Journal of Law, Medicine & Ethics (2025), **53**, 1, 41–46
doi:10.1017/jme.2025.36

CAMBRIDGE UNIVERSITY PRESS

Symposium Articles

Managing Multi-Institutional Jurisdiction in Cases of Research Misconduct

Leslie Thornton[1], Devin Cohen[1], Mark Barnes[1,2*] and Barbara E. Bierer[2,3*]

[1] Ropes & Gray LLC, Boston MA and Los Angeles CA; [2] Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard, Boston MA and [3] Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston MA

Abstract

Multi-institutional scientific research projects are increasingly common. Nevertheless, regulations and guidelines do not yet adequately address which entity should assume responsibility for research misconduct proceedings in multi-institutional research. This article explores the challenges of determining jurisdictional roles in research misconduct matters in collaborative science and proposes the application of a "jurisdictional interests test" as a framework for determining jurisdiction in multi-institutional research misconduct proceedings.

Keywords: Research Misconduct; Jurisdiction; Multi-Institution; Cross-Institution; Collaboration; Cooperation

I. Introduction

As research becomes increasingly collaborative across researchers and organizations, allegations of research misconduct and related data integrity concerns can fall within the jurisdiction of multiple parties, both public and private — universities, academic medical centers (AMCs), hospitals, industry entities, and others. Currently, when multiple entities are involved in a research misconduct case, there are no formal regulations or guidelines addressing which entity should assume responsibility for assessing allegations or adjudicating other data integrity issues, which entity should carry out any inquiry and/or investigation, and how the entities involved should communicate with one another about the process and outcome.

This article explores the challenges of determining jurisdictional roles in research misconduct matters in collaborative science, as well as the proposed application of a "jurisdictional interests test" as a framework for determining jurisdiction across collaborative partners or other entities or organizations. While a jurisdictional interests test typically favors the organization where the research was primarily conducted, other considerations may tip this jurisdictional balance away from the organization where the research was conducted, or it may suggest that shared jurisdiction across multiple organizations is best (e.g., where the research at issue was conducted in more or less equal parts across those multiple organizations). These other considerations include, among others, an organization's ability and capacity to carry out a formal process to adjudicate allegations of research misconduct, and, as part of that process, its willingness to share necessary information and to collaborate with other involved organizations. This paper explores the nuances of these jurisdictional issues, including the special case of research collaborations involving industry partners such as pharmaceutical companies, as well as the importance and utility of anticipating such jurisdictional issues in advance of entering into research collaboration agreements.

II. Federal Requirements for Research Misconduct

A. AMC and University Interactions with Federal Agencies

AMCs and universities rely heavily upon federal funding to carry out their research activities. From 2010 to 2021, federal government funds supported over 50 percent of higher education research and development expenditures, with the US Department of Health and Human Services (HHS) providing over half of these funds, much of that awarded through the National Institutes of Health (NIH).[1] Federal funds awarded to AMCs and universities rarely are allocated to individual investigators (including principal investigators) or other key personnel, but rather to the institutions with primary responsibility for overseeing the funded research activities, with those institutions typically employing the primary investigators carrying out the research.[2]

Among the many strings attached to federal awards, federal funding recipients (often termed "non-federal entities" by federal agencies) are required to establish research misconduct policies and associated procedures that allow complainants to make allegations of research misconduct and that allow institutions receiving those complaints to carry out a fair and highly structured review process.

*Co-Senior Authors

Corresponding author: Barbara E. Bierer; Email: bbierer@bwh.harvard.edu

Cite this article: L. Thornton, D. Cohen, M. Barnes, & B.E. Bierer. "Managing Multi-Institutional Jurisdiction in Cases of Research Misconduct," *Journal of Law, Medicine & Ethics*, **53**, 1 (2025): 41–46. https://doi.org/10.1017/jme.2025.36

Institutions must adhere to their policies when reviewing any allegation of research misconduct related to research carried out with federal funds. The Public Health Service (PHS) (comprised of ten public agencies that sit within HHS, including NIH), the National Science Foundation, the US Department of Defense, and the US Department of Energy each has its own set of research misconduct regulations and guidance.[3] Most non-federal institutions that receive federal funding choose to apply federal regulations — often PHS regulations — across all institutional research activities, regardless of whether those activities are supported by federal dollars, as part of an effort to promote enterprise-wide, consistent research integrity standards.

