2026 Annual Ethics Cases: Academic Freedom, Taking Initiative

The Committee on Scientific Conduct and Ethics (CSCE) has prepared two cases for 2026 that deal with some important topics relating to academic freedom and what it means to take initiative in research at NIH. These include:

Case 1: Potential Suppression of Research Findings

Case 2: Taking Initiative

CONTENTS

Case 1: Potential Suppression of Research Findings

Dr. PI is a senior investigator at NIH who has been studying the carcinogenicity of Chemical X, a commonly used food additive, for more than 10 years. Two years ago, a professional cancer research organization wrote a position paper stating that Chemical X is most likely carcinogenic, based on studies for which all the associated data were publicly available. A government agency, which has access to both public and proprietary data, has published a safety assessment concluding that the chemical is unlikely to be carcinogenic. During a meeting with several lab members, Dr. PI discusses this disagreement between the professional organization and the government agency and how to help resolve it. The group comes up with the idea of conducting a meta-analysis and systematic review of published papers on this subject. After the meeting, Dr. PI asks a postdoctoral fellow in the lab, Dr. Fellow, to help with this project, who eagerly agrees. Dr. PI, working with the IC's Tech Transfer office, spends more than a year negotiating agreements with the key private funders of research on the chemical, whose proprietary data were used by the government agency in reaching their assessment. Dr. PI submits a Data Management and Sharing (DMS) Plan indicating that all scientific data except for the proprietary data will be shared, and the Plan is approved by Dr. PI's Scientific Director.

After 18 months, Dr. PI, Dr. Fellow, and two more junior fellows complete the systematic review and metanalysis and conclude that Chemical X is not likely to be a human carcinogen. They draft a paper reporting their results and submit it for manuscript review to their Branch Chief. Before the paper can be submitted for publication, it must be reviewed for regulatory compliance by the Branch Chief, on behalf of the IC's Scientific Director. The Branch Chief was on the committee convened by the professional organization that determined that Chemical X is most likely a human carcinogen and the Branch Chief's research group has published several papers independently demonstrating that Chemical X increases the risk of kidney and bladder cancer in transgenic mice. Two months have passed and the Branch Chief has still not approved Dr. PI's manuscript for submission to a journal, when typically, manuscript review is completed within a couple of weeks. Dr. PI emails the Branch Chief to ask what is causing the delay. A week later, after a follow-up email from Dr. PI, the Branch Chief responds that the manuscript cannot be approved because the study violates the 2023 NIH Data Management and Sharing Policy. The Branch Chief says that the paper can be approved only if the proprietary data are made publicly available at the time of publication. Dr. PI does not believe this to be an NIH policy requirement, and contacts Dr. Charles Dearolf in the Office of Intramural Research for confirmation. OIR confirms that there is no violation of the NIH DMS Policy, and Dr. PI shares this information with the Branch Chief, who still does not approve the manuscript. Frustrated, Dr. PI begins to suspect that the Branch Chief's delay is intentional and

considers whether a formal complaint of violating the NIH Academic Freedom Policy is warranted.

Discussion questions (Facilitator notes with guidance on each question are provided in **bold type** below.):

1. Did the Branch Chief violate NIH's Academic Freedom Guidance?

   It is possible that the Branch Chief has violated the guidance. According to the guidance, the manuscript review process should focus on

   "NIH's role as the institutional authority overseeing NIH-conducted research. Reviewers are not to serve as an additional layer of scientific review, but instead, ensure appropriate policy and regulatory reviews and/or compliance measures are included/described." https://oir.nih.gov/sourcebook/submitting-research-publications/intramural-academic-freedom-guidance

   The Branch Chief claimed to be blocking submission of the paper on the grounds that it violates the NIH data sharing policy. However, the paper does not violate NIH policy, the Branch Chief was informed of this, but did not complete the review of the manuscript after learning this, and thus there is a perception that the Branch Chief is blocking submission because of a disagreement with the outcome of the study. The NIH Data Management and Sharing Policy expects researchers to maximize the appropriate sharing of scientific data, but recognizes that there may be some limitations, for example when working with proprietary data:

