

2023 Ethics Cases + Facilitator Notes

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?

This answer depends in part on the details of the agreement made between Dr. Cooper and Dr. Jiang. The way the case is written, it is unclear if Dr. Cooper knew that another trainee in the lab had been assigned the project at all or if Dr. Rivas was aware of the original agreement. At a minimum, since Dr. Rivas was not actively involved in the agreement, Dr. Rivas made a reasonable choice in going directly to Dr. Jiang with their data and protocol challenges. As the PI, it was Dr. Jiang's responsibility to ensure that communication was clear amongst all members of the team and to honor the original agreement. However, if a team dynamic had been established by Dr. Jiang that put Drs. Rivas and Cooper into direct contact with each other, it would likely have been expected that Dr. Rivas either reach out directly to Dr. Cooper or include Dr. Cooper in the communications, particularly if major changes were to be made on a project where Dr. Cooper is the lead and presumed first author.

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?

The criteria for establishing authorship can be found here:

https://oir.nih.gov/system/files/media/file/2021-08/guidelines-authorship_contributions.pdf.

If Dr. Rivas had drafted the manuscript, first authorship would have been warranted. Shared first-authorship is reserved for when authors have contributed equally to the work. While Dr. Cooper generated the original idea for the paper, if another lab member physically performed the experiments after troubleshooting an existing protocol and then drafted the manuscript, it is unlikely that co-first-authorship would have been warranted. However, there is tremendous PI discretion in making the determination about the level of contributions of each author, and Dr. Cooper could have regularly contributed ideas that were critical for the success of the project. If Dr. Cooper had helped to continually steer the project, that would be one factor in favor of first (or potentially co-corresponding) authorship, but the fact that Dr. Rivas (and Dr. Jiang) did not seem to include Dr. Cooper in their regular communications and troubleshooting about the project also implies that the Dr. Cooper's level of involvement on this project was not particularly high and unlikely to merit this level of authorship.

Best practices surrounding authorship include collective agreement at the beginning of the project of presumed authorship (particularly first-authorship), but include the recognition that changes are possible as the project progresses. Transparency in communication with all team members as the project progresses is critical to this approach.

3. Does Dr. Jiang's promise to name Dr. Cooper as first author carry any weight?

Promises about authorship in general are common but often do not pan out as planned as projects move in unexpected directions, which is very common in science, and the final manuscript often looks very different from the original vision. Ultimately, the NIH guidelines for authorship contributions must be followed when determining final authorship, regardless of any promises made at the outset of a project. The promise itself is not enough to change the authorship order and should have been stated as a plan as opposed to a "promise".

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?

Dr. Jiang absolutely should have spoken with Dr. Cooper if their original agreement about authorship was changing, but ideally, Dr. Cooper would have been receiving regular updates about the status of the project so that any changes in the project's contributions and direction would have been increasingly apparent as opposed to delivering a single unpleasant shock. If Dr. Jiang was unsure of how to proceed with a potential authorship conflict as the project evolved, they could have contacted any number of individuals or offices at the NIH for advice- the IC Scientific Director or Lab/Branch Chief, the Training

Director, the NIH Agency Intramural Research Integrity Officer (AIRIO), or the NIH Office of the Ombudsman.

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?

When a trainee leaves the NIH, there is the expectation that a former PI mentor will continue to support that trainee's career. In this case, at a minimum, there was a lack of transparent communication on a project for which a trainee had been promised ownership. The outcome in this case gives the impression that an empty promise may have been made in order for the lab to retain ownership of a project, which may ultimately harm the relationship between Drs. Jiang and Cooper. The downstream decisions and lack of communication also cost Dr. Cooper the ability to be involved with the experiments that were designed to support or refute the hypothesis that they had originally generated. On the other hand, allowing for a neutral party to conduct experiments is a good practice among PIs that can lead to less bias in data interpretation and additional technical validation of the results. In terms of mentoring, with departing trainees who are taking independent research positions, an arrangement is often made that determines which piece of their project will transition with them into their new position. In this case, that may have been a cleaner arrangement that would have better supported Dr. Cooper's transition to independence, as opposed to creating a situation that ultimately pitted them as a competitor against their former mentor.

