct interviews or site visits, or consult experts.

Compliance Evaluation Outcomes. After conducting its evaluation, OHRP provides the institution with a determination letter specifying its findings. If OHRP finds no evidence of noncompliance, it may still recommend improvements to the institution's policies. If OHRP identifies noncompliance with regulations regarding the protection of 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/or (3) recommending that an institution or investigator be debarred from receiving Federal funds for research. If institutions or complainants disagree with OHRP's determination, they may request that OHRP's director reconsider the results of the

²² 42 U.S.C. § 289(b).

²³ OHRP, *OHRP's Compliance Oversight Procedures for Evaluating Institutions*, October 14, 2009.

evaluation.²⁴ OHRP publicly posts its determination letters from compliance evaluations on its website.

Mandatory Incident Reports from Institutions (Incident Reports). HHS regulations require that institutions have written procedures to ensure that the following types of incidents pertaining to research are promptly reported to OHRP: (1) any unanticipated problems involving risks to subjects or others; (2) any serious or continuing noncompliance; and (3) any suspension or termination of IRB approval.²⁵

Prior OIG Work

Recent OIG work evaluated the extent to which OHRP followed its procedures during a for-cause evaluation of the Surfactant, Positive Pressure, and Oxygenation Randomized Trial (SUPPORT). In its evaluation of SUPPORT, OHRP issued a compliance determination that the informed-consent document used in the study was inadequate. OHRP's determination received significant attention in the media and research community. Although OIG determined that OHRP followed its procedures, it found that those procedures are broadly drawn and allow for substantial discretion in how OHRP carries out its evaluations.²⁶ Subsequent OIG work found that NIH encouraged OHRP to reverse its determination following OHRP's evaluation of SUPPORT and that NIH provided input on OHRP's correspondence to the research institution.²⁷ OHRP reaffirmed its determination, but it also suspended corrective actions for this particular case and committed to providing guidance to the research community. OIG found no law, regulation, or written policy that prohibits or restricts the kind of consultation that occurred between OHRP and NIH.

METHODOLOGY

For purposes of this study, we consider independence for OHRP to be characterized by the ability to decide how to fulfill its mission to protect human subjects. This includes OHRP's ability to obtain the information it needs and to make determinations without interference from other entities,

²⁴ As of June 2016, OHRP was developing dispute resolution procedures for its evaluations.

²⁵ OHRP, *Guidance on Reporting Incidents to OHRP*. Accessed at <http://www.hhs.gov/ohrp/compliance-and-reporting/guidance-on-reporting-incident/> on March 28, 2017.

²⁶ OIG, *Memorandum Report: The Office for Human Research Protections' Evaluation of the Surfactant, Positive Pressure, and Oxygenation Randomized Trial* (OEI-01-14-00560), September 2014.

²⁷ OIG, *Report of OIG Review of Allegations of Interference in OHRP Compliance Determination for SUPPORT* (OIG-12-14-04), September 2014.

most notably from the HHS agency that funded the research or from the research institution conducting the research.²⁸

To determine the extent to which OHRP independently initiates, conducts, and makes determinations about compliance evaluations, we used five main sources of data.

1. We analyzed data on OHRP's activities from its Compliance Activity Tracking System (CATS) 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 administered an online survey to research institutions that were the primary subjects of a for-cause or not-for-cause OHRP compliance evaluation closed from 2010 through 2015. The survey covered the research institutions' experiences with OHRP and the extent to which they thought OHRP operated independently during its evaluations.
3. We reviewed documents from eight closed compliance evaluations and an open incident report.
4. We conducted interviews of OHRP staff, HHS officials outside of OHRP, and individuals with expertise in protections for human subjects.
5. We reviewed our memorandum report, *The Office for Human Research Protections' Evaluation of the Surfactant, Positive Pressure, and Oxygenation Randomized Trial* (OEI-01-14-00560), issued in September 2014.

See Appendix A for a detailed methodology.

Limitations

We did not independently verify the data that we received from OHRP, nor did we independently verify other self-reported data from research institutions, relevant Government agencies, and individuals with expertise in protections for human subjects. We also did not assess the appropriateness of OHRP's responses to allegations or of its determinations in its compliance evaluations.

Standards

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

²⁸ OIG does not consider consultation with experts or with the entity being reviewed to constitute interference.

FINDINGS

According to our review, OHRP appeared to independently carry out its compliance activities for protecting human subjects

Given that no law establishes OHRP's independence and that OHRP has considerable discretion in conducting evaluations, OHRP could appear vulnerable to interference. However, our review found that OHRP has been largely able to make decisions about its compliance evaluations, obtain the information it needs, and maintain its determinations without interference.

OHRP independently decided how to use its resources—over time, initiating fewer compliance evaluations while increasing its use of other mechanisms in response to allegations

According to OHRP, it has the final say on whether to initiate a compliance evaluation. OHRP explained that it decided over the years to initiate fewer compliance evaluations both to better leverage its limited resources and to focus the evaluations on broad policy issues in protections for human subjects. Between 2000 and 2015, OHRP received an average of 123 allegations of noncompliance each year (see Exhibit B-1 in Appendix B). In 2000, OHRP conducted 60 compliance evaluations in response to allegations, compared to an average of 5 such compliance evaluations over the last 5 years (2011 through 2015). (See Exhibit 1.) Of note, the percentage of allegations that OHRP determined it did not have jurisdiction to investigate increased from 10 percent in 2006 to 54 percent in 2015.²⁹

One example of OHRP's leveraging its resources is its decision to limit compliance evaluations for multisite studies to the lead institution. In these instances, OHRP copies the other institutions on its determination letters. OHRP said that in this way, it was both more efficient and achieved the same impact as separate but similar evaluations. OHRP used this approach when it addressed allegations it received about SUPPORT, conducting its evaluation at the University of Alabama, Birmingham, but also sending its determination to the other 22 institutions involved in the research.