   "NIH understands that some scientific data generated with NIH funds may be proprietary…NIH recognizes that the extent of data sharing may be limited by restrictions imposed by licensing limitations attached to materials needed to conduct the research. Applicants should discuss projects with proposed collaborators early to avoid agreements that prohibit or unnecessarily restrict data sharing. NIH staff will evaluate the justifications of investigators who believe that they are unable to share data." https://grants.nih.gov/policy-and-compliance/policy-topics/sharing-policies/dms/policy-overview

   If the Branch Chief refuses to approve the paper after being informed that its publication is consistent with the NIH data sharing policy, the Branch Chief may be in violation of the Academic Freedom Guidance.

2. Who should Dr. PI contact for advice about how to handle this situation?

Anyone who has questions about the Intramural Academic Freedom Guidance should contact Dr. Kathy Partin, NIH Research Integrity Officer, Kathryn.Partin@NIH.gov. Individuals with questions are welcomed to pose "hypothetical scenarios" to the AIRIO about putative suppression of academic freedom, if they are seeking guidance about whether an action could fall under the applicability of this guidance. More information about allegations of suppression of academic freedom is located in this Standard Operating Procedure. They could also talk to the NIH Ombuds Office.

3. Does NIH's Data Management and Sharing Policy allow the kind of project that Dr. PI conducted; i.e., a project involving proprietary data that can't be shared publicly?

   Yes, see above.

4. Does the Branch Chief's involvement on the committee that made a carcinogenicity finding constitute a potential conflict of interest to review the manuscript objectively? How should this be addressed? Who could Dr. PI contact about this issue?

   Although it does not meet the definition of a conflict of interest according to government ethics rules, it clearly could create the appearance of a conflict of interest because a reasonable person might question the Branch Chief's impartiality concerning the review of Dr. PI's paper. https://ethics.od.nih.gov/coi Dr. PI could contact their IC's Deputy Ethics Counselor about this issue, but this will also be assessed if Dr. PI files an allegation of suppression of academic freedom.

5. What is the impact on Dr. Fellow's career if the Branch Chief does not allow the manuscript to be submitted? On Dr. PI's career?

   The impacts could be substantial for everyone involved, but especially the fellows, who have devoted considerable time to this project and would have nothing to show for it. Dr. PI has tenure, but every paper is still important in judging progress.

6. Is it ever appropriate not to allow a manuscript to be submitted for publication?

   Yes, if it does not comply with NIH policies or federal laws or regulations; for example, if it involves human subjects but there has been no IRB approval or exemption; animal subjects with no ACUC approval, or it involves significant dual use (i.e., biosecurity) issues that have not been adequately addressed.

[End of Case Study 1]

Please take the survey by either clicking on the link below or scanning the QR code on your hand-held device: https://www.surveymonkey.com/r/5BNR2CP

Case 2: Taking Initiative

X is a second-year predoctoral fellow whose dissertation research involves a formal collaboration between an NIH principal investigator (PI A) and a PI at a local university (PI B). X's project focuses on preparing and analyzing zebrafish tissue samples following behavioral testing. The zebrafish colony, behavioral assays, and euthanasia procedures are maintained at the local university under PI B's approved animal protocol, while the downstream tissue analyses are conducted in PI A's NIH laboratory. X regularly moves between the two sites and is mentored by both PIs.
At a recent graduate committee meeting, PI A encourages X to begin "taking more initiative" in shaping the direction of the project, emphasizing the importance of developing independence as X works toward defending a thesis. X leaves the meeting motivated, but somewhat uncertain about what "taking initiative" should look like. Inspired by the PI's encouragement, X begins reviewing the literature for ideas before a planned two-week vacation abroad later that week.

Shortly before leaving for vacation in a foreign country, X identifies in the literature a recently developed zebrafish behavioral assay that appears relevant and potentially complementary to their work. X learns that a lab near the vacation destination, led by PI C, has the necessary setup. X also realizes that a former lab member is currently a senior member in PI C's lab. Seeing an opportunity, X reaches out directly to PI C, making introductions and asking about the possibility of using the equipment while visiting the area. The email is brief and informal, but PI C responds positively, interpreting the request as part of a potential collaboration and assuming that X's mentors are aware of it.

