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Fraud and abuse risks associated with research misconduct

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Research misconduct proceedings focus primarily on fabrication, falsification, and plagiarism in scientific and medical research; research practices that seriously deviate from commonly accepted methods within the relevant scientific community may also yield research misconduct concerns. (Honest errors or differences in interpreting data do not constitute research misconduct. Research is not limited to published data; it also includes proposing, conducting, and recording research.)

The institution receiving a federal research grant is the grantee of those public health service grant funds and has legal and financial accountability for those awards.[1] Grantee institutions are obliged to assure that their researchers produce accurate supporting data for funded programs and grant applications.[2] In addition to the U.S. Department of Health & Human Services, other federal agencies may distribute research grants; for these grants, grantee obligations are substantially identical.

Grantee institutions are required to have policies in compliance with federal guidelines as a condition of applying for and accepting any award.[3] Research misconduct inquiries and investigations are usually conducted using institutional procedures. If public health service funds are involved, institutional findings will be forwarded to the Office of Research Integrity (ORI) for evaluation and possible imposition of additional sanctions. (Public Health Service grant misconduct is overseen by the ORI; misconduct associated with the National Science Foundation-funded research is the responsibility of the National Science Foundation Office of Inspector General.) Upon determination that research misconduct has occurred, ORI typically issues administrative sanctions, such as debarment from federally funded research, supervision requirements, and/or retractions of compromised data and publications.

Where there is evidence of civil or criminal fraud, ORI must promptly relay those allegations to the U.S. Department of Justice, the Office of Inspector General, or other investigative bodies. A few recent cases have demonstrated that research misconduct may implicate potential violations of fraud, waste, and abuse laws and regulations.

The Physician Self-Referral Law (Stark Law)

The Stark Law[4] prohibits a physician from making a referral of a Medicare/Medicaid patient for designated health services to an entity that furnishes those designated health services if the physician (or immediate family member) has a financial relationship with the entity. Exceptions have been formulated to allow for certain financial relationships; these exceptions must be followed exactly to apply. The Stark Law is a strict liability law; Stark does not require intent as part of the foundation of a Stark Law violation.[5]

While research misconduct cases grounded in Stark Law risks are not as common as those founded in other fraud,

waste, and abuse laws, there may be issues when the research relationship creates a financial relationship between the physician-researcher and an entity with which the physician-researcher has a Medicare patient referral relationship.

Certain practices may assist in alleviating these risks. For example, prior to conducting any research or receiving payments related to the research, research clinicians not employed by the grantee institution should have a valid agreement with the institution, in which the basis for research-related compensation is clearly defined, reflects reasonable compensation, documents responsibilities, sets compensation prior to beginning the research, and specifies any required documentation (such as time sheets or activity logs). Personal services or other agreements for research work conducted by physician-researchers should emphasize that payments are not related to factors such as research outcomes, quantity of tests ordered, referrals of the research-physician's patients, or the number of subjects recruited for the study.