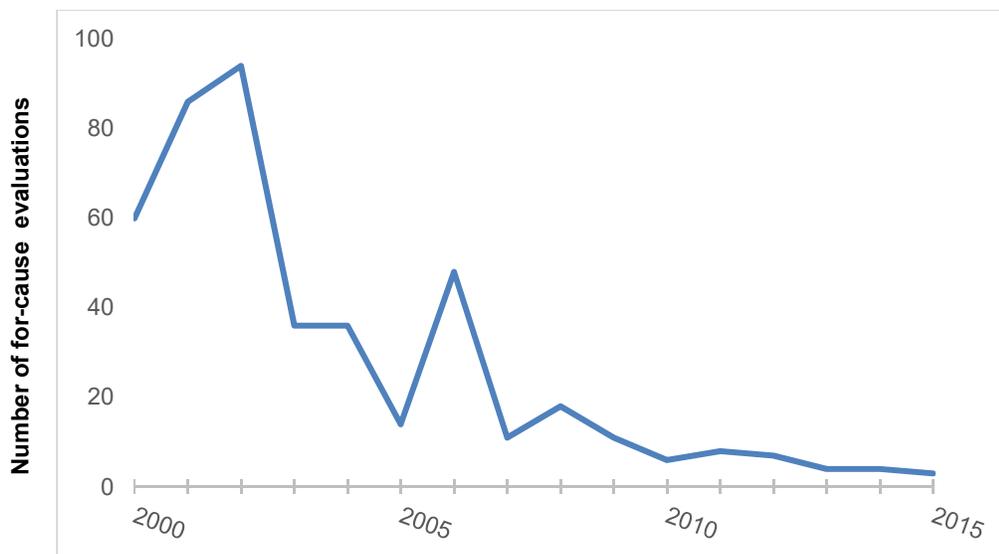
The SUPPORT evaluation also reflected OHRP's interest in focusing compliance evaluations on broader policy issues—in this case,

²⁹ When appropriate, OHRP forwarded an allegation outside its jurisdiction to the appropriate funding entity or research institution.

determining and communicating risks in standard-of-care research designed to compare the effectiveness of treatments.³⁰ Another policy issue that OHRP addressed through a compliance evaluation involved determining whether certain types of research are exempt from IRB review.

Although it conducted fewer compliance evaluations, OHRP reported that it increased its use of other mechanisms—for example, contacting the research institution directly—to address allegations of noncompliance. For example, OHRP worked directly with a research institution to resolve a complaint about a surgeon performing experimental orthopedic surgeries without IRB approval. The research institution substantiated the complaint and required the surgeon to complete additional training and withdraw a publication about the research. OHRP accepted these corrective actions but never opened a compliance evaluation or issued a determination letter.

Exhibit 1: For-Cause Compliance Evaluations Conducted by OHRP by Close Year, 2000–2015



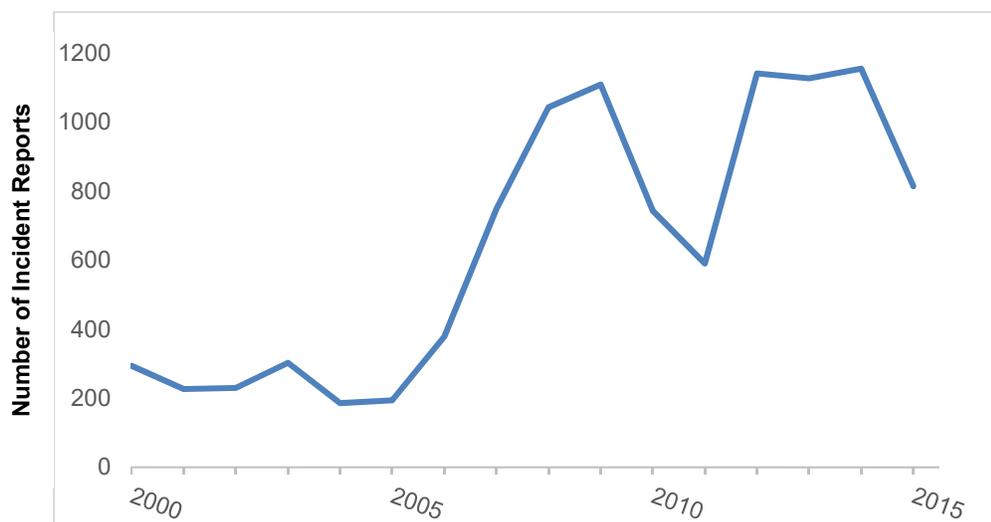
Source: OIG analysis of OHRP CATS data, 2016.

Finally, in addition to responding to allegations of noncompliance, OHRP responded to mandatory incident reports from institutions, which have nearly tripled since 2000 (see Exhibit 2 and Exhibit B-2 in Appendix B). Although OHRP reviewed several hundred of these each year, it decided

³⁰ The term “standard of care” refers to treatments that are commonly used in health care for a given type of disease or medical condition. Diseases and medical conditions may have multiple standards of care. Standard-of-care research aims to determine the more effective treatment by comparing treatments within the standards of care.

to initiate a compliance evaluation in response to an incident report in only a few cases, such as in cases involving the death of a human subject. OHRP said that the increased volume of incident reports might be the result of its issuing more guidance and education about incident reports to research institutions.