While visiting PI C's lab, X performs the behavioral experiments on genetically modified zebrafish with the senior member (former lab member/colleague of X) of PI C's lab, seeing promising results and recording them in a paper-based notebook instead of the electronic lab notebook back home. X is aware that this new direction has not been discussed in detail with either PI A or PI B, but reasons that presenting promising pilot results will be more compelling than proposing a speculative idea. Upon the return trip to the United States, X brings some of the zebrafish tissue samples from the behavioral tests in a suitcase, planning to use them for analysis in PI A's lab.
After performing analyses at the NIH with the transported tissue, X begins to think about how the new findings might fit into a broader scientific story. Although X has limited experience writing manuscripts and has not yet discussed publication plans

with any of the PIs, X writes a rough draft of a paper combining existing and newly generated data. Hoping to merit first authorship, X shares the draft with all three PIs, who are also listed as authors on the paper.

The responses are mixed and unexpected for X. PI A is surprised to learn that zebrafish tissue were transported internationally and brought to the NIH and begins to consider which policies may have been violated. PI B, meanwhile, believes the new behavioral data diverge from the original goals of the project, that the new behavioral assay is scientifically valid and that PI B's own lab should be the only source of behavioral data for the project. PI C is surprised and concerned that assays were performed in PI C's lab without PI C being informed or providing approval and without the knowledge and approval of the other PIs. All three PIs question whether the collected data are sufficiently developed to support a manuscript and question X for keeping them in the dark about what they were doing and not following proper procedures. After reviewing X's data and notes, PI B complains that the record-keeping for the research conducted in PI C's lab is not sufficient for others to reproduce the findings. PI A complains that the tissue analyses are not usable because they do not link to any original raw behavioral data.

X is left trying to reconcile these differing reactions. Having believed that X's efforts demonstrated initiative and would lead to a first-author publication, X instead begins to question whether a career in research is achievable or even desirable.

Discussion questions (Facilitator notes with guidance on each question are provided in **bold type** below.):

1. Did X act appropriately in "taking initiative"? What could X have done better? What was a better way for the PIs to handle this situation?

   X acted appropriately in reviewing the scientific literature and identifying a potential new assay that could be useful for the project. At that point, X should have discussed this possibility with one (if not both) of the PIs to see if that avenue seemed promising and worth investing time and resources into, and to understand any additional requirements associated with working in a foreign third party lab, documenting research results, and bringing biological materials into the United States. In reaching out directly to PI C without first discussing this possibility with either PI A or PI B (or

both), X risked appearing to represent the wishes of the PIs, as any collaborations represent the commitment of research resources and therefore need the agreement of each group's PI. It was also inappropriate for the fellow to work in PI C's lab during vacation; at least with respect to NIH, such activities must be approved in advance. In the US and most foreign countries, work with research animals requires prior approval from an ethics committee at that institution. The actions of X may have violated policies and regulations of the foreign country, which could potentially be enforced against X. Once the PIs were aware of the situation, they could have determined how to move forward with the project while adhering to institutional policies and import requirements and setting clear expectations for the trainee.

2. Can a trainee take initiative without risking major errors? What are some strategies PIs can use to help develop independence?

   When communicating with trainees, it is important for the PI to gradually increase independence with clear boundaries at each stage, rather than suddenly and vaguely tell a trainee that they should generally be taking more initiative with no obvious next steps. Having clear examples of what initiative looks like for the specific project and stage would be helpful for the trainee, as well as explicitly checking in with the trainee about how the trainee believe they are progressing toward their goals. Scientific training is inherently a learning experience and mistakes are unavoidable, but having a supportive mentoring structure with clear communication and expectation-setting will help to mitigate major errors.