6. What should Dr. Cooper do to remedy a disagreement with Dr. Jiang about being placed as second, not first author on the paper?

There are several NIH resources available to help resolve authorship disputes- if direct dialogue is ineffective, the NIH Office of the Ombudsman can provide mediation that allows all parties to confidentially discuss the conflict. Other potentially helpful resources during informal dispute resolution include but are not limited to the Scientific Director, Lab/Branch Chief, or Training Director. If the dispute cannot be resolved through informal channels, additional processes for authorship dispute resolution can be found in the Sourcebook here: <https://oir.nih.gov/sourcebook/ethical-conduct/authorship-guidelines-resources/nih-irp-authorship-conflict-resolution-process>.

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?

The team should have an open discussion about how the data were collected and interpreted. The NIH Office of the Ombudsman is an available resource to help navigate workplace conflicts such as this. When a paper is submitted, all authors must agree to the submission, so removing Dr. Cooper as an author is an option, but only if the paper no

longer contains Dr. Cooper's contributions. Removing Dr. Cooper's contributions should only be done for scientifically justifiable reasons and may not be possible if Dr. Cooper was fundamental to the experimental design of the project as a whole. If a team member meets the criteria for authorship as outlined by the NIH or the specific journal, they must be included as an author and it is unethical to remove them as an author or submit without their consent in an effort to expedite publication. If the paper is published with Dr. Cooper as a co-author but without their consent, Dr. Cooper can write to the editor of the journal with the claim or discuss with the NIH Agency Intramural Research Integrity Officer (AIRIO). If the paper is published without Dr. Cooper as a co-author and without their consent, they may pursue the NIH processes for authorship dispute resolution.

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

When one is wedded to a particular hypothesis, they are driven to pursue the findings that support their preferred hypothesis and ignore or minimize findings that do not, leading to bias in data generation and analysis and interpretation. When a person in a position of power (e.g., the PI or group leader) is wedded to a particular hypothesis, it sends the message to the group that any data that do not support the lab's preferred hypothesis will not be regarded as favorably as data that do support it. This puts all direct reports (but particularly trainees) in a precarious position in which they must balance the pursuit of scientific truth with the pursuit of pleasing the mentor who is a gatekeeper to their future careers. Examining all data with as little bias as possible (or at least recognizing that there is a bias in perspective that must be consciously overcome) is a good place to start. Bringing in a new lab member that is unaware of the scientific bias within a particular group often brings a fresh and useful perspective that can transform the direction of a research program, but only if the PI/group leader and lab group has created a culture that is conducive to openly receiving that perspective. Pursuing informal feedback from other knowledgeable PIs in the program may also help elucidate the issues.

[End of case study]

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Sourcebook chapter on authorship resources and conflict resolution: <https://oir.nih.gov/sourcebook/ethical-conduct/authorship-guidelines-resources>

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>

Sourcebook chapter on Publication and Abstract Clearance: <https://oir.nih.gov/sourcebook/submitting-research-publications/publication-abstract-clearance>

Sourcebook chapter on Foreign Interference: <https://oir.nih.gov/sourcebook/personnel/policies-recruitment-processes/guide-nih-intramural-principal-investigators-navigate-international>

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?

Authorship should be based on a substantial contribution to the conceptualization, design, execution, or interpretation of the research, as well as to the drafting or substantively reviewing or revising the research article (https://oir.nih.gov/system/files/media/file/2021-11/guidelines-conduct_research.pdf). Many PIs would determine that the conceptualization in this case merited authorship, and if not, would definitely merit acknowledgement. Dr. Murphy may have simply forgotten how the idea got conceived, which could have been an honest error, or Murphy could have intentionally omitted Mx. Tegene's name for reasons that are not clear in this case study.

2. How can Mx. Tegene be acknowledged at this point?

If Dr. Murphy inadvertently omitted Mx. Tegene's name, they can contact the journal editor and explain the situation. Usually, if all authors on a published article agree to a minor correction due to an inadvertent error, such as failing to include an acknowledgement, the journal will agree and publish a correction after publication.