Exhibit 2: Number of Incident Reports Reviewed by OHRP by Close Year, 2000–2015



Source: OIG analysis of OHRP CATS data, 2016.

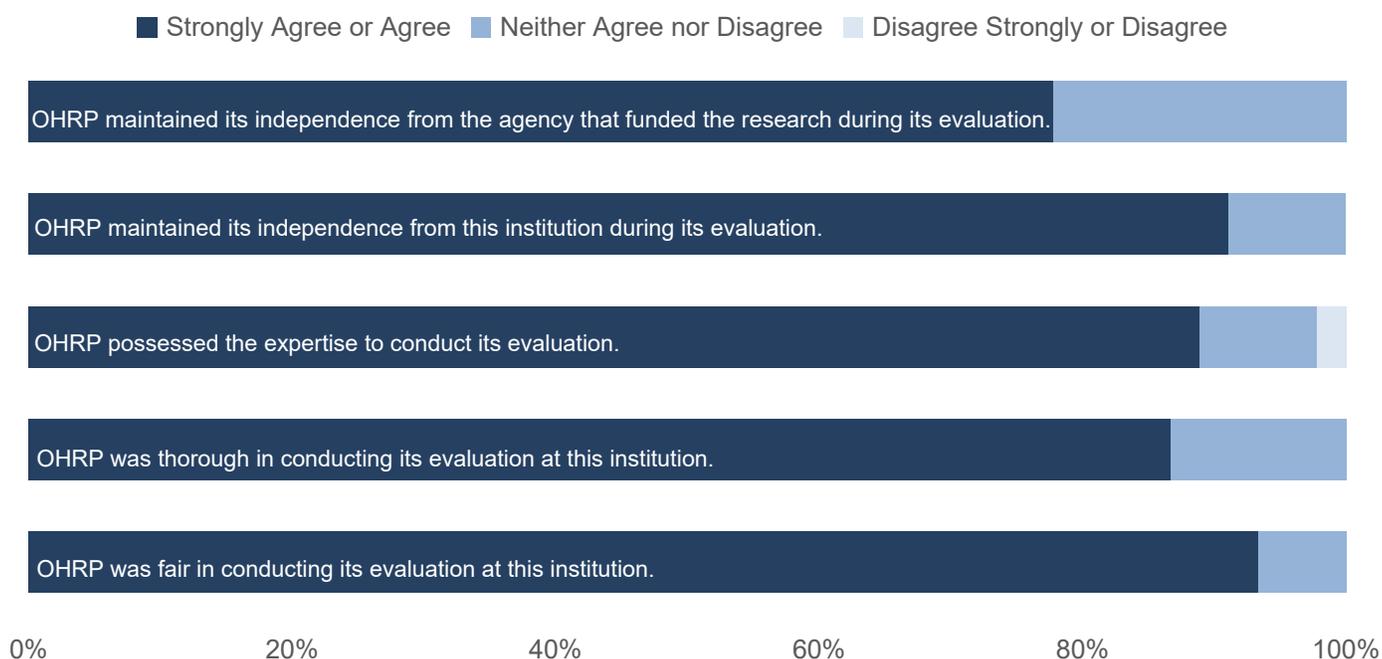
When OHRP initiated compliance evaluations, it determined the scope of the evaluations and what methods to employ

OHRP used its discretion to determine the scope of each compliance evaluation. For example, OHRP focused each evaluation on the compliance concerns specific to the allegation and research study. OHRP conveys the focus of its compliance evaluations in its initial inquiry letters to the respective research institutions, and it copied the corresponding HHS funding agency on these letters. This practice indicates that OHRP did not expect research institutions and HHS funding agencies to provide it with input regarding the scope and focus of its evaluations.

OHRP also used its discretion to determine what methods to employ in carrying out its compliance evaluations. OHRP can review records, conduct a site visit, or engage experts, among other methods, and OHRP selected methods according to the needs and priority of the evaluations. For example, site visits are resource-intensive, spanning 2 ½ days and involving four to six OHRP staff. OHRP reported that it conducts site visits for most of its not-for-cause evaluations, which are broad reviews of institutions’ systems of protections for human subjects. OHRP stated that

it conducts site visits during for-cause evaluations only if it has difficulty resolving the allegation. OHRP typically engages experts for its site visits. The experiences reported by research institutions that were the subjects of OHRP compliance evaluations support that OHRP conducted its evaluations independently. For example, no institutions disagreed with statements that OHRP maintained its independence from the agency that funded the research or the research institution itself. Furthermore, institutions agreed that OHRP possessed the necessary expertise and was thorough and fair in conducting its evaluations (see Exhibit 3).

Exhibit 3: Research Institution Responses to Statements About Working With OHRP



Source: OIG survey of research institutions that were the subjects of OHRP compliance evaluations between 2010 and 2015.

OHRP was able—with some delays—to access the information it needed to conduct its compliance evaluations

OHRP’s ability to obtain the information necessary to carry out its evaluations is critical for ensuring their quality and thoroughness, but also for supporting OHRP’s independence and effective oversight. If OHRP did not receive the full information it needed from those involved in the allegations, it may be vulnerable to producing biased results. OHRP reported that—with some delays—it received what it needed from HHS funding agencies and research institutions.

HHS funding agencies generally responded to OHRP's routine requests for information, such as requests for research protocols and informed-consent documents. OHRP said that HHS funding agencies sometimes took several months to respond to OHRP's request, which OHRP considered to be a delay, or directed OHRP to obtain information directly from the research institution. When OHRP faced these challenges, it continued to remind the funding agency of its request until it obtained the information it needed.

