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HHS OIG Issues Self-Disclosure Program Guidance for Research Grants and Contracts

Universities, academic medical centers, companies and other recipients and sub-recipients of federal biomedical and basic research funds are under increased scrutiny and facing stiffer penalties for fraud and other improper conduct in connection with grants, contracts and other agreements. Recently, the Office of Inspector General (“OIG”) of the Department of Health and Human Services issued guidance on mandatory and voluntary self-disclosure actions, the *HHS OIG Grantee Self-Disclosure Program*, which gives specific expectations and processes for reporting. This is important for awardees to consider carefully as they assess and remediate grant compliance problems.

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Under the 21st Century Cures Act, OIG gained new authorities under the Civil Monetary Penalties Law (“CMP”), at [42 U.S.C. §§ 1320a-7a\(o\)\(1\)-\(5\)](#), including for false or fraudulent claims, as well as for making or causing to be made false statements, omissions, or misrepresentations of material facts in connection with applications and funded awards. OIG sanctions include civil monetary penalties, assessments, and exclusion from receipt of federal funds or participation in federal health care programs. Fines under the law can include penalties in the amount of \$0 to \$10,000 or \$50,000 per individual offense or \$10,000 for each day certain offenses are concealed, depending on the circumstances, and additional damages of up to three times the government’s actual losses for some claims. OIG may also exercise its administrative federal health care program exclusion authority, which is often the more significant threat to awardees’ operations.

Applicants, awardees and sub-awardees are obligated to self-disclose to OIG, and separately to the HHS funding component, certain conduct involving criminal offenses. Reporting is required for violations or potential violations of criminal laws relating to fraud, bribery or gratuity violations involving a research award. HHS grant regulations at 45 CFR 75.113 identify the offenses for which mandatory disclosure is required.

Voluntary disclosure to OIG is available for other activities and offers the prospect of direct benefit to the discloser. Reporting to OIG is voluntary for violations or potential violations of the CMP law and any other conduct that may violate civil or administrative law that is not included within the scope of offenses listed at 45 CFR 75.113.

Several benefits may attach to voluntary disclosure, which is common in other areas over which OIG has authority, such as Medicare or Medicaid fraud. These benefits include lower penalties, often half or two-thirds of the treble damages OIG is authorized to seek. They also include a presumption against an integrity agreement (and its increased compliance, auditing and disclosure duties) in exchange for OIG’s releasing its exclusion authority, and the prospect of a coordination to assist in a global settlement of any related claims with the Department of Justice and the HHS funder, e.g., for potential False Claims Act and criminal claims.

Before making a disclosure and after a reportable event is identified, OIG expects the discloser to investigate and assess potential government losses, undertake corrective action, and prepare a written report in accord with the requirements set forth in the *Grantee Self-Disclosure* guidance, and the checklist OIG provides with it. Disclosures should include:

- Descriptions of the recipient and the disclosing party, the award or awards at issue, the funding agency or agencies, including whether disclosure has been or will be made to them and the names of grant officers, and the funds involved, including costs to the government and methodology for determining them.

- A description of the conduct at issue and corrective actions taken, with specifics relating to who, what, when and where, as well as the criminal, civil or administrative laws potentially violated. This should include any known investigations or inquiries into the matter from other federal, state or local government agencies, with contact information for those agencies where applicable.
- A list of all federal agencies providing any support to the discloser.
- The name of an individual authorized to enter into a settlement agreement on behalf of the discloser and a certification by the discloser, or his or her authorized representative, that the disclosure “contains truthful information and is based on a good faith effort to bring the matter” to the OIG.

After disclosure, OIG seeks to resolve most cases through a negotiated settlement with the discloser. All self-disclosures of course should be complete and thorough, which, in some cases, may require independent assessment or verification of findings.

The decision to make a voluntary self-disclosure involves legal and business risks requiring careful fact-finding and analysis. At present, OIG’s grantee self-disclosure website lists three grantee self-disclosure settlements, beginning in December 2018 and most recently in June 2019. *See* Grantee Self-Disclosure Settlements, <https://oig.hhs.gov/fraud/enforcement/cmp/grantee.asp>. Risk-benefit evaluation for voluntary disclosure will be informed by more settlements as they become public over time.

The *HHS OIG Grantee Self-Disclosure Program* is available here: <https://oig.hhs.gov/compliance/self-disclosure-info/grant.asp>.