When an institution (per its research misconduct policy) concludes that research misconduct was committed, and the research at issue was supported by federal dollars, cognizant federal agencies can, in addition to any remediation or corrective actions taken by the institution, take their own actions against the institution and/or respondent(s).[4] When the research at issue is funded by PHS, these actions include, without limitation: (1) requiring corrective actions be taken by the institution or individual researcher(s), including, for example, independent supervision of the respondent(s)' laboratory or publications; (2) publishing findings of noncompliance, typically through a government website; (3) correcting the scientific record; (4) recommending to HHS the institution's or individual's debarment or suspension from federal funding, or the individual's exclusion from serving in any federal advisory roles; and/or (5) requiring the organization to return research funds, in full or in part.[5] Accordingly, even when federal funds are awarded to an institution, federal agencies can and do take action against individuals who are carrying out federally funded research at those institutions and who are found to have committed research misconduct as related to that research.

In one recent case, for example, a researcher whose work had been supported by PHS funds entered into a voluntary settlement agreement with the Office of Research Integrity (ORI) in March 2024, whereby he agreed to research supervision obligations for five years (under a supervision plan submitted by the respondent and approved by ORI) and to request correction or retraction of a paper relying on certain falsified and/or fabricated data.[6] In another example, ORI debarred a respondent from participating in covered and procurement transactions for three years, prohibited the respondent from serving in any advisory capacity to PHS for three years, and determined that, in accordance with applicable regulations, HHS would provide notice to the journal where the affected research was published regarding ORI's findings and the need for retraction or correction.[7]

In addition to triggering federal agency remediation authority, a finding of research misconduct may provide the basis for a claim under the False Claims Act, which penalizes persons who knowingly submit, or cause to submit, a false claim to the federal government (including knowing use of a false research record in federally funded research).[8] For example, in a 2019 case, a university was alleged knowingly to have submitted falsified or fabricated data in 30 grant applications from 2006 to 2018, which allegedly had caused the NIH and the Environmental Protection Agency to award millions of dollars in grants to the university that those agencies otherwise would not have paid. The parties ultimately settled, with the university agreeing to pay the government $112.5 million to resolve the allegations.[9]

B. Private Company Interactions with Federal Agencies

Private life sciences companies (often referred to as "industry") prioritize commercialization of their research and development activities, which often requires interactions with and approvals from regulators such as the US Food and Drug Administration (FDA) or the European Medicines Agency (EMA). Separate from those federal funding requirements discussed above, these national regulators of drugs, devices, biologics, and diagnostics have their own standards and requirements for research integrity, as applied to research carried out within their jurisdiction, data from which support marketing applications.[10] These standards are meant to help these agencies fulfill their charge to protect the public's health and assure the safety and efficacy of products made for human consumption and use.

FDA maintains extensive enforcement authority to encourage research compliance. For example, if a private company uses problematic research data to support a marketing application for one of its products, then FDA, if it identifies the data integrity issue (e.g., during an FDA site visit or audit, or through a referral to FDA from another federal agency), may compel that submitting company to correct its FDA submissions. If the private company fails to correct those regulatory submissions, FDA could delay or deny approval for the affected products — which may cause direct financial harm to the regulated entity.[11] FDA also may impose or seek to impose civil or criminal liability on a company if FDA concludes that the entity has deliberately or recklessly submitted inaccurate or unreliable data.[12] Further, companies and their leadership can be held civilly or criminally liable if the company's products and data underlying those products have been misrepresented to shareholders and investors, including via enforcement by the US Securities and Exchange Commission (SEC), as demonstrated in the widely publicized Theranos legal proceedings.[13]

Historically, private companies have not applied for or accepted federal research funding, primarily because as for-profit entities, they often do not qualify for such funding and because as rational economic actors, they prefer to avoid the many restrictions and obligations imposed by federal agencies on the research they support — specifically, as related to data sharing (e.g., the NIH Data Management and Sharing Policy) and intellectual property rights (e.g., the Bayh-Dole Act).[14] Nonetheless, certain private entities do forge relationships with federal funders through use of Cooperative Research and Development Agreements or Other Transaction Authority/Agreements, which set forth (among other things) certain rights of government to use data and practice intellectual property generated under those arrangements.[15] In recent years, certain areas of research have seen a greater influx of federal funds into private entities' research and development activities, driven by urgent public health needs (e.g., COVID-19-related research).[16] Accordingly, there are circumstances in which federal funding requirements, including those related to research misconduct, can attach to private companies' research activities, whether those companies are receiving funds directly from a federal agency or those companies are collaborating with entities that receive federal funds such that federal requirements may apply to joint effect, comingled activities.

