2025 Annual Ethics Cases: Good Recordkeeping, Responsible AI Use, and Laboratory Safety

The Committee on Scientific Conduct and Ethics (CSCE) has prepared three cases for 2025 that deal with some important topics relating to good recordkeeping and reproducibility, use of AI in writing official and clinical documents and maintaining laboratory safety. These include:

Case 1: Recordkeeping, Reproducibility, and Authorship

Case 2: Responsible use of AI in Preparing IRB Submissions

Case 3: Laboratory Safety as a Shared Responsibility

Since it may not be possible to cover all three cases in the allotted time, we suggest that facilitators cover the cases that meet the needs and interests of their audience.

Case 1: Recordkeeping, Reproducibility, and Authorship

After five years of work on a project in an NIH research group, a postdoctoral fellow ("postdoc") wrote a manuscript to report the exciting discovery of a novel human cancer protein. The plan was to submit the manuscript to a high-visibility journal with the postdoc as first author and with the postdoc's Principal Investigator (PI) and a clinical collaborator as co-authors. With a job opportunity in hand, the postdoc departed the NIH in a rush, leaving the draft manuscript with the PI to submit.

The PI appointed a postbaccalaureate fellow ("postbac") to the research group shortly after the postdoc left, with the intent of continuing the postdoc's project. The PI asked the postbac to reproduce one of the key experiments from the draft manuscript. Unfortunately, examination of the postdoc's incomplete electronic lab notebook and clinical files made it difficult for the postbac to understand some of the details from the initial experiments, and the methods section of the manuscript was quite brief. The postbac, who had never performed research full-time previously, asked the PI what to do. The PI, looking through the lab notebooks more closely, found the level of information entered to be minimal and wondered if there was supporting information stored elsewhere in the lab. Although the PI had felt confident about providing proper instruction in good recordkeeping practices to lab members, the PI did not actually review the records regularly and in this case, regretted not having reviewed them prior to the postdoc's departure. The PI emailed the postdoc to ask for any possible additional information, but the postdoc replied that everything necessary had been entered into the electronic lab notebooks that each lab member had been assigned in June 2024. The postdoc noted that there were some paper notes from before 2024, along with more recent scrap paper in a drawer in the lab that might provide some additional insight but that the postdoc did not think those rose to the level of inclusion in the electronic lab notebook.

The postbac found the paper notes and, together with the PI, pieced together what had been done experimentally. The postbac repeated the experiment and found results that were similar to those in the manuscript, but with some key differences. The PI, concerned about the reproducibility of the data, asked the postbac to repeat the other experiments as well. The PI, now less confident in the data generated by the postdoc, closely examined the manuscript figures, found some suspicious duplications within a key image and feared that the data might be unreliable. Over several months, the postbac was able to successfully recreate all the postdoc's experiments. While the main scientific story had not changed, the PI decided to replace the figures from the original manuscript with those generated by the postbac, as they had clearer supporting details recorded in an electronic lab notebook. The postbac then helped to edit the manuscript, rewriting some sections. The postdoc, who was concerned that there had not yet been an update about the manuscript being submitted, emailed the PI to ask if it was going to be submitted soon. The PI had doubts about whether the postdoc should still be first author (or even an author at all) anymore because the updated manuscript did not contain any of the postdoc's original data, but the

PI did not want to upset the postdoc, so the PI replied that the group was still working on the edits to the manuscript.

Discussion Questions:

1. Why is it important to keep highly detailed records of laboratory and clinical research data and analyses – which should have been electronic at the NIH since June 2024?
2. Is it acceptable for a fellow to decide that some notes do not need to be included in the official lab notebook? How detailed does a lab notebook need to be?
3. Is it unusual for a new lab member to be unable to replicate previous experimental results?
4. Should the postdoc be the first author or a co-author on the new version of the paper?
5. Could the postdoc's low quality of recordkeeping lead to suspicions of research misconduct? How should the PI respond in this case?
6. Was it fair for the PI to ask a new lab member, especially a postbac to reproduce experiments in a manuscript that is ready to be submitted to a high visibility journal? What kind of pressure does this situation put on the postbac?
7. What could each person have done differently to prevent the problems that occurred in this case?

