

2023 Ethics Cases

We have prepared three cases for 2023 that deal with some important topics relating to authorship, credit, and mentoring. These include:

Case 1: Transfer of a Project and Scientific Disagreement

Case 2: Authorship or Acknowledgement of a Post-baccalaureate Trainee

Case 3: Collaboration and Outside Activities

Cases #1 and 2 may be suitable for all while case #3 is more specialized and related to CRADAs.

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 the audience.

Facilitators are encouraged to provide their audiences the information to the NIH IRP Authorship Conflict Resolution process (updated in May 2023) and other useful authorship resources, that can be found in the NIH Intramural Sourcebook (<https://oir.nih.gov/sourcebook/ethical-conduct/authorship-guidelines-resources>).

Note: In these case studies we use proper names to identify characters, which do not represent real persons affiliated with NIH. The names have been randomly chosen to accurately mirror the rich diversity of the NIH intramural community. Readers are cautioned to question stereotypes they associate with names that may suggest a specific race, national origin, ethnicity, gender, or sex.

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Case 1: Authorship, Transfer of a Project, and Scientific Disagreement

Dr. Cooper had a four-year postdoctoral fellowship in an NIH neuroscience laboratory headed by Dr. Jiang before leaving the NIH for a tenure-track research position at a university. Dr. Cooper published several first-author papers that supported a hypothesis (H1) concerning the role of the immune system in the formation of amyloid- β (A β) plaques in Alzheimer's disease in transgenic mice. Dr. Cooper came up with the idea for H1 while in graduate school and joined Dr. Jiang's lab as a postdoctoral fellow with the goal of testing and refining H1. Toward the end of the fellowship, Dr. Cooper began working on a project to determine whether blocking interleukin-10 causes the immune system to remove amyloid- β (A β) plaques from the brain. Dr. Cooper developed a protocol for the project and gathered some preliminary data that resulted in their selection for a tenure-track position at the end of the 3rd year of the fellowship. Before leaving, Dr. Cooper and Dr. Jiang agreed, by email, that Dr. Cooper would continue working on the project as an NIH Special Volunteer, would have access to NIH data, and would be the first author of a paper reporting the project's results. Dr. Jiang assigned the project to Dr. Rivas, another postdoctoral fellow. After having difficulty replicating Dr. Cooper's preliminary data, Dr. Rivas consulted with Dr. Jiang, but not Dr. Cooper, and made substantial changes to the protocol. Following these changes, the experiments proceeded smoothly. After completing data collection and analysis, Dr. Rivas wrote the first draft of a manuscript, which listed Dr. Rivas as the first author, Dr. Cooper as second author, and Dr. Jiang as last and corresponding author, with several other coauthors. Dr. Jiang sent the manuscript to Dr. Cooper, who read it carefully and became very upset because 1) Dr. Cooper is listed as second author and not first; 2) Dr. Cooper disagrees with the interpretations of the data, which undermine support for H1 and lend support to a different hypothesis proposed by Dr. Rivas; and 3) Dr. Cooper disagrees with changes to the protocol made by Dr. Rivas without consultation with Dr. Cooper and believes these may have impacted the findings.

- 1. Should Dr. Rivas have consulted with Dr. Cooper before making changes to the protocol?**
- 2. Who should be first author of this paper? Should Drs. Cooper and Rivas be co-first authors? What factors would you consider in making this decision?**
- 3. Does Dr. Jiang's promise to name Dr. Cooper as first author carry any weight?**
- 4. Should Dr. Jiang have talked to Dr. Cooper before naming Dr. Rivas as first author? Should Dr. Jiang have done anything else? Who should be listed as co-authors on a paper?**
- 5. Do you have any concerns about Dr. Jiang's mentoring of Dr. Cooper? Could Dr. Jiang have done a better job of mentoring Dr. Cooper? How?**
- 6. What should Dr. Cooper do to remedy a disagreement with Dr. Jiang about being placed as second, not first author on the paper?**
- 7. How should the team go about resolving the dispute about interpreting the data? If they cannot resolve this issue, would it be ethical to publish the paper without naming Dr.**

Cooper as an author but mentioning Dr. Cooper in the acknowledgments? What should Dr. Cooper do if the paper is published without their consent?

8. What are the benefits and risks of being wedded to a particular hypothesis?

[End of case study]

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Sourcebook chapter on Outside Activities for FTEs and Outside Activities for non-FTE trainees: <https://oir.nih.gov/sourcebook/ethical-conduct/government-ethics/guidelines-non-ftes-trainees-nih-related-activities-outside-activities>

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NIH policy on CRADAs: <https://www.techtransfer.nih.gov/policy/cradas>

Researchers can always reach out to the NIH Office of the Ombudsman for advice on how to navigate challenging situations at work - <https://ombudsman.nih.gov/>