III. Assigning Jurisdiction over Research Misconduct Matters

A. Considerations for Assigning Jurisdiction

Issues of jurisdiction, as a general matter, are not novel. When multiple national or state jurisdictions have an interest in reviewing and deciding a case, courts have employed choice of law rules to decide which jurisdiction's laws should apply, for instance, in cases involving contract and tort claims.[17] As an example, if a tort is committed in Texas on an Arkansas resident by another Arkansas

resident, both states arguably would have an interest in hearing and deciding claims related to that tort, and a cognizant court would need to decide which state's laws to apply in a resulting tort case. Choice of law tests vary by state and national jurisdictions, and choice of law doctrine traditionally balances a wide variety of factors, including location of the relevant acts or transactions, public policy considerations, which state has better defined law applicable to the matter, and predictability of results, among others.[18] Also, under the principle of comity, separate jurisdictions with legitimate interests in a claim cooperate to avoid conflict and ensure claims are reviewed efficiently.

Generally, choice of law tests are used to determine jurisdiction by examining the nexus between a dispute and each jurisdiction's ties to, and interest in, a case. For the research misconduct context, we propose an analogous framework to determine jurisdiction across collaborative partners and other entities or organizations, which we refer to as a "jurisdictional interests test." In the research misconduct sphere, there is neither formal regulation, nor guidance from funding agencies, nor informal common practice to steer such determinations, resulting in much variation in jurisdictional decision-making across and within entities from proceeding to proceeding. The jurisdictional interests test provides a framework for jurisdictional decision-making through examination of the nexus between the research at issue and the various individuals and entities involved, including the acuity of any actual or potential institutional conflicts of interest (i.e., when an institution's financial interests, or those of its senior officials, create actual or potential risk of undue influence on decisions related to the institution's interests). This test tends to favor the location where the specific research whose results are in question was conducted. Most often, the entity at which the problematic data were obtained, analyzed, and reported would be favored to exert jurisdiction over the allegations directly involving those data. However, the location where research was conducted may not be readily determinable at the outset of a research misconduct proceeding because multiple researchers over multiple institutions may have collaborated on the research in question, and the site where specific data problem(s) arose may not be identified until far into the proceeding. Moreover, location is not invariably a clear indicator of the appropriate jurisdiction, as other factors must be examined and may weigh more heavily than location. Among the other factors that must be considered are, for example, each institution's capacity and resources to carry out the research misconduct review, the academic positions and seniority of the respondents, and which institution has acted as the prime awardee of any external funding used to support the research at issue.

A spectrum of outcomes may result from an institution's use of the jurisdictional interests test, none of which necessarily is the "right" or "wrong" outcome, and all of which are determined based on the application of the jurisdictional interests test to the specific facts of a given proceeding. Institutions may decide to cede jurisdiction to another, single institution; may decide to split jurisdiction among themselves, with the institutions divvying up the allegations to be reviewed; may conduct a joint review, with each institution reviewing the same allegations together; or may conduct their own, entirely separate reviews in parallel or sequentially. In each case, the institutions would need to define and engage in degrees and methods of collaboration.

Even when the jurisdictional interests test favors ceding jurisdiction to one collaborating institution, this does not absolve the ceding institution from responsibility for the matter. This notion of reliant versus joint review is paralleled in the institutional review board (IRB) context, in which an institution (the relying or ceding institution) may agree to cede review to another institution's IRB (the reviewing institution and reviewing IRB) for a certain study, even though the ceding institution retains responsibility for the conduct of the study at its site.[19] For example, a university may cede ethical review of a study to an external IRB, but the university remains responsible for ensuring that the study is carried out at the university's site(s) in accordance with applicable law, regulation, and policy.