3. When should X have discussed the new project ideas with PI A? PI B? PI C?

   At a minimum, X should have discussed the new project ideas with PI A after identifying the assay in the literature and before reaching out to other PIs, as PI A was the one who was encouraging X to take more initiative on the project direction. X could have waited for PI A to agree or tried to have that conversation simultaneously with PI B, as PI B oversaw the zebrafish and behavioral assays and would have had valuable thoughts on whether the new behavioral assay was promising. Only once X had agreement from both PI A and PI B should any communication have gone out to PI C, and a decision made about establishing a potential collaboration. If so, the regulatory implications of the collaboration could have been explored prior to work being done.

4. What approvals, if any, are necessary before transporting biological specimens:
    - Internationally?

      Every transfer of materials into the NIH from an outside party, whether international or not, must take place in accordance with a Material Transfer Agreement, or another agreement including terms appropriate for material transfer, between NIH and the outside party; such agreements are the responsibility of the appropriate IC Technology Transfer Office (TTO). If the agreement is for human materials, the agreement will also include specific protections and restrictions on the use of such materials. A request for importation must be submitted to the NIH Quarantine Permit Service Office (QPSO) when importing biological products, diagnostic, or infectious materials into the United States. A request for importation must be submitted for the transfer of previously permitted imported material. When sending any and all biological material from NIH facilities to an overseas destination, an export declaration must be signed by NIH QPSO. Depending on the material being shared, importation permits may be required for transport into the US by the CDC or USDA, or into the receiving country. QPSO can advise on these requirements. All packaging must comply with the Department of Transportation (DOT), the Federal Aviation Authority (FAA) and the International Air Transport Association (IATA) dangerous goods regulations. Federal and international regulations require that the packager successfully complete job-specific training and be trained to ship biological products, diagnostic or infectious materials. For this scenario, the fellow would be expected to properly package the materials, declare them, and present approved importation documents/ permits during the customs inspection. Placing such samples in a suitcase without declaring them could potentially be viewed as "smuggling" samples into the US.

      Questions should be directed to the NIH QPSO at (301) 496-2960.
      https://ors.od.nih.gov/sr/dohs/safety/laboratory/BioSafety/Pages/shipping_biological_material.aspx

    - Between NIH and other US institutions?

      A material transfer agreement (MTA) is required to transport biological specimens between the NIH and other institutions. If the specimen is a human sample, sharing of specimens must be consistent with the institutional review board (IRB) approved human research protocol and consent form. The material may also be required to be registered with the institutional biosafety committee (IBC). In these cases, IBC sign-off may also be required to ensure that appropriate safety standards and

containment methods are in place for transportation, handling, and storage.

- Among different NIH labs/ICs?

  An MTA is not required but is highly encouraged as best practice. Transportation must be consistent with the relevant approved protocols and IBC registrations.

How are the answers different if we are talking about data instead of biological samples?

There are far fewer restrictions on data, but there are some. First, original data are federal records and cannot be taken from the NIH. Original data must be stored electronically on NIH servers and devices. Trainees may take copies of original data only with permission, beginning with filling out NIH Form 3000 at least 45 business days in advance (https://oir.nih.gov/sourcebook/personnel/policies-recruitment-processes/departing-staff-request-remove-copies-nih-records). If the data contains personally identifiable information (PII), IRB sign-off is required to make sure that sharing the data is consistent with the protocol and consent form. Sharing may require a data use agreement or other agreement type. If the data is from humans, the agreement must include specific protections and restrictions on the use of the data. Depending on the data being shared, IBC review and approval by the NIH biosafety officers would be required. In more rare cases, if the data or information raises dual use research of concern or dangerous gain of function questions, additional clearances by the Division of Safety and NIH may be required.

5. What are some generally accepted standards for keeping a lab notebook? How should researchers who are collaborating address potential conflicts between record-keeping standards among their home institutions?

