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The Need for Whistleblower Protections at the Office for Human Research Protections

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According to a recent investigative report by the Department of Health and Human Services (HHS) Office of Inspector General (OIG), employees' fear of reprisal may limit the Office of Human Research Protections' (OHRP) ability to enforce protections for human subjects at research institutions with HHS-funded grants or contracts.

OHRP is charged with responding to "requests for clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects[.]" 42 U.S.C. § 289(b)(1). In that role, OHRP routinely receives and responds to allegations of noncompliance with human subjects protections such as researchers' failure to adequately obtain informed consent. These allegations are the primary mode by which OHRP learns about potential violations of HHR regulations. As the report notes, employees of research institutions can be especially informative sources because they have "insider knowledge of the circumstances [and] can help identify noncompliance . . . earlier than other complainants or OHRP oversight activities."

When OHRP identifies an instance of noncompliance, it is authorized to take a variety of enforcement actions, including requiring a research institution, itself, to take corrective action; restricting or suspending research at the noncompliant institution; and recommending that the institution be debarred from receiving federal research funds. But these procedures cannot be set in motion if employees decline to come forward out of fear of reprisal from their employers.

Under existing law, employees of research institutions with HHS-funded grants or contracts are entitled to whistleblower protections for disclosing suspected noncompliance to only a handful of statutorily-enumerated entities, including the OIG; an official of the relevant grant-awarding agency, such as the National Institutes of Health (NIH); and an employee of the research institution responsible for investigating misconduct. 41 U.S.C. § 4712(a)(2). Notably, employees are not entitled to whistleblower protections for disclosing suspected noncompliance directly to OHRP.

As the report reveals, this gap in protection may seriously hamper OHRP's effectiveness. OHRP often receives requests for whistleblower protections from prospective complainants and, once informed they would not be entitled to such protections, some of them decline to proceed. Of five closed OHRP compliance evaluations reviewed by OIG, four showed evidence of fear of reprisal.

To mitigate employees' fear of reprisal and thereby encourage them to report suspected violations, the report recommends that OHRP better inform potential complainants about how to obtain whistleblower protections. For example, OHRP could post on its website information regarding which entities are authorized to receive protected disclosures and include such information in its routine outreach to research institutions.

More importantly, the report also recommends that HHS "consider the adequacy of whistleblower protections for complainants who make disclosures to OHRP about human subjects protections." Specifically, the report recommends that HHS consider pursuing legislative changes authorizing OHRP

and other HHS entities not responsible for contract or grant oversight management to receive protected disclosures. This is by far the stronger recommendation.

It makes sense that the OIG report recommends a change that would protect disclosures to OHRP and HHS entities that do not oversee grants and contracts because that is the only way to preserve the independence of compliance review. HHS has long acknowledged the potential conflict between OHRP's compliance function and the grant-awarding functions of entities like NIH. In 2000, it relocated OHRP from the Office of the Director of NIH to the Office of the Secretary of HHS in an effort to strengthen OHRP's investigatory independence by "minimiz[ing] 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." Indeed maintaining separation between OHRP evaluations and NIH funding decisions helps ensure the integrity of OHRP's compliance function by eliminating an institution's need for funding as a factor in enforcement decisions.

Maintaining that separation is also critical to the willingness of researchers to report suspected violations of human subjects protections. Researchers understandably would be loath to "bite the hand that feeds them" by reporting suspected violations of protections for human subjects to the entities funding their research. Requiring them to do so to obtain whistleblower protections ignores the obvious disincentives the Department has itself acknowledged and jeopardizes the effectiveness of OHRP's compliance function. The OIG's recommended legislative fix would alleviate this problem. Although Congressional intransigence remains an impediment to any legislative action, legislation granting employees whistleblower protections for disclosures made directly to OHRP is the best way to bolster the Office's effectiveness and, ultimately, protect the rights of human subjects.