Further, when multiple institutions decide to carry out a joint proceeding, the recent revisions to the PHS Policies on Research Misconduct set forth at 42 CFR Part 93 clarify that a single institution should be designated the "lead institution."[20] The lead institution is responsible for obtaining the research records and evidence from the other institutions. In such case, the institutions jointly make, or may task the lead institution with making, determinations as to whether an inquiry or investigation is warranted, whether research misconduct occurred, and the institutional actions to be taken.[21] Commentary to the final rule notes that ORI intends to issue additional guidance on how institutions should handle complex cases involving more than one institution, including how to determine which institution should serve as lead.[22]

The following are salient, but not exclusive or exhaustive, considerations that should be considered as part of the jurisdictional interests test.

Location of Research Activities. The location where the research was primarily conducted is a primary factor in assigning jurisdiction over a research misconduct case. This typically is the "default" factor in determining which entity takes jurisdiction, as the place where the research was conducted is likely to have the best access to relevant records, witnesses, and other resources needed to probe the research at issue. Moreover, if federal or other external funding was involved, the institution where the misconduct allegedly occurred (whether a prime awardee or subrecipient) has a continuing obligation to investigate the allegations, report back to the funding agency (or, if a subrecipient, to the prime awardee), and potentially return some or all related research funds.[23] In short, the funded entity has an ethical responsibility to the public and to the funder to ensure that any disseminated research results are reliable. However, in a research collaboration, the same study may be carried out by different researchers, at different institutions (including in different geographies), using different resources, such that relevant records, staff, and other resources are spread across multiple institutions.[24] In such cases, there may not be a single research location that would be considered primary, making other factors of greater importance as part of the jurisdictional determination. For example, a postdoctoral fellow may carry out research as an employee of one institution, with federal salary or stipend support through that institution, and conduct or later continue that same research at another institution; it may be difficult, if not impossible, to determine which institution was the situs of the offending conduct. Also, even in cases where the location appears dispositive (i.e., all research activities were carried out at one location), there may be other considerations, such as institutional conflicts of interest, respondents' current employment, or expertise and capacity issues, that weigh against basing jurisdiction on location (solely or at all).

Capacity and Expertise. Each entity in the collaboration should evaluate whether it has the capacity and expertise, including needed infrastructure, professional staff, committee membership and expertise, and other resources, to carry out an appropriate assessment and, as applicable, inquiry and investigation. If an entity

does not have the available resources, capacity, or expertise, the jurisdictional choice may favor another of the relevant institutions that does have the needed capacity and expertise. If all institutions have the capacity and expertise to take jurisdiction, other factors should be weighed to determine which has the strongest jurisdictional claim under the jurisdictional interests test.

Position and Seniority of Respondents. An additional factor in the jurisdictional decision is the academic position and seniority of the potential respondent whose work is under scrutiny, including their position and seniority at the time that the research at issue was conducted and at the time of the complaint and resulting review (if different). Many institutions would not want another entity to have control over an assessment, inquiry, or investigation involving their leaders and most senior researchers. Other institutions may simply not want another institution to take up a misconduct proceeding against any of their current faculty or employees, regardless of their seniority. This can be further complicated when older research and associated manuscripts are scrutinized. In such a case, if original research records and witnesses are no longer available at the institution where the problematic research occurred, then there may be few functional reasons to prefer that that institution retain jurisdiction, as opposed to the institution at which the respondents currently serve. It would be true that the institution currently employing the researcher would have more ability to compel that respondent to cooperate in a research misconduct proceeding, although it might also be said that the current employer has an incentive not to find that its current faculty member or leader committed misconduct in his or her previous institution.

Arguably, the institution at which the respondent has a prominent leadership role at the time of the complaint may have a greater stake in any research misconduct proceeding as compared to the institution where the respondent was a more junior researcher years earlier. In this scenario, the current employer may take jurisdiction as opposed to the institution where the research took place, although that institution taking jurisdiction may have had no direct connection to the research under scrutiny and, therefore, no direct connection to the staff, record, and other resources used to carry out the questioned research. In any event, the ability of the respondent's current institution to take jurisdiction will rest in part on how willing respondent's prior institution is to cooperate in the current institution's review process by providing access to otherwise inaccessible people, records, and other needed resources, and what level of confidence that previous institution has in the process of the respondent's current employer — its fairness, its thoroughness, and the soundness of its documentation.