   Lab notebooks (required to be electronic for all research conducted by all NIH intramural researchers since July 2024) must be complete regarding all research details including dates, detailed methods, materials used, and where any associated data are being stored for each experiment or assay. The central concept is that a competent scientist (and you) should be able to reproduce your work based on what you have recorded in the notebook. It should be easy to search, copy, and/or archive, link to any data set not in the electronic lab notebook, be sharable, be readily accessible at all times to

the PI or other supervisor and be easily stored on the cloud. For example, NIH's LabArchives is readily available using an internet connection from anywhere in the world via https://elnla.cancer.gov. More lab notebook best practices can be found through the NIH Sourcebook. For NIH researchers who collaborate with extramural institutions, it is the responsibility of the NIH researchers to ensure that all records generated for their project are electronically accessible. For collaborators who may still be using paper records, the PIs of the research groups should agree on how to make those records shareable electronically, preferably as part of an established collaboration agreement.

6. If a paper is written, even if it was not directed by any of these PIs, does X's contribution warrant first authorship, and who decides?

   In order for a manuscript for merit first authorship, the PIs associated with that manuscript must approve its ultimate submission to a reputable scientific journal. If the underlying data are deemed by the PI(s) to be irreproducible, low quality, unsupportive of a scientific story, or otherwise not of publication quality, then there is no authorship to be awarded. While every first draft will ultimately be edited, there is a line between edits and a complete reconstruction of a manuscript, and it is the PI who makes the decision about whether there is enough usable data to move forward with a draft. If the PI does not believe the draft is usable, then first authorship is not merited. Each PI's expectations and philosophies regarding (first) authorship generally should be clearly communicated to all research group members when they join the group. Authorship specifics such as authorship order for a given project should be revisited regularly as projects evolve to keep all group members aware of any changes. Many of the PIs' decisions about authorship are within the scope of the NIH IRP Authorship Conflict Resolution Policy.

7. Would it be selfish or unethical for PI B to want the main focus of the paper to be on data collected in PI B's own research group versus a collaborator's?

   Bias and intent are important considerations here, though they are often difficult to discern in the moment, as even the PI may not be aware of the PI's own motivations. If the PI is purely motivated by producing the highest quality scientific story and believes the new assay is not valuable to the project, then it is not selfish or unethical. It is only once the PI's motivation is driven by a desire to be territorial or exclusive despite knowing that the

additional data would be scientifically valuable that issues arise, though the decision about what to include in a manuscript ultimately rests with the PI. A clear and effective collaboration agreement between PI A and B might specify how the data are used, and what related research can be performed outside of the collaboration.

8. What are some of the challenges associated with co-mentorship? The advantages?

   Some advantages of co-mentorship include but are not limited to: a combination of expertise that can lead to unique and multidisciplinary projects; additional mentorship that can fill gaps when one mentor's style or background is not an ideal match for the trainee; resources that can not only span research groups but also institutions. A major challenge is with communication, as clear communication and expectation-setting is a challenge with only one mentor, so each additional mentor provides new opportunities for communication gaps and mismatches (along with different mentoring or scientific philosophies), which is confusing for the trainee. A clear and effective collaboration agreement can provide guidance on these issues.

9. What needs to be done at this point to move forward with this project? Who needs to be contacted?

   All the PIs and X need to get together and figure out how to move forward constructively with this project (if at all). Research compliance officials, such as animal program directors, biosafety officers and human subject's compliance coordinators, should be contacted about any health or safety issues with bringing the samples to the NIH campus. The NIH PI should request their IC TTO's assistance in putting in place 1) a Confidential Disclosure Agreement (CDA) in advance of any conversation with PI C (assuming that confidentiality between PI A and PI B is already covered in a separate agreement), and 2) an appropriate collaboration and/or material transfer agreement that clearly lay(s) out the rights and responsibilities of the parties; even if the PIs decide not to move forward with this project, it would be best practice to enter into such an agreement(s) retroactively for the materials already transferred and the work already performed, It might be a good idea for the PI and X to contact OITE about this situation and how best to support X's "taking initiative." Another useful resource might be the

NIH Ombuds Office to sort out the conflicting expectations and each of the collaborating lab and institutional requirements.

[End of Case Study 2]

Please take the survey by either clicking on the link below or scanning the QR code on your hand-held device: https://www.surveymonkey.com/r/5BNR2CP