[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/M68XD9V

Case 2: Responsible use of AI in Preparing IRB Submissions

A busy, understaffed assistant clinical investigator decides to take advantage of the NIH's AI tool, ChIRP (Chatbot for the Intramural Research Program), to write initial drafts of documents for a submission to the Institutional Review Board (IRB), including the protocol and the informed consent form. The investigator shares these documents with the clinical research coordinator (CRC) and asks the CRC to review and edit them for IRB submission. The investigator informs the CRC that ChIRP wrote these initial drafts, but neither the investigator nor the CRC disclose the use of the AI to the scientific review committee. The study is a Phase II trial of an off-label use of commercially available blood pressure medication to treat symptoms of an enlarged prostate. Two months after the study begins, a participant dies from renal failure. An investigation into the incident determines that participant's death was due to an adverse interaction between the study medication and an over-the-counter medication that the participant was taking but did not inform the investigator about. The adverse drug interaction was reported only in studies published in the last year, which was beyond the range of the AI's training data. Since the investigator relied solely on the AI to perform the literature review included in the protocol and other documents submitted to the IRB, the literature did not mention these drug interactions. Furthermore, the consent form did not include any questions regarding the concomitant use of other drugs while the patients were in the study trial. Following an investigation into the incident, the clinical investigator admits to using the AI to perform the literature review and write an initial draft of the protocol and informed consent form and takes full responsibility for this tragedy.

Discussion Questions:

1. Is it ethically permissible to significantly rely on or even use AI to help write documents, such as the protocol or informed consent form, submitted for IRB review?
2. What are the investigator's and CRC's responsibilities when using AI to help prepare an IRB submission?
3. Should the investigator and CRC have disclosed the use of the AI to the scientific review committee?
4. What are the responsibilities of the scientific review committee and/or the IRB in this case?
5. What sorts of uses of AI are permissible and useful at NIH?
6. What types of uses of AI within NIH should be disclosed?
7. Do you think people are hesitant to disclose the use of AI in drafting documents?

[End of case study #2]

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Case 3: Laboratory Safety as a Shared Responsibility

Dr. C's pathology lab is being moved to a new building. Dr. C is not happy about this and complains about it to other members of the lab repeatedly. Dr. C is especially upset about the disruption in work that will occur and loss of time to perform important experiments needed to get a paper (returned for revisions) accepted in a high-impact journal, which will help with Dr. C's upcoming tenure review. The moving day arrives, and members of the lab begin unpacking boxes in the new location. A senior postdoc asks for a boxcutter to help open boxes. After looking for a boxcutter but failing to find one, the postdoc decides to use a scalpel to open boxes. On the fourth box, the scalpel slips and cuts the postdoc's thumb, which starts bleeding profusely. A technician quickly grabs some tissues and uses them to apply pressure to the thumb to control the bleeding. The technician and postdoc wash the thumb with water from the laboratory sink and pour some alcohol on it to sterilize the wound. The technician also creates a make-shift bandage for the thumb. Dr. C enters the room and says, "I heard someone cry out. Is everything OK in here?" The postdoc responds, "I just nicked my thumb while opening a box. We bandaged it and it is all good". Dr. C reminds the postdoc that, according to the annual safety training they both took recently, the postdoc should contact OMS to report it. The postdoc, who did not pay close attention to the training, looks at the pile of boxes remaining to be unpacked and decides not to report the incident to Occupational Health. Dr. C, who does not see the postdoc's bandaged thumb, returns to the office.

Discussion Questions:

1. How could this accident have been avoided?
2. What are some of the factors that contributed to this accident?
3. Why in your opinion didn't the postdoc tell Dr. C exactly what happened?
4. Was the postdoc responding to pressure from Dr. C, whether real or perceived?
5. Was it appropriate to not report this incident to Occupational Health?
6. Who was responsible for reporting the incident to OMS?
7. Was Dr. C promoting a safety culture in the lab?

[End of case study #3]

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