Recent cases spotlight research misconduct in clinical research

July 14, 2017

Research misconduct and fraud in the context of clinical research is an area of compliance that many health care organizations do not have a good handle on. Even health care organizations with robust compliance programs may not put many resources into clinical research compliance and often have no idea what their organizations are doing when it comes to clinical research. A couple of recent high-profile cases are shining a light on this often-neglected area of compliance.

In United States of America ex rel. Joseph M. Thomas v. Duke University, et. al., a North Carolina federal judge refused to dismiss a lawsuit that accuses Duke University (Duke) and some of its faculty of knowingly falsifying medical research data in order to get federal grants. The lawsuit—brought under the federal False Claims Act (FCA) by a former lab analyst in Duke's pulmonary division (the whistleblower)—alleges that Erin Potts-Kan, a former Duke researcher within the same pulmonary division as the whistleblower, manipulated data gathered from machines that researchers use to test lung function of mice to study respiratory ailments. Potts-Kan then used the data and accompanying research articles to fraudulently secure an additional $200 million in research grants from the federal government. In addition, the lawsuit alleges that the whistleblower's supervisor ignored warnings of research misconduct. With the judge refusing to dismiss the lawsuit, it is set to move forward, and Duke faces potential liability of up to $600 million (the FCA provides for treble damages) if Duke is found to have submitted false claims or statements in order to secure the federal grant funds.

In another recent research misconduct case, on April 27, 2017, the U.S. Attorney's Office announced that Partners HealthCare System and one of its hospitals, Brigham and Women's Hospital (collectively, Brigham), agreed to pay $10 million to resolve allegations that a Brigham stem cell research laboratory run by Dr. Piero Anversa fraudulently obtained grant funding from the National Institutes of Health (NIH). The settlement was the result of a self-disclosure to the government wherein Brigham voluntarily disclosed that its researchers failed to follow protocol, fabricated data and images, and submitted misleading data in NIH research grants and in publications. Even with self-disclosure, this research misconduct cost Brigham $10 million, highlighting the potential exposure and liability for health care providers whose compliance programs are not overseeing the clinical research that is going on it their facilities.

These research misconduct cases are just two examples of the potential risks associated with the types of clinical research activities that are taking place in hospitals and other health care organizations every day. In order to mitigate such risks, organizations with clinical research programs should include clinical research compliance in their compliance programs and take steps to:

- Identify the types of clinical research being conducted within the organization.
- Create a process for tracking all clinical research being conducted within the organization and establish a single point of entry for new clinical research studies.
- Develop and monitor compliance with operational policies and procedures for the conduct of clinical research in the organization and for preventing and detecting research misconduct and fraud.
- Ensure that personnel involved in research compliance are aware of the ways to report suspected research misconduct internally to the organization's compliance program.
- Have internal control and review mechanisms for monitoring the ethical and quality aspects of ongoing clinical research

studies.

- Identify the role of the IRB at the organization in safeguarding interests of clinical research participants and, as necessary, strengthen that role to improve human subject protections.
- Train investigators and other researchers regarding the potential harm and potential liability for the researcher and the organization related to research misconduct.

Authors