3. If Mx. Tegene is not acknowledged, would this be plagiarism? How would one prove plagiarism?

Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. Plagiarism does not include honest error or differences of opinion (https://oir.nih.gov/system/files/media/file/2021-08/policy-nih_irp_research_misconduct_proceedings.pdf). In this case, Mx. Tegene and Dr. Murphy had collaborated scientifically on the issue of medication adherence, so one could argue that they both have some ownership of the idea of using an interactive game to promote medication adherence. The HHS Office of Research Integrity (ORI) has determined that this matter would likely be an authorship dispute, and not plagiarism that was intentional, knowing, or reckless (research misconduct):

Many allegations of plagiarism involve disputes among former collaborators who participated jointly in the development or conduct of a research project, but who subsequently went their separate ways and made independent use of the jointly developed concepts, methods, descriptive language, or other product of the joint effort. The ownership of the intellectual property in many such situations is seldom clear, and the collaborative history among the scientists often supports a presumption of implied consent to use the products of the collaboration by any of the former collaborators. For this reason, ORI considers many such disputes to be authorship or credit disputes rather than plagiarism. Such disputes are referred to institutions for resolution.

(<https://ori.hhs.gov/ori-policy-plagiarism#:~:text=As%20a%20general%20working%20definition,includ%20authorship%20or%20credit%20disputes.>)

4. Should Dr. Murphy have asked Mx. Tegene to collaborate with the research team on the adherence project and possibly be an author?

Dr. Murphy had to decide who is best able to accomplish the research. Sometimes it is feasible to have a postbac make significant contributions to a project such as this, and sometimes it is just not possible due to time constraints or due to the training and background of the postbac. In this case, the paper came out two years later, suggesting that perhaps the project was not feasible for Mx. Tegene due to the short training period for postbacs. It is not possible, based on the information provided, to know if Dr. Murphy should have asked Mx. Tegene to participate in the research based on their initial concept of the game.

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?

Mx. Tegene could earn authorship by virtue of their initial conceptualization of the project, followed by participation in drafting and reviewing the manuscript. All authors are responsible for ensuring that a paper has integrity, and so they must be involved in the process of writing the paper. The criteria for authorship (Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND Drafting the work or revising it critically for important intellectual content; AND Final approval of the version to be published; AND Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved) are not intended for use as a means to disqualify colleagues from authorship who otherwise meet authorship criteria by denying them the opportunity to participate in the writing of the manuscript.

(<https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>) Therefore, all individuals who make a significant contribution (such as with the conceptualization of the game) should have the opportunity to participate in the review, drafting, and final approval of the manuscript.

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?

Dr. Murphy could well have added a statement to the acknowledgements to credit Mx. Tegene, such as: “The authors are grateful to Mx. Tegene for early discussions about the use of games to improve medication adherence.” Dr. Murphy could have also acknowledged others who they had discussed the idea with (if known). It was Dr. Murphy’s responsibility to be sure that all contributors were credited, either through authorship or acknowledgement. The Corresponding author should start by reading the instructions to authors for corrections on the journal’s website explaining their policies.

7. Should members of the research group have written down Mx. Tegene’s medication adherence idea when it was discussed at the lab meeting?

Documentation of lab meetings can become very important when there are authorship disputes or claims of misappropriation of ideas. Data presentations and discussions that take place at a lab meeting are considered part of the research record, the record of data or results, both physical and electronic, that embody the facts resulting from scientific inquiry; including but not limited to emails, research proposals, laboratory records, progress reports, abstracts, theses, presentations, internal reports, and journal articles (https://oir.nih.gov/system/files/media/file/2021-11/guidelines-conduct_research.pdf). When there is an allegation of plagiarism or an authorship dispute, the records of what took place at a lab meeting are sometimes examined. It is always important for the PI and the

research staff/trainees to take complete notes, whether to support any subsequent research integrity issue or to support any intellectual property development.

[End of case study]

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<https://oir.nih.gov/sourcebook/ethical-conduct/authorship-guidelines-resources>

Sourcebook chapter on Outside Activities for FTEs and Outside Activities for non-FTE trainees:
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Sourcebook chapter on Publication and Abstract Clearance:
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Sourcebook chapter on Foreign Interference:
<https://oir.nih.gov/sourcebook/personnel/policies-recruitment-processes/guide-nih-intramural-principal-investigators-navigate-international>

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 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?