HHS funding agencies told us that working with OHRP during its compliance evaluations is a collaborative and positive experience. One agency reported that it provided answers to OHRP's questions about technical aspects of the research and the agency's procedures. Two HHS funding agencies reported that they accompanied OHRP onsite visits to research institutions. In these instances, the agencies reported that OHRP planned and led the site visit while the HHS funding agency staff observed and asked additional questions.

OHRP also reported that it faced few challenges in obtaining information from research institutions during its compliance evaluations. However, 5 of 45 research institutions that were the subjects of an OHRP compliance evaluation reported difficulties fulfilling OHRP's request for hard copies of documentation. These institutions reported that OHRP requested voluminous documentation and that it was a challenge to compile and send documents to OHRP. Research institutions reported that OHRP most commonly requested IRB documents, protocols, membership information, and meeting minutes, as well as approved informed-consent documents. One institution suggested that it would be more efficient to send OHRP the documentation electronically.

OHRP maintained its determinations, changing only 1 finding in 492 evaluations since 2000, a record consistent with operating independently

OHRP has almost always maintained its findings after conducting its compliance evaluations. After an evaluation, OHRP communicates its findings to the research institution in a determination letter, which is later made public on OHRP's website. A single determination letter often contains multiple findings. Since 2000, OHRP has conducted 492 compliance evaluations. OHRP told us that during this time it reversed only one finding after issuing a determination letter. In this instance, the research institution provided additional evidence that prompted OHRP's reversal.

OHRP also maintained its determinations when challenged. OHRP reported that out of its 492 compliance evaluations since 2000, 3 had

determinations that were challenged by some in the research community who encouraged OHRP to reverse its decisions. These determinations addressed broad policy issues, such as communicating risks in standard-of-care research and determining whether research is exempt from IRB review. In each of these cases, OHRP maintained its determinations, but revised its corrective actions. For example, in its determination regarding SUPPORT, OHRP suspended its call for corrective actions and instead committed to providing guidance on how to communicate risks to human subjects enrolled in research comparing different treatments within the standard of care.

However, certain factors may limit or appear to limit OHRP’s ability to operate independently

In considering OHRP’s independence, we also looked at the extent to which OHRP is able to decide how to fulfill its mission to protect human subjects. We considered potential risks of interference from other Federal agencies and from entities outside Government. We also considered how resources are allocated to OHRP and how this may affect its capacity to fulfill its mission.

Varying interpretations of OHRP’s role—whether it is oriented more toward enforcing compliance or toward setting broader policy—may limit OHRP’s ability to operate independently

The lack of agreement among stakeholders regarding OHRP’s role in enforcing protections for human subjects may undermine OHRP’s ability to act independently. OHRP bases its decisions and actions in part on how it defines its role in protecting human subjects. Likewise, stakeholder reactions to OHRP’s actions can depend on how those stakeholders perceive and interpret OHRP’s role. We found that the recent public discourse on the different interpretations of OHRP’s role may have prompted OHRP to act less decisively and more cautiously. As a result, OHRP may miss opportunities to take action that could further its mission to strengthen protections for human subjects.

In 2013, the varying interpretations of OHRP’s role played out publicly in a series of editorials, letters, and articles published in high-profile peer-reviewed medical journals. (See Appendix C for examples.) This discourse addressed OHRP’s determination in SUPPORT, which sparked controversy regarding how OHRP considered research risks that exceeded the specifics of that particular trial. For example, one article, coauthored by the director of NIH, documented not only NIH’s disagreement with OHRP on SUPPORT, but also NIH’s fundamental difference with OHRP

as to how the regulations should be interpreted.³¹ Likewise, others claimed that OHRP overreached in its conclusion that SUPPORT investigators violated Federal regulations.³² Conversely, some articles supported OHRP's determination and its role in clarifying regulations and guiding IRB decisions. For example, one article by physicians and bioethicists agreed with OHRP's determination by stating it was "justified and did not overreach."³³

The varying interpretations of OHRP's role can be represented along a continuum between a focus on enforcing compliance and shaping policy. (See Exhibit 4.) Stakeholders favoring OHRP's role in ensuring compliance emphasize that OHRP should react to allegations of noncompliance by confirming that institutions fulfill specific regulatory requirements, such as those for IRB membership and review of research.³⁴ This interpretation tends to view OHRP's monitoring of IRB operations as appropriate, but not OHRP's evaluating of IRB decisions.³⁵

In contrast, those favoring OHRP's role in shaping policy emphasize that OHRP should prevent violations of protections for human subjects by clarifying regulations and guiding IRBs in their decisions.³⁶ This interpretation may call for OHRP to review research protocols and informed-consent documents earlier, and it focuses more on prospective improvement.

³¹ Kathy L. Hudson, Alan E. Guttmacher, and Francis S. Collins, "In Support of SUPPORT—A View From the NIH." *The New England Journal of Medicine*, June 20, 2013. Accessed at <http://www.nejm.org/doi/full/10.1056/NEJMp1306986> on March 28, 2017.

³² Benjamin S. Wilfond et al., "The OHRP and SUPPORT." *The New England Journal of Medicine*, June 20, 2013. Accessed at <http://www.nejm.org/doi/full/10.1056/NEJMc1307008> on March 28, 2017.