External Funding. Already discussed above is the compelling interest of the entity that was the awardee of any external funding used to support the research at issue. Funding comes from many different agencies that have certain requirements pertaining to research misconduct review.[25] For example, upon receiving a research misconduct allegation, institutions must adhere to the required processes for reviewing the allegation, which include sequestering research evidence and conducting the research misconduct review.[26] The collaborating parties should consider that if a party takes jurisdiction over the research misconduct proceeding and is *not* the prime awardee of funds used to carry out the research at issue, restrictions imposed by a funding entity (and borne by the institution receiving that federal funding) may still attach to a research misconduct process. Academic institutions may be more attuned to these risks because they rely heavily on federal funds for their research enterprise and have an existing infrastructure to manage these risks. However, unlike academic institutions, private companies are more likely to use private funds to support their research. Therefore, a private company may be less familiar with the risks related to accepting federal funding or support for research and is less likely to have an infrastructure geared toward fulfilling the requirements of federal research misconduct regulations. In cases involving research collaborations that span academic and industry entities and that involve federal funding, this may weigh in favor of jurisdiction going to the federal award recipient, as that institution may have more experience and a much more robust compliance infrastructure in place, even though the private industry entity likely will be loath to cede jurisdiction and control of that matter to the academic entity.

B. Multiple Reviewing Institutions, Multiple Review Processes

When research misconduct and data integrity issues arise in research collaborations, one or all institutional collaborators may desire to carry out separate review processes, rather than assigning review jurisdiction to a single institution or participating in a joint review. This can occur when different portions of the research at issue were conducted at different institutions, and those institutions decide to divide the allegations and corresponding review amongst themselves, often according to the location of the research whose results are under scrutiny. This also occurs when different institutions have different processes or interests that attach to the misconduct or integrity review process and, therefore, determine that each institution will carry out a full review in parallel, with each institution reviewing each allegation.

For example, an industry collaborator may insist on conducting its own review of the research misconduct issues if its academic entity collaborator's priorities, obligations, or policies governing research misconduct or research integrity differ greatly from those of the industry collaborator. Specifically, the industry collaborator is likely to object to audits being controlled by another party, or it may have investor relations, intellectual property, or conflict of interest concerns that make difficult the quick sharing of information identified in its internal investigation of a research misconduct allegation, and company policies may differ significantly from those of its academic collaborator, including as to record retention and reporting obligations. For example, a company may be more concerned with conducting an efficient and speedy review, as opposed to academic institutions whose research misconduct processes often take years to complete, with the delay impeding the industry collaborator's reporting obligations to regulators like FDA and SEC.[27] As another example, a private company might license intellectual property from an academic institution where the suspect research occurred, with the intellectual property used to develop medical technology that is under review by FDA. As a result, a private company should be cognizant of an obligation to correct the research record promptly, revise its FDA submissions, and thus ensure public safety.

Ultimately, when multiple institutions carry out research misconduct reviews, all these entities should preserve their ability to access research records, evidence, and witnesses, in a manner that permits their respective compliance with government requirements attached to the funding and with their respective internal policies.

IV. Operationalizing Jurisdictional Rules

Ideally, cross-party research collaborations should include forward-looking, agreed-upon terms that anticipate and address potential research misconduct issues, including the practical handling of

proceedings. Even if such terms are not in place at the start of a collaboration, such terms may be put in place at the point at which an actionable complaint of research misconduct is received by one or all institutional collaborators. And in the initial cross-party discussions about a particular proceeding, the jurisdictional interests test can be deployed to aid the division of responsibilities across, and to clarify the expectations of, the parties as to the proceeding at hand, and ultimately inform the content of any written agreement between the parties governing such proceeding.

Agreements on access to and sharing of information, resources, and review findings, composition of committees, and required reporting, can and should be established using confidentiality agreements and memoranda of understanding (MOUs). These agreements are of particular importance when multiple institutional collaborators will conduct reviews of a particular complaint (whether dividing the review or conducting parallel, joint, or sequential reviews), when the sharing of information, resources, and review findings across entities is critically important.