Case 2: Authorship or Acknowledgement for a Post-baccalaureate Trainee

Mx. Tegene was an NIH post-baccalaureate trainee with a BS in psychology, supervised by Dr. Murphy, an endocrinologist and clinical researcher at the NIH. Mx. Tegene spent a year at NIH before enrolling in medical school. While at NIH, Mx. Tegene assisted Dr. Murphy with a research project on medication adherence and health outcomes for patients with Type II diabetes. Other people working on the project included a pharmacy fellow, Dr. Raj, a social worker, Mx. Puig, and a research nurse, Mx. Vilensky. The project involved collecting the medical and social history of study subjects/patients, reviewing medications, collecting blood and urine samples, and administering several surveys/interviews. After a long day of interviews, Mx. Tegene was having coffee and talking with Mx. Vilensky about some ways of potentially improving medication adherence. Mx. Tegene suggested that using an interactive game on cell phones might improve medication adherence. The following week, Mx. Tegene gave a report at a lab meeting summarizing their initial findings. During the discussion period, Mx. Tegene said that it might be interesting to test whether using an interactive game on cell phones could improve medication adherence. Dr. Murphy seemed interested in this idea but not incredibly impressed. Two years after leaving the NIH, Mx. Vilensky sent Mx. Tegene a paper recently published in *The American Journal of Diabetes Management* describing the results of a study testing the efficacy of using an interactive cell phone game to promote medication adherence, which showed that playing the game increased medication adherence by 30% and glycemic control by 25%. The authors included Dr. Raj, Mx. Vilensky, Mx. Puig, and Dr. Murphy but not Mx. Tegene. Mx. Tegene was not even acknowledged in the paper. Mx. Tegene is upset after reading the paper because of not being credited for the study's original idea. Mx. Tegene contacts Dr. Murphy about this issue and demands an explanation. Dr. Murphy replies that Mx. Tegene was not acknowledged because it was not Mx. Tegene's original idea. Dr. Murphy mentions discussing this idea with other NIH colleagues before, but when pressed by Mx. Tegene, Dr. Murphy cannot remember precisely when this occurred.

- 1. Should Mx. Tegene have been an author of this paper? Should Mx. Tegene be acknowledged in this paper?**
- 2. How can Mx. Tegene be acknowledged at this point?**
- 3. If Mx. Tegene is not acknowledged, would this be plagiarism? How would one prove plagiarism?**
- 4. Should Dr. Murphy have asked Mx. Tegene to collaborate with the research team on the adherence project and possibly be an author?**
- 5. Assuming that Mx. Tegene would not collect any data due to their commitment to medical school, what would Mx. Tegene need to do to qualify as an author?**
- 6. If you know that an idea has been discussed by others but not published or presented formally, should you acknowledge it? How would you do this?**
- 7. Should members of the research group have written down Mx. Tegene's medication adherence idea when it was discussed at the lab meeting?**

[End of case study]

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Case 3: Authorship, Collaboration, and Outside Activities

Dr. Johansson is a postdoctoral researcher at Cutting Edge University who is working and training at the NIH via a Special Volunteer appointment under the direction of Dr. Fathi. Dr. Fathi, Dr. Parekh, a Professor at Cutting Edge University, and researchers from BioAI, a private company, have been collaborating on developing artificial intelligence (AI)/machine learning (ML) programs that predict how respiratory viruses interact with human lung epithelial cells.

The collaboration is governed by a Cooperative Research and Development Agreement (CRADA) between NIH, Cutting Edge University, and BioAI. As part of this collaboration, Dr. Fathi agreed to have Dr. Johansson work and train at the NIH for two years. The NIH provides Dr. Johansson with training, access to facilities, equipment, expertise, and data but not stipend/salary support, which is provided by Cutting Edge University. The AI/ML programs that Dr. Johansson is working on have been developed using NIH data. Some of the software is open source, but some is under development and not yet published or shared widely. The CRADA permits the sharing of computer code between NIH, Cutting Edge University, and BioAI.

One morning, Dr. Takekazu, Dr. Fathi's Branch Chief, asks Dr. Fathi to meet in person about an urgent matter. Dr. Takekazu informs Dr. Fathi about a paper recently published online in the *Journal of Machine Learning in Biomedicine* that describes an AI/ML model for predicting how the herpes simplex virus interacts with genital cells. Dr. Johansson is the paper's first author, Dr. Parekh is the last author, Dr. Fathi is the second to last author, and 3 authors from BioAI are middle authors. Dr. Johansson's affiliation is listed as with the NIH and Cutting Edge University. The paper lists funding support from Cutting Edge University and BioAI and acknowledges NIH's support. The paper also mentions that software patents are being applied for. Dr. Takekazu further notes that: (1) there is no record of the article having gone through the NIH manuscript clearance process, and (2) no employee invention report (EIR) has been submitted to the NIH Office of Technology Transfer.

Dr. Fathi is surprised to hear this news, explaining that they were unaware of this manuscript and are now hearing about this research for the first time. Dr. Fathi is additionally dismayed at not knowing about Dr. Johansson's undisclosed work for this research, which was not part of the research plan described in the CRADA.

- 1. What are some of the ethical/legal/policy concerns created by this situation?**
- 2. What should the NIH/Dr. Fathi do? Should Dr. Fathi write to the journal and ask to have their name removed from the paper? Should Dr. Fathi ask the editors to withdraw the paper because computer codes were used without permission?**
- 3. Can Dr. Johansson remain the first author but not list their NIH affiliation?**
- 4. Should the NIH contest the patents that are being applied for?**

5. How could this situation have been prevented? What steps would need to be taken for this type of collaboration to occur without violating ethical or legal rules or NIH policy?
6. Do you see any problems with Dr. Fathi's mentoring of Dr. Johansson? Should Dr. Fathi have done a better job of explaining to Dr. Johansson about the scope of the collaboration under the CRADA and what was allowable?

[End of case study]

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