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The Slippery Slope into Research Misconduct: Research Records

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Introduction

When we think of research misconduct, what generally comes to mind are the biggest cases: Wakefield (MMR and autism), Hwang (production of human embryonic stem cells) and Croce (cancer). These cases resulted in newspaper headlines, a multitude of retractions and likely other sanctions that were not reported. But even seemingly innocuous practices may result in research misconduct allegations that create, at best, an inconvenient disruption and, at worst, an actual finding of research misconduct that can lead to career-ending consequences. In the hurried, fast-paced world of clinical and translational research, it is easy to make a mistake or take a "harmless" shortcut. When time is short and the days are overwhelming, it can be tempting to try to cover up those errors or "correct" them without documentation or telling anyone. What may seem innocuous can snowball into something disastrous. Alternatively, errors can avoid becoming research misconduct with timely reporting, correction and mitigation.

What Is Research Misconduct?

The Public Health Service defines research misconduct as follows:

> Research misconduct means fabrication, falsification or plagiarism in proposing, performing or reviewing research or in reporting research results.
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> - Fabrication is making up data or results and recording or reporting them.
> - 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.
> - Plagiarism is the appropriation of another person's ideas, processes, results or words without giving appropriate credit.
>
> Research misconduct does not include honest error or differences of opinion.

The research misconduct regulations define a "research record" very broadly. Institutions may use more granular definitions, such as the following:

> A research record is any data, document, computer file, digital medium or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted or reported research that constitutes the subject of an allegation of research misconduct. It includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; notes; printed or electronic correspondence; memoranda of telephone calls; videos; photographs; X-ray film; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; and patient research files.

Allegations of fabrication, falsification or plagiarism can extend beyond the realm of research findings and publications. Rather, because of the importance of protecting the integrity of the research process writ large, any failure to ensure that the records match the actual practice of research can result in an allegation of research misconduct. Research misconduct includes, but is not limited to, the following acts, even if it may not actually affect the final research findings or results:

- Altering eligibility dates, test results etc.
- Creating documentation for visits/tests/interactions that did not exist
- Eliminating outlier data without so stating
- Falsely reporting the number of study subjects
- Back-dating consent forms/authorization forms
- Falsely reporting the credentials of study personnel

Examples

The following are a few examples of actual research misconduct cases that have come to the attention of the authors:

Example 1

A Research Coordinator (RC) is in charge of a very complex clinical trial involving hundreds of subjects. Her duties include dispensing medications, enrolling subjects, scheduling quarterly visits, tracking medical records, making payments to subjects, etc. She has been around forever — before background and degree/license checking — so no one questions her credentials, experience or performance. The RC begins falling behind in her heavy workload. The Principal Investigator (PI) does not respond to her requests for help because she is a superstar scientist who does not have the time or open mind for complaints. The PI often travels to give lectures, etc., so she is not on-site on a regular basis. She knows the RC has always managed just fine through challenging periods in the past.

The RC then has a medical event involving neurological issues. She eventually returns to work at half capacity, but her work has really piled up. The PI does not want to use her funds to hire another RC. In her haste to catch up, the RC begins to make mistakes and tries to cover them up by indicating visits, etc. that did not occur. Subject medications come up missing. The study sponsor notices and reports some problems to the PI, who promises more oversight but does not deliver.

The PI has signed off on the delegation log attesting to the RC's qualifications. The PI subsequently becomes aware of the RC's false credentials but does not act.

The institution receives a report about the situation. Its investigation determines that the RC falsified documentation. While the PI did not falsify anything, her lack of oversight contributed to research misconduct.

> **Observations:** In this example, the definition of "research record" is critical. While no publications had yet resulted from the research activity, the institution's definition of "research record" led to a finding of falsification of credentials and subject records. The institution found both the PI and RC at fault.

Example 2

A graduate student research assistant (RA) funded on an NIH study was expected to conduct an intervention on and monitor a rack of rats over the weekend. These tasks slipped her mind until Monday morning, when she quickly wrote her "observations" in the lab book. A few days later, the PI saw notations in the lab book that seemed a bit irregular. She contacted the Research Integrity Officer (RIO) with her concerns. The RIO then contacted the RA, who confirmed that she had performed the tasks on Saturday and Sunday as required. When confronted with the fact that there was no record on the card access logs of her entering the facility, she claimed she had "piggy-backed" on someone else's entry. When asked to identify who that was, she finally admitted her failure to work in the lab over the weekend and falsely recording that she had done so.

> **Observations:** While not following approved protocol procedures is obviously a protocol violation, the activity also became research misconduct when the RA recorded in laboratory records that she had completed procedures which she in fact had not. The cover-up is what made it research misconduct, not the failure to conduct the work over the weekend.

Example 3

The PI of a federally funded study of non-injecting heroin users was accused by another researcher, after reading his publication, of having dropped data points and in other ways conducted the data analysis in a manner designed to get the results he wanted. This person then submitted an allegation of research misconduct to the RIO. During the assessment of the allegation, although it was determined that the statistical analysis was indeed, at minimum, problematic, it was dropped as a research misconduct case because the publication included a footnote with an extensive description of what he had done with the data.

> **Observation.** While the strategy for organizing and analyzing the data may be controversial or even scientifically "wrong," it was not research misconduct, since the research record identified everything the PI did with the data.

Example 4

A federally funded study was being conducted on the experiences of drug addicts who overdose and end up in the hospital's emergency room. The researchers trained assistants (former addicts) to approach the patients, obtain informed consent and record their answers to survey questions during a meeting. Participants who agreed were given gift cards and vouchers for transportation from the hospital. One of the assistants observed another assistant entering data after, not while, meeting with patients. In addition, time spent with participants appeared to be too short to obtain informed consent and properly complete the survey. An investigation determined that the assistant in question was completing the informed consent and survey forms without the patients' involvement.

> **Observation.** While this matter is clearly a human subjects violation, it also became research misconduct because research records (informed consent and survey forms) were falsified.

Prevention and Mitigation Strategies

Institutions may develop and implement a wide variety of approaches to reduce and even prevent practices that may result in research misconduct. At minimum, institutions should roll out a robust outreach program of education throughout their research communities, as well as other resources and tools. The following approaches have been found to be very useful:

- Conduct an educational program, including webinars and workshops focused on both big picture and very specific areas of research misconduct, using real-world examples, such as those above, to diverse audiences, such as:
    - Academic unit and departmental faculty meetings
    - Research coordinators
    - Other compliance committees
    - Create a standing committee of senior, experienced researchers with diverse and relevant expertise who can contribute to inquiries and investigations, and who can also serve as ambassadors within their academic units and departments
    - Provide guidelines, requirements and tools for data reporting/documentation, management and retention, as well as institutional resources for quality assurance checks
    - Provide continuing medical education credits for individuals who attend research integrity training sessions, contribute to investigations, and make quality assurance checks

Conclusion

As the above examples reveal, research is a complicated and very human process. Everything must be properly carried out. It must also be properly documented — but only if actually carried out. At times, researchers may fail to carry out processes as required. But, as illustrated in the examples above, such failures can grow into something qualitatively different and more serious when there is an effort to cover up the initial failure by fabricating or falsifying the research record. As we see so often in politics, business and other arenas, the cover-up is often more serious than the original offense.

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