Parties often agree that any information related to allegations of research misconduct or integrity must be disclosed and held in confidence amongst the parties — unless additional further disclosure is required to meet certain legal or regulatory reporting obligations — to help mitigate each party's concerns related to confidentiality. Confidentiality expectations reach to protecting the reputation of those involved but should not restrict an institution's (and more specifically, a research integrity officer's) *bona fide* ethical and/or legal interests in promptly alerting another institution whose interests are implicated in a research misconduct proceeding. Many institutions are reluctant to disclose information regarding potential research misconduct to other institutions that may be implicated, due to confidentiality concerns. Yet this reluctance to share information and strict reliance on nondisclosure agreements can be counterproductive and often hinder institutions' ability to effectively and fairly process research misconduct allegations. This reluctance also runs counter to the recent revisions to the PHS Policies on Research Misconduct set forth at 42 CFR Part 93, in which HHS has made clear that, during a proceeding, one institution may disclose to "collaborating institutions" the identity of respondents, complainants, and witnesses, so long as those collaborating institutions have a "need to know," as determined by the disclosing institution.[28] In fact, HHS expressly fashioned the final rule "to provide latitude for institutions to decide confidentiality requirements for themselves."[29]

Although prompt action and communication often are required between organizations, circumstances may arise in which delayed communication between institutions is justified (e.g., an institution's internal review of conflict of interest issues associated with the proceeding). In these circumstances, these practices become more complicated. Collaborating institutions should consider requiring each collaborator to disclose to the other(s) any relevant research misconduct allegations (typically after an institution has determined through its assessment that such allegations are credible and specific) and promptly sequester records and evidence relevant to the allegations, to the extent within their reasonable control. The sequestration process, including chain of custody of sequestered records, is essential to any research misconduct process, particularly when multiple parties are involved, each with its own set of data and information. In the case of academic institutions, unless an institution's policy dictates otherwise, cross-party communications should be initiated through each institution's research integrity officer, whereas in industry-academic collaborations, the academic institution's research integrity officer ideally should use institutional in-house counsel to reach out to the industry entity's Office of General Counsel. Such steps help to maintain "common interest" privilege for communications between the entities, as well as to preserve evidence and increase trust in the process, which are essential to promote ongoing stakeholder participation.

Information sharing is another key contract term. Parties should guarantee each institutional collaborator reasonable, real-time access to research records and information as needed to conduct their research misconduct proceedings, including remediation efforts stemming from such proceedings. In certain circumstances, it may be appropriate to allow each collaborating institution real-time access to transcripts and reports generated during any assessment, inquiry, or investigation, including inquiry and investigation reports, along with permitting each collaborating institution, regardless of jurisdiction over the proceeding, to observe or review proceedings or otherwise review updates at an agreed-upon cadence. These terms ensure cooperation and trust, and help to establish cooperation, of the collaborating institution ceding its jurisdiction.

If institutions agree to joint review of research misconduct allegations, the parties must clearly allocate responsibilities and expressly convey to respondent(s) that agreed-upon allocation of duties and roles, including in any written notice of inquiry or investigation. It also is important to identify the policies and procedures to be applied by the institutions in their respective processes. The research integrity officers (and/or legal counsel) of each institution should keep in close contact throughout each institution's process, exchanging information as needed.

To the extent collaborating institutions resist cross-institutional cooperation during research misconduct proceedings, and those problems are not resolvable through any preexisting agreement terms, the collaborating institutions may consult external funders (as applicable) for assistance in resolving any disputes or differing conclusions. However, many funders, including federal agencies, are not always willing or able to step in to resolve conflicts between parties or otherwise dictate where or how proceedings should be carried out. Even if they are willing to intervene or advise, funders may delay in their response, as they tend to be unaccustomed to these situations. So long as the parties are within the bounds of any contractual or regulatory restrictions imposed by the funder, the funder typically leaves it to the parties to resolve these issues.

V. Conclusion

With the growth of research collaborations across and between private and public entities in "team science" environments, operational and legal concerns in determining jurisdictional roles for research misconduct cases are increasingly complex. By assigning jurisdiction over research misconduct and data integrity reviews between respective entities based upon the jurisdictional interests test (and often looking to where the research was conducted), and whenever possible by anticipating these situations in their initial collaboration agreements, institutional collaborators can develop a framework to allocate responsibility for review that appropriately accounts for their respective capabilities and funding histories and leads to more secure and reliable outcomes of research misconduct proceedings in which the institutions have some form of common interest.