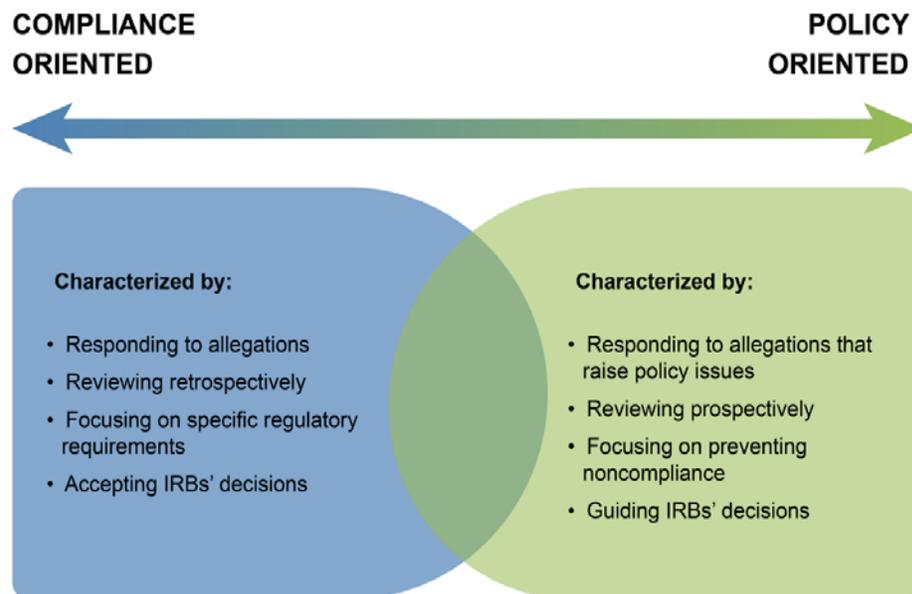
³³ Ruth Macklin et al., "The OHRP and SUPPORT—Another View." *The New England Journal of Medicine*, July 11, 2013. Accessed at <http://www.nejm.org/doi/full/10.1056/NEJMc1308015> on March 28, 2017.

³⁴ Benjamin S. Wilfond et al., "The OHRP and SUPPORT." *The New England Journal of Medicine*, June 20, 2013. Accessed at <http://www.nejm.org/doi/full/10.1056/NEJMc1307008> on March 28, 2017.

³⁵ Ruth Macklin et al., "Informed Consent and Standard of Care: What Must Be Disclosed." *The American Journal of Bioethics*, November 12, 2013. Accessed at <http://dx.doi.org/10.1080/15265161.2013.849303> on February 28, 2017.

³⁶ Daniel D. Federman et al., "Responsible Research: A Systems Approach to Protecting Research Participants." *National Academies Press*, 141-143, 2002. Accessed at https://www.ncbi.nlm.nih.gov/books/NBK43563/pdf/Bookshelf_NBK43563.pdf on March 27, 2017.

Exhibit 4: OHRP's Role: A Continuum of Interpretations



OHRP defines its role as more on the policy side of the continuum. OHRP sees its role as educational and its compliance evaluations as opportunities to strengthen human subjects protections in future research. Furthermore, OHRP told us that it is looking for opportunities to clarify regulations and to guide research institutions in their decisions earlier in the process, before they enroll human subjects in research.

However, OHRP appears to be less decisive in implementing this vision of its role. For example, in response to an incident report, rather than directly requesting documentation from NIH (such as research protocols and informed-consent documents) before human subjects were enrolled, OHRP went to OASH for permission to do so. As of April 2017, OHRP had yet to obtain this documentation. In another example, OHRP reported that it sent OASH its proposed response to an allegation for OASH's review because the study was controversial and NIH had not yet provided some of the information that OHRP requested. Lastly, some stakeholders told us that they thought OHRP may be hesitating to address certain policy issues in an attempt to avoid the type of controversy that its SUPPORT decision generated.

Finally, HHS's language describing OHRP's mission may contribute to the lack of agreement regarding OHRP's role. The HHS budget justification describes OHRP's mission as one that includes ensuring the interests of the research it oversees, while OHRP's stated mission focuses

solely on protecting human subjects involved in HHS research.^{37, 38} The differences in how OHRP's mission is described across HHS may influence stakeholder perceptions of OHRP's role.

OHRP's position in the HHS hierarchy and HHS's control over its resources may limit its ability to operate independently

OHRP is under the Assistant Secretary for Health, whereas the agencies that fund research—such as NIH—are directly under the Secretary of Health and Human Services. This means that OHRP is at a lower level in the HHS organizational hierarchy than the research-funding agencies and may face greater pressure in arguing its decisions because it does not have an equal voice with those agencies. In fact, OASH noted that OHRP, as a small agency, often “punches above its weight.”

Furthermore, HHS determines OHRP's resources. HHS allocates OHRP's annual budget from Congress's appropriations to HHS for general departmental management. This means that OHRP's budget is not directed by the Office of Management and Budget or by Congress. OHRP's budget has generally been flat, averaging about \$6.9 million annually since 2000. Currently, 4 staff in OHRP's Division of Compliance oversee more than 13,000 research institutions, whereas in previous years, as many as 8 staff fulfilled this role.³⁹ Meanwhile, the number of research grants that NIH awards is growing—from about 30,000 in fiscal year (FY) 2000 to 34,206 in FY 2015.^{40, 41} OHRP reported that in addition to its oversight, its priority has been finalizing revisions to the Common Rule, which means that its resources have been focused on this task. Some stakeholders and one research institution reported that they considered OHRP to be understaffed and underresourced. For example, a respondent from the research institution said that he “did not feel that OHRP has enough staff to fulfill its obligations.”

