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Testimony before the Secretary's Advisory Committee on Human Research Protections Regarding the July 2017 Office of Inspector General Report, *OHRP Generally Conducted its Compliance Activities Independently, but Changes Would Strengthen its Independence*

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The July 2017 report from the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG)[1] revealed that the Office for Human Research Protections' (OHRP's) enforcement of regulations for the protection of human subjects has literally become moribund.

OHRP's compliance oversight procedures

OHRP has long-standing written procedures, last updated in 2009, for its compliance evaluations.[2] The procedures for for-cause compliance investigations begin by stating that "[f]or-cause evaluations occur, at *OHRP's discretion*, in response to OHRP's receipt of substantive written allegations or indications of non-compliance with the HHS regulations." They further note that the agency "may choose to use other mechanisms to address allegations or indications of noncompliance rather than conducting a for-cause evaluation."

The public reasonably expects that OHRP will exercise such enforcement discretion judiciously and that the use of other mechanisms to address substantive allegations or indications of noncompliance will be the exception, not the rule.

Importantly, OHRP's written procedures for conducting for-cause compliance evaluations include provisions to ensure the transparency of the agency's enforcement activities for complainants, institutions, and the public, including the following:

- Notifying complainants as to whether OHRP will open a compliance evaluation of the allegations raised
- Upon completion of an evaluation, informing the complainant in writing of OHRP's determinations and any corrective actions taken by the institution

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[1] Department of Health and Human Services Office of Inspector General. OHRP Generally Conducted Its Compliance Activities Independently, but Changes Would Strengthen Its Independence. July 2017. https://oig.hhs.gov/oei/reports/oei-01-15-00350.pdf. Accessed July 9, 2018.

[2] Office for Human Research Protections. Compliance oversight procedures for evaluating institutions (2009). October 14, 2009. https://www.hhs.gov/ohrp/compliance-and-reporting/evaluating-institutions/index.html. Accessed January 26, 2018.

- Posting on the agency's website each determination letter no later than 10 business days after the letter is issued to the institution
- Once a compliance oversight evaluation is closed, making available upon request under the Freedom of Information Act all documents related to the evaluation

OHRP's written compliance procedures also stipulate an appeals mechanism under which a complainant (or institution) may request that the OHRP Director reconsider any determinations from a for-cause compliance oversight evaluation.

The OIG report's findings

The most striking observation presented in the OIG's July 2017 report was the steep decline in the rate at which OHRP has initiated formal for-cause compliance evaluations in response to allegations of noncompliance since 2000. For the four-year period from 2000 to 2003, the agency received a total of 487 allegations and initiated for-cause compliance evaluations for 195 (40 percent) of these. In contrast, for the four-year period from 2012 to 2015, OHRP received 456 allegations but initiated for-cause compliance investigations for only 22 (5 percent) of these.

Although this dramatic falloff is due partially to an erosion of resources as well as an increase in the proportion of allegations that are related to research deemed to be outside of OHRP's jurisdiction, much of the decline clearly reflects a fundamental — and troubling — change in how OHRP approaches its enforcement of the HHS human subjects protection regulations.

Indeed, OHRP explained to the OIG that "it decided over the years to initiate fewer [for-cause] compliance evaluations both to better leverage its limited resources and to focus the evaluations on broad policy issues in protections for human subjects." This explanation is disturbing for two reasons. First, deciding whether to open a formal for-cause compliance evaluation based on whether a particular allegation raises "broad policy issues" enshrines an approach to enforcement that by its very nature is arbitrary and capricious. In particular, the public, complainants, and other stakeholders do not know when or on what basis OHRP has decided which policy issues are broad enough and of sufficient interest to use as a litmus test for deciding whether a particular substantive allegation warrants a for-cause compliance evaluation. Nor do they know which broad policy issues OHRP is using to make these decisions at any particular time or whether the agency is applying them consistently and fairly.

Second, many substantive allegations of noncompliance do not raise broad policy issues but nevertheless often constitute the most serious types of noncompliance with the HHS human subjects protection regulations — such as conducting non-exempt human subjects research without appropriate review and approval by an institutional review board or without the informed consent of the human subjects. In such cases where the potential for harm to the rights and welfare of human subjects is greatest, there is no sound basis for bypassing OHRP's written procedures for conducting formal for-cause compliance evaluations.

The OIG report revealed that OHRP is abusing its discretion when deciding whether to initiate formal for-cause compliance evaluations of substantive written allegations. Use of "other mechanisms" has become the rule rather than the exception for OHRP's approach to addressing

substantive allegations of noncompliance, effectively eclipsing the agency's procedures for conducting formal for-cause compliance evaluations. As a result, OHRP has undermined the integrity of its enforcement activities.

For example, by routinely using "other mechanisms" to address substantive allegations, OHRP and the institutions that conduct research in violation of regulations escape public scrutiny. Complainants are kept in the dark about the outcome of the agency's review, and determination letters describing regulatory violations and any corrective actions taken by institutions are not written by OHRP or made publicly available on the OHRP website, even in circumstances where serious allegations of noncompliance are confirmed. Complainants also apparently are deprived of the right to appeal to the OHRP director the agency's determinations in most compliance matters.

Most importantly, OHRP has signaled to the research community, with this lax approach, that there is little chance that the agency will formally investigate allegations of even serious regulatory violations. Indeed, since October 2016, OHRP has issued only a single compliance oversight determination letter, and that letter appears to have resulted from a not-for-cause compliance oversight evaluation.[3] This dearth of compliance oversight activity demonstrates that OHRP has become a paper tiger when it comes to addressing allegations of noncompliance and properly enforcing the HHS regulations for the protection of human subjects.

Public Citizen urges the Secretary's Advisory Committee on Human Research Protections to demand that OHRP cease abusing its discretion when deciding whether to initiate formal for-cause evaluations in response to substantive allegations or indications of noncompliance with the HHS regulations for the protection of human subjects.

[3] Office for Human Research Protections. Letter to the Fred Hutchinson Cancer Research Center. December 1, 2017. https://www.hhs.gov/ohrp/december-1-2017-fred-hutchinson-cancer-research-center.html. Accessed January 26, 2018.