Particularly in the context of industry-academic collaborations, potential cooperation issues can be anticipated and addressed before research misconduct issues arise, through developed contractual terms negotiated in confidentiality agreements and MOUs.

By establishing joint administrative, operational, and jurisdictional expectations related to allegations of research misconduct, respective organizations can effectively avoid later disputes and better ensure that if they arise, research misconduct concerns can be handled quickly and effectively.

Acknowledgements. The authors wish to thank Bailey Jenks, JD, and Nathaniel Jaffe, MA, JD for their contributions to the preparation of this article. Disclosures Mark Barnes, JD, LLM, Devin A. Cohen, JD, and Leslie A. Thornton, JD, PhD are attorneys at Ropes and Gray LLP, an international law firm that represents many entities in health care and academic sectors, including advising academic medical centers, institutions of higher education, pharmaceutical and medical device companies, and other research institutions on research misconduct matters at all stages of review. Mark Barnes regularly serves as acting research integrity officer for universities and academic medical centers. Barbara E. Bierer, MD formerly served as Senior Vice President of Research and the Research Integrity Officer at the Brigham and Women's Hospital and often serves on peer review committees conducting research misconduct proceedings on behalf of research institutions.

Leslie A. Thornton, JD, PhD is counsel in Ropes & Gray LLP's health care practice group and holds a PhD in public health from Johns Hopkins University.

Devin A. Cohen, JD is a partner in Ropes & Gray LLP's health care practice group.

Mark Barnes, JD, LLM is a partner in Ropes & Gray LLP's health care practice group, a visiting lecturer at Yale Law School, and a faculty co-chair of the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard Medical School.

Barbara E. Bierer, MD is a Professor of Medicine (Pediatrics) at Harvard Medical School and a hematologist/oncologist at the Brigham and Women's Hospital.