³⁷ HHS, *FY 2017 General Departmental Management: Justification of Estimates for Appropriations Committee*. Accessed at <http://www.hhs.gov/sites/default/files/fy2017-budget-justification-gdm.pdf> on April 5, 2017. “OHRP's mission is to assure that the well-being of volunteers is strongly protected and ensure that any harm, real or perceived, does not negatively impact the pool of volunteers for scientific studies and clinical research trials, delay the outcome of study results or prevent them altogether.”

³⁸ OHRP, *Education & Outreach*. Accessed at <https://www.hhs.gov/ohrp/education-and-outreach/index.html> on March 28, 2017.

³⁹ OHRP, *History: OHRP History*. Accessed at <http://www.hhs.gov/ohrp/about-ohrp/history/index.html> on March 28, 2017.

⁴⁰ NIH, *NIH Budget Summary*. Accessed at <http://archive.hhs.gov/budget/fy01budget/hhs2000.pdf>, on March 28, 2017.

⁴¹ HHS, *HHS FY2016 Budget in Brief*. Accessed at <https://www.hhs.gov/about/budget/budget-in-brief/nih/index.html>, on March 28, 2017.

OHRP’s practice of not reporting publicly on all of its compliance activities may give the appearance of limited oversight and independence

OHRP does not publicly report much of its oversight activity, which may make it appear to stakeholders and the public that OHRP plays a smaller role or is less active in protecting human subjects than it actually is. The decrease in determination letters over the years may increase stakeholders’ concerns that OHRP is being prevented from conducting evaluations. OHRP makes public only its final determination letters from its compliance evaluations, and these letters do not reflect the extent or breadth of OHRP’s compliance activities. OHRP also does not report publicly on the number of allegations it receives or on how it assesses these allegations to determine whether to initiate an evaluation.

Furthermore, stakeholders are likely unaware of OHRP’s increasing workload of incident reports. OHRP does not publicly report information on the volume of incident reports it receives (which has nearly tripled since 2000) or on how it assessed and responded to these reports. One stakeholder, whose institution submitted about 30 incident reports to OHRP each year, questioned the benefit of reporting and the extent to which OHRP reviews such reports. In fact, OHRP reviews each incident report and decided whether to obtain more information or to accept the research institution’s corrective actions. OHRP told us that it has considered posting this information publicly on its website; however, it has no timeline to do so and was concerned that the media might take the data out of context. OHRP recently published this information in a peer-reviewed journal.⁴²

⁴² Kemnique Ramnath, Sarita Cheaves, Lisa Buchanan, Kristina Borrer, and Marinna Banks-Shields, “Incident Reports and Corrective Actions Received by OHRP.” *IRB: Ethics & Human Research*, November-December 2016. Accessed at http://www.thehastingscenter.org/irb_article/incident-reports-corrective-actions-received-ohrp/ on March 28, 2017.

CONCLUSION AND RECOMMENDATIONS

OHRP plays an important role in the system for protecting human subjects by providing leadership in the protection of the rights, welfare, and well-being of volunteers involved in research supported or conducted by HHS. OHRP oversees a system that relies on IRBs and research institutions, as well as the funders of research, to protect human subjects through a review of the ethics and merits of any particular study. Given the potential for volunteers to experience risks, a robust oversight system is important in ensuring their protections. Congress requested that OIG make recommendations to strengthen protections for human subjects and to ensure OHRP's independence.

Because no law or mandate makes OHRP independent, its independence relies on a shared understanding across HHS that such independence is important for ensuring that human subjects are protected. OHRP does have latitude in how it operates, and its independence is apparent in its ability to decide how and when to respond to allegations of noncompliance. However, at a time when the research community must adjust to a revised Common Rule—its first major revision in 25 years—and research continues to evolve, stakeholders disagree on the fundamental scope of OHRP's oversight role. The differences in how OHRP's mission is described across HHS may contribute to this lack of agreement among stakeholders. In addition, OHRP's resources and placement in HHS can mean the office does not have an equal voice with the HHS agencies that fund research. These factors may affect OHRP's independence or the appearance of its independence.

Therefore, we have recommendations for both HHS and for OHRP:

HHS should address factors that may limit OHRP's ability to operate independently

In light of Congress's request to OIG for recommendations to ensure OHRP's independence, it is vital that there be a shared understanding across HHS that OHRP's independence contributes to a robust system of protections for human subjects. Absent that understanding and commitment to OHRP's independence, the office and its mission could be marginalized. Therefore, HHS should address the factors that limit or appear to limit OHRP's ability to operate independently. HHS could do this by:

- Issuing guidance that clarifies (for stakeholders and the public) OHRP's role;
- Evaluating OHRP's position within HHS, including (1) whether to place OHRP at the same hierarchical level within HHS as the

research agencies it oversees and (2) the potential advantages and disadvantages of such a change; and

- Evaluating the sufficiency of OHRP’s resources to carry out its mission and exploring with the Office of Management and Budget and congressional appropriators ways to elevate the prominence of OHRP’s budget—for example, by including it as a line item in the President’s budget.

Finally, HHS should consider seeking statutory authority for OHRP’s independence.

**OHRP should post the following on its website:
(a) a description of its approach to oversight and (b) data
(in aggregate) on the full array of its compliance activities**

This information would provide context for interpreting OHRP’s responses to allegations of noncompliance as well as provide more insights to OHRP’s role in receiving incident reports. OHRP should post information including, but not limited to, the numbers of allegations and incident reports it receives and data on its actions. OHRP could present these data in aggregate to mitigate any privacy or confidentiality concerns.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

OASH provided HHS's response and neither concurred nor nonconcurred with our recommendation that HHS should address factors that may limit OHRP's ability to operate independently. OASH said that HHS would consider our recommendation as part of a comprehensive review of HHS's structure and functions, known as "Reimagine HHS," which is underway and may identify revisions to OHRP's organizational location, mission, and budget.

