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Complete Healthcare Compliance Manual 2024
Clinical Research: Research Misconduct

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What Is Research Misconduct in Clinical Research?

Research misconduct (sometimes called scientific misconduct) is one of several behaviors related to research activities that are generally considered to be unethical or dishonest. Most people learn early in life that these behaviors are unacceptable. Nevertheless, rules exist to draw a distinct line separating allowable research behavior from research misconduct.

Research misconduct is limited to the following three behaviors: (1) fabrication, (2) falsification, and (3) plagiarism. There are many other unethical or incorrect behaviors that a researcher may engage in, such as noncompliance with research protocols or failing to disclose a significant financial interest with a research sponsor. These and many other fraudulent behaviors, however, are dealt with through other regulatory or administrative mechanisms. The following is a closer look at the three specific behaviors of research misconduct.

Fabrication is making up data or results and, subsequently, recording or reporting them. Fabrication is perhaps the most serious form of research misconduct because it is outright deception—the results are conjured up from the deceiver's imagination. It is science fiction posing as fact because the empirical work from which results have been reported either (1) was never conducted or (2) bore out results that were contrary to and replaced by those reported.

Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record. Falsification is similar to fabrication inasmuch as it is a form of deliberate deception, but different in its magnitude and often its subtlety. For example, a study that yields merely promising results can be made to look like a major breakthrough by selectively removing data points that are not consistent with the desired outcome—an act of falsification.

Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. Plagiarism differs from fabrication or falsification in that results or reports may be entirely accurate and true, except for the matter of who actually did the work. Plagiarism is a deception and more; the plagiarist commits a form of theft by taking credit for the work of others.[2]

There are any number of reasons why research misconduct might occur, but some of the most common motivators are pressure to publish or the desire for professional recognition or money. Another reason for misconduct may come from failures at the site level, such as lack of resources, staff turnover, lack of training, or absence of policies and procedures that should be in place to protect both the institution and the researchers.

It is important to remember that research misconduct is narrowly defined. It does not include honest differences of opinion among scientists, inadvertent errors, or disputes about the order of appearance in a list of authors' names. Likewise, the use of sloppy research techniques or suboptimal record keeping, even the republishing of an author's original or collaborative work (so-called "self-plagiarism"), are not considered instances of research misconduct. These activities, however, do represent inappropriate and sometimes unethical behavior,

and institutions may choose to develop policies or procedures that address these behaviors, although they are not under the purview of the federal Office of Research Integrity (ORI).[3]

The ORI oversees and directs research integrity activities of the U.S. Public Health Service (PHS) on behalf of the Secretary of the U.S. Department of Health & Human Services (HHS), with the one exception: the regulatory research integrity activities of the U.S. Food and Drug Administration (FDA). Organizationally, the ORI is located within the Office of the Assistant Secretary for Health (OASH), which is in Office of the Secretary of Health and Human Services (OS) in HHS.[4] According to its website,

> ORI carries out its responsibilities by:
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> - developing policies, procedures and regulations related to the detection, investigation, and prevention of research misconduct and the responsible conduct of research;
> - reviewing and monitoring research misconduct investigations conducted by applicant and awardee institutions, intramural research programs, and the Office of Inspector General in the Department of Health and Human Services (HHS);
> - recommending research misconduct findings and administrative actions to the Assistant Secretary for Health for decision, subject to appeal;
> - assisting the Office of the General Counsel (OGC) to present cases before the HHS Departmental Appeals Board;
> - providing technical assistance to institutions that respond to allegations of research misconduct;
> - implementing activities and programs to teach the responsible conduct of research, promote research integrity, prevent research misconduct, and improve the handling of allegations of research misconduct;
> - conducting policy analyses, evaluations and research to build the knowledge base in research misconduct, research integrity, and prevention and to improve HHS research integrity policies and procedures;
> - administering programs for: maintaining institutional assurances, responding to allegations of retaliation against whistleblowers, approving intramural and extramural policies and procedures, and responding to Freedom of Information Act and Privacy Act requests.[5]

A **finding of research misconduct** requires that:

1. A significant departure from accepted practices of the relevant research community occurred;
2. The misconduct was committed intentionally, knowingly, or recklessly; and
3. The allegation be proven by a preponderance of the evidence.[6]

A robust research compliance program is certainly a key to keeping an institution educated, trained, and on the lookout for any signs of impending research misconduct. Such a program will have policies and procedures ready to identify and manage any allegations of research misconduct, if they arise. Also, the program will have a designated research integrity officer (RIO) to carry out any necessary inquiries and investigations. Each of these aspects of a robust program will be described in greater detail.