References

1. See Michael Gibbons, "Universities Report Largest Growth in Federally Funded R&D Expenditures since FY 2011," National Center for Science & Engineering Statistics, Dec. 15, 2022, https://ncses.nsf.gov/pubs/nsf23303.
2. See *e.g.*, Mike Lauer, "Wait…It's Not MY Grant?," National Institutes of Health Office of Extramural Research Extramural Nexus, May 29, 2018, https://nexus.od.nih.gov/all/2018/05/29/waitits-not-my-grant/.
3. 42 C.F.R. part 93; 45 C.F.R. § 689; US Department of Defense, *Research Integrity and Misconduct*, DoD Instruction 3210.7 (Department of Defense, October 15, 2018); 10 C.F.R. § 733.
4. See *e.g.*, 42 C.F.R. § 93.403.
5. See *e.g.*, Office of Research Integrity, "Frequently Asked Questions," US Department of Health and Human Services (Aug. 4, 2016): Nos. 10 and 11, https://ori.hhs.gov/frequently-asked-questions.
6. Office of Research Integrity, "Case Summary: Brigidi, Gian-Stefano," US Department of Health and Human Services, https://ori.hhs.gov/content/case-summary-brigidi-gian-stefano (last visited Nov. 11, 2024).
7. See Office of Research Integrity., "Case Summary: French, Ivana," US Department of Health and Human Services https://ori.hhs.gov/content/case-summary-de-domenico-ivana (last visited Nov. 11, 2024).
8. 31 U.S.C. §§ 3729–3733.
9. Office of Public Affairs, "Duke University Agrees to Pay U.S. $112.5 Million to Settle False Claims Act Allegations Related to Scientific Research Misconduct," US Department of Justice, Mar. 25, 2019, https://www.justice.gov/opa/pr/duke-university-agrees-pay-us-1125-million-settle-false-claims-act-allegations-related.
10. *E.g.*, 21 C.F.R. § 312.70 (regarding submission of false information to the FDA); Food & Drug Administration, Compliance Policy Guide § 120.100, Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities (1991); "Anti-Fraud Strategy," European Medicines Agency, https://www.ema.europa.eu/en/about-us/how-we-work/anti-fraud-strategy (last visited Nov. 11, 2024).
11. See *e.g.*, John Carroll, "FDA Accusations of 'Corrupt' Lab Practices Push Cetero into Bankruptcy," *Fierce Biotech*, March 26, 2012, https://www.fiercebiotech.com/outsourcing/fda-accusations-of-corrupt-lab-practices-push-cetero-into-bankruptcy (noting that a 2010 FDA inspection of studies carried out by a contract research organization, Cetero Research, revealed "hundreds of examples of faked research work," after which the company filed for bankruptcy); Letter from Leslie K. Ball, M.D., Director (Acting), U.S. Food & Drug Admin., to Roger N. Hayes, Ph.D., President, Bioanalytical, Cetero Research (July 26, 2011).
12. 21 U.S.C. §§ 333 and 335b.
13. See *e.g.*, 17 C.F.R. § 240.10b-5; "Theranos, CEO Holmes, and Former President Balwani Charged With Massive Fraud," *US Securities and Exchange Commission*, March 14, 2018, https://www.sec.gov/news/press-release/2018-41.
14. See *e.g.*, Nat'l Inst. Health, NOT-OD-21-013, Final NIH Policy for Data Management and Sharing (2020), https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html; Patent and Trademark Law Amendments Act (Bayh-Dole Act), Pub. L. No. 96-517, 94 Stat. 3015.
15. "CRADAs," National Institutes of Health, https://www.techtransfer.nih.gov/partnerships/cradas (last visited Nov. 13, 2024); "Other Transactions," National Institutes of Health, https://grants.nih.gov/funding/funding-categories/other-transactions (last visited Nov. 11, 2024).
16. See *e.g.*, "Accelerating Covid-19 Therapeutic Interventions + Vaccines," Foundation for the National Institutes of Health https://fnih.org/our-programs/accelerating-covid-19-therapeutic-interventions-vaccines-activ/ (last visited Nov. 11, 2024).
17. Legal Information Institute, "Conflict of Laws," Cornell Law School, https://www.law.cornell.edu/wex/conflict_of_laws (last visited Nov. 11, 2024).
18. See *e.g.*, Bode & Grenier, LLP v. Knight, 808 F.3d 852, 864 (D.C. Cir. 2015) (noting that the District of Columbia choice of law test for contract actions applies a blend of "governmental interest analysis" and the "most significant relationship test" by first looking to location of events involved, which is the primary factor considered, and subsequently weighing which jurisdiction has the most interest in the events).
19. See Nat'l Inst. Health, NOT-OD-16-094, Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research (2016), https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html; Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. 7149, 7246–47 (Jan. 19, 2017). NIH and HHS generally require sites participating in multi-site studies to use a single institutional review board. The institutions enter into a reliance agreement that sets out roles, responsibilities, and communication between the institution providing the review and the site relying on it.
20. See 89 Fed. Reg. 76280, 76301–02 (Sept. 17, 2024) (to be codified at 42 C.F.R. Part 93).
21. *Id.*
22. 89 Fed. Reg. 76280, 76288 (Sept. 17, 2024) (to be codified at 42 C.F.R. Part 93).
23. 42 C.F.R. §§ 93.301, 93.304, and 93.407.
24. Further complications can arise if the records were compiled by or kept with international collaborators. In this case, the location of the records may weigh against jurisdiction being given to the location where the research was conducted.
25. Many non-PHS federal agencies award funding to support research and have agency-specific research misconduct requirements. *See*, e.g., 45 C.F.R. § 689; "Proposal & Award Policies and Procedures Guide," US National Science Foundation (January 30, 2023), https://beta.nsf.gov/policies/pappg/23-1. Nevertheless, the definition for research misconduct and the evidentiary standards across agencies often is the same. Compare 42 C.F.R. § 93.104 (denoting the standards for PHS-supported research) with 45 C.F.R. § 689.2(c) (using the same language for National Science Foundation-supported research).
26. See, *e.g.*, 42 C.F.R. §§ 93.305–93.319.
27. Although federal regulations establish specific time limits, the regulations generally allow for extensions so long as the entity conducting the proceeding demonstrates progress. See, *e.g.*, 42 C.F.R. §§ 93.307(g) and 93.311(a).
28. 89 Fed. Reg. 76280, 76298 (Sept. 17, 2024) (to be codified at 42 C.F.R. Part 93).
29. *Id.* at 76281, 76283–84.