OHRP concurred with our recommendation that it post a description of its approach to oversight and data (in aggregate) on the full array of its compliance activities. OHRP stated that it will post additional information on its website within the next few months regarding the full array of its compliance activities.

OIG supports OHRP's and OASH's efforts to enhance the system of protections for human subjects. OIG requests details on their efforts and the results of their efforts in its final management decision. We will monitor these efforts through our recommendations-tracking process.

For the full text of the comments received, see Appendix D.

APPENDIX A

Detailed Methodology

Scope

This study assessed the extent to which OHRP independently initiated, conducted, and made determinations about compliance evaluations between 2000 and 2015. To look for trends, we analyzed data provided by OHRP on allegations it received and compliance activities it conducted from January 1, 2000, through December 31, 2015. We did not assess the appropriateness of OHRP's responses to allegations or its determinations in its compliance evaluations.

OHRP Compliance Evaluation Data

We requested and obtained from OHRP all data on its compliance activities from its Compliance Activity Tracking System. 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. We conducted a trend analysis on OHRP's compliance activities for which allegations had been received and/or compliance activities had been opened or closed between January 1, 2000, and December 31, 2015. After consulting OHRP, we considered for-cause evaluations and activities categorized as "No Action" to represent allegations, because these are the two possible outcomes for each allegation that OHRP receives. We determined the number of allegations using the dates they were received. We determined the number of mandatory incident reports (from institutions), for-cause evaluations, and not-for-cause evaluations by year using the dates they were closed. We also determined the percentage of for-cause evaluations for each type of allegation source, such as research participant, researcher, or anonymous complainant. In addition, we requested and received from OHRP its budget and staffing data over this time period and analyzed the data for trends.

Survey of Research Institutions

OHRP provided us with the contact information for the current Signatory Officials at all institutions that had been subject to any OHRP compliance evaluation closed between January 1, 2010, through December 31, 2015. We administered an online survey to 48 research institutions between February 11, 2016, and March 22, 2016. We asked questions to learn about research institutions' experiences with OHRP and the extent to which they thought OHRP operated and made decisions independently during its respective evaluations. We analyzed survey responses by

categorizing and counting responses. We received responses from 45 institutions, a 94-percent response rate.

OHRP Files on Specific Compliance Evaluations

From our analysis of data from OHRP's compliance evaluations and responses to our survey of research institutions, we selected eight closed compliance evaluations that OHRP conducted between 2010 and 2015. We selected these evaluations on the basis of the type of compliance evaluation, the duration of the evaluation, the location of the research institution, the presence of involvement from the HHS agency funding the research, and the survey responses from research institutions. We requested and obtained from OHRP the administrative files for these compliance evaluations. OHRP also provided us with an open incident report to review. We reviewed files to learn how OHRP initiated and conducted its evaluations and how OHRP collaborated with relevant Federal entities and research institutions. We conducted this review at the OHRP offices in Rockville, MD.

Interviews

We conducted interviews by telephone or in person.

OHRP. We conducted structured onsite interviews with staff in OHRP's Compliance Division and in OHRP's Office of the Director to learn about how they responded to allegations of noncompliance and conducted compliance evaluations. We asked about the factors that contributed to the trends in OHRP's responses to allegations of noncompliance from 2000 through 2015. We also asked about OHRP's policies and procedures for its compliance evaluations and any challenges it faced in conducting such evaluations independently. In addition, we asked how OHRP worked with relevant Federal Government entities and research institutions during their compliance evaluations and other activities.

Relevant Government entities. We conducted nine structured interviews with representatives from relevant HHS entities (e.g., NIH, FDA, OASH, and the Office of Research Integrity) to learn about OHRP's interactions with these entities. We reviewed selected administrative files of OHRP compliance activities to identify representatives of relevant Government entities that had direct involvement with a compliance evaluation. We interviewed multiple representatives from NIH, including its policy divisions (e.g., its Office of Science Policy) and two NIH institutes. We asked about policies and procedures for working with OHRP and the extent to which the representatives were involved with OHRP's compliance evaluations. We also asked about challenges these entities faced during OHRP's compliance evaluations and whether OHRP

operated independently or made decisions independently during evaluations. We had a 100-percent response rate to our request for interviews.

Individuals with expertise in human subjects protections. We conducted structured interviews with five individuals with expertise in human subjects protections. We identified these five individuals through research, literature, and individual recommendations. They represented a patient advocacy group, a teaching hospital, and research institutions. We asked about OHRP's independence and compliance activities and about opportunities to enhance protections for human subjects in future research.

Prior OIG Work

We reviewed our memorandum report, *The Office for Human Research Protections' Evaluation of the Surfactant, Positive Pressure, and Oxygenation Randomized Trial* (OEI-01-14-00560), issued in September 2014. This OIG work (discussed on page 5) evaluated the extent to which OHRP followed its procedures during the for-cause evaluation of SUPPORT.

APPENDIX B

Trends in OHRP Compliance Activity Data from 2000 to 2015

Exhibit B-1: Allegations OHRP Received From 2000 to 2015

Year Received	Total Allegations	Allegations For Which OHRP Initiated a Compliance Evaluation	Allegations For Which OHRP Did Not Initiate a Compliance Evaluation
2000	147	91	56
2001	112	42	70
2002	109	30	79
2003	119	32	87
2004	119	18	101
2005	154	43	111
2006	121	16	105
2007	128	15	113
2008	99	9	90
2009	135	5	130
2010	146	8	138
2011	125	7	118
2012	126	8	118
2013	134	3	131
2014	142	5	137
2015	54	6	48

Source: OIG analysis of OHRP CATS data, 2016.

Exhibit B-2: OHRP Compliance Evaluations and Incident Reports from 2000 to 2015

Year Closed	For-Cause Compliance Evaluations	Not-For-Cause Compliance Evaluations	Mandatory Incident Reports From Institutions
2000	60	0	294
2001	86	0	227
2002	94	1	230
2003	36	3	303
2004	36	4	186
2005	14	4	194
2006	48	1	379
2007	11	4	749
2008	18	4	1044
2009	11	3	1110
2010	6	6	744
2011	8	3	591
2012	7	5	1142
2013	4	2	1128
2014	4	4	1156
2015	3	2	815

Source: OIG analysis of OHRP CATS data, 2016.

APPENDIX C

Examples of Editorials, Letters, and Articles Responding to OHRP's Determination in SUPPORT, in Chronological Order

1. Jeffrey M. Drazen, Caren G. Solomon, and Michael F. Greene, "Informed Consent and SUPPORT." *The New England Journal of Medicine*, May 16, 2013. Accessed at <http://www.nejm.org/doi/full/10.1056/NEJMe1304996> on March 28, 2017.
2. David Magnus and Arthur L. Caplan, "Risk, Consent, and SUPPORT." *The New England Journal of Medicine*, May 16, 2013. Accessed at <http://www.nejm.org/doi/full/10.1056/NEJMp1305086> on March 28, 2017.
3. Michael Carome and Sidney Wolfe, "Public Citizen: The SUPPORT Study Was Even Worse Than We Thought." *The Hastings Center*, May 21, 2013. Accessed at <http://www.thehastingscenter.org/public-citizen-the-support-study-was-even-worse-than-we-thought/> on June 15, 2017.
4. Sidney Wolfe, "The SUPPORT Study and the Standard of Care." *The Hastings Center*, May 21, 2013. Accessed at <http://www.thehastingscenter.org/the-support-study-and-the-standard-of-care/> on May 30, 2017.
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10. "Subject to Question." *Nature*, August 22, 2013. Accessed at http://www.nature.com/polopoly_fs/1.13573!/menu/main/topColumns/topLeftColumn/pdf/500377a.pdf on June 15, 2017.
11. Elliott M. Weiss and Steven Joffe, "Promoting Informed Decision Making for Comparative Effectiveness Randomized Trials." *Journal of the American Medical Association*, September 2015. Accessed at <http://archpedi.jamanetwork.com.ezproxyhhs.nihlibrary.nih.gov/article.aspx?articleid=2344552> on April 4, 2017. [Note: This link works only for HHS users.]
12. Jeffrey M. Drazen, Caren G. Solomon, Stephen Morrissey, and Michael F. Greene, "Support for SUPPORT." *The New England Journal of*

- Medicine*, October 8, 2015. Accessed at <http://www.nejm.org/doi/full/10.1056/NEJMe1511158> on March 28, 2017.
13. Clyde J. Wright and Ola D. Saugstad, "OHRP and SUPPORT: Lessons in Balancing Safety and Improving the Way We Care for Patients." *Journal of Pediatrics*, November 2013. Accessed at <http://dx.doi.org/10.1016/j.jpeds.2013.08.061> on March 28, 2017.
 14. Gregory E. Kaebnick, "Ongoing Controversy Over SUPPORT." *The Hastings Center*, January 19, 2015. Accessed at <http://onlinelibrary.wiley.com/doi/10.1002/hast.405/full> on May 30, 2017.
 15. Chana A. Sacks and Celestine E. Warren, "Foreseeable Risks? Informed Consent for Studies within the Standard of Care." *The New England Journal of Medicine*, January 22, 2015. Accessed at <http://www.nejm.org/doi/full/10.1056/NEJMp1415113> on March 28, 2017.
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APPENDIX D

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

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

JUN 13 2017

TO: Daniel R. Levinson
Inspector General

FROM: Acting Assistant Secretary for Health

SUBJECT: *OIG Report OHRP Generally Conducted Its Compliance Activities Independently, But Changes Would Strengthen Its Independence*, OEI-01-15-00350

Thank you for the opportunity to provide responses to the report "OHRP Generally Conducted Its Compliance Activities Independently, But Changes Would Strengthen Its Independence." Below are our responses to the report's recommendations:

Response to HHS Recommendations

At the direction of the President, Secretary Price has initiated a comprehensive review of all of HHS' structures and functions, through the "Reimagine HHS" process now under way. The organizational location and mission of OHRP may well be identified for revision as a result of that process, and this would in turn carry budget implications. HHS appreciates OIG's suggestion and will consider this as "Reimagine HHS" advances of the next few months.

Response to OHRP Recommendations

- Whether your agency concurs with the recommendation. **We concur**
- For concurrences, please describe:
 - the specific actions, if known, that your agency proposes to take; **OHRP proposes to post additional information on our website regarding the range of compliance oversight activities we perform (alternatives to opening cases, incident report metrics, numbers of allegations received).**
 - if your agency proposes to take alternative actions to those recommended, the reason it believes those actions are preferable; and
 - a draft timeline for any actions, if available. **We will post this information within the next few months.**

If you have any questions please contact Dr. Kristina Borrer, Director, Division of Compliance Oversight, Office for Human Research Protections, Office of the Assistant Secretary for Health at kristina.borrer@hhs.gov.

Don Wright MD MPH

Don Wright, M.D., M.P.H.

cc: Suzanne Murrin
Melicia Seay

U.S. Public Health Service

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Office of Inspector General

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