There are a number of inter-related concerning issues in this case.

Dr. Fathi from the NIH, Dr. Parekh from Cutting Edge University, and researchers from BioAI have entered into a [Cooperative Research and Development Agreement](#) (CRADA). A CRADA is a specific kind of collaboration agreement that allows an NIH laboratory to partner with industry and academic scientists in pursuit of a specific research objective. A CRADA is particularly advantageous in that it allows an NIH laboratory to receive intellectual input as well as research resources from the partners. In return, the non-federal partners have the

option to license inventions that emerge from research conducted under the CRADA. By facilitating commercialization in this way, CRADAs help translate NIH laboratory research developments into products that benefit public health.

Every CRADA contains a detailed “Research Plan” that defines the scope of research activity (i.e., “CRADA research”) covered by the CRADA. Making sure all parties agree on the scope is critically important. Under the terms of the CRADA in the present case, Cutting Edge University is paying Dr. Johansson to conduct CRADA research as a Special Volunteer postdoc in Dr. Fathi’s lab. A major concern, therefore, is that in collaboration with Dr. Parekh and BioAI, Dr. Johansson has apparently been conducting research that falls outside the scope of the CRADA. Even worse, Dr. Johansson has kept this activity secret from their NIH advisor, Dr. Fathi.

While it is not uncommon for postdocs to work on multiple projects at the same time and participate in various professional activities, [NIH policy](#) dictates what is and is not allowed and when approval is required. Collaboration with an outside investigator requires supervisory approval, which Dr. Johansson does not have for the non-CRADA research. Even if Dr. Johansson thought it permissible to do this non-CRADA work outside working hours, on their own time, they would be mistaken.

That Dr. Johansson failed to consult Dr. Fathi about the non-CRADA research is concerning for reasons beyond policy; it constitutes a breach of trust that is not consistent with a productive mentor-mentee relationship. Even if Dr. Johansson were not particularly familiar with CRADAs or NIH policy governing allowable activities, it is difficult to imagine why they would not make their mentor aware of a project so closely related to the CRADA research subject.

It is particularly problematic that Dr. Johansson’s non-CRADA research appears to be closely related to the CRADA research, as it suggests that Dr. Johansson may have applied software methods developed under the CRADA to a data set that was not part of the CRADA. This would violate the terms of the CRADA and would explain why Dr. Fathi is included as co-author on the publication even though they weren’t even aware of the work. Of course, including an author without their knowledge is a serious breach of authorship/publication policy and norms.

The handling of patent applications in the present case is also concerning. One beneficial feature of a CRADA is that policy and process around the management of intellectual property is clearly defined. An important basic requirement is that information about any invention activity must be shared among all the CRADA partners. Clearly this did not happen in the present case.

The facts in this case do not include details about inventorship or which entity is filing for patents, but since no NIH Employee Invention Report (EIR) was submitted (itself a violation of NIH policy since the publication includes two NIH scientists), the NIH certainly did not file

and there is no indication that any NIH scientists are considered inventors. However, if the work underlying the inventions was performed all or in part at the NIH (or with NIH resources) then, by law, rights to any invention must be assigned to the US government, and any NIH staff (including FTEs, trainees, Special Volunteers and sometimes contractors) involved in the work are potential inventors. (Non-NIH inventors, however, may also be named.)

Finally, it is significant that, as Dr. Takekazu observes, the publication apparently did not go through the [NIH manuscript clearance process](#), a requirement for any manuscript submitted for publication that includes at least one author from the NIH intramural research program. The manuscript clearance process is an important checkpoint for making sure that the research described was conducted and is being reported in accordance with NIH and institute policy. This includes confirming that any CRADAs were properly adhered to and intellectual property issues are being properly handled.

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?

Given the potential for misunderstanding, Dr. Fathi should start by contacting Dr. Parekh, the lead author on the published project. Dr. Parekh has a lot of explaining to do.

Perhaps the clearest course of action resides with the circumstance where Dr. Fathi has substantive objections to the manuscript. In that case, Dr. Fathi should contact the editors of the journal. The journal likely would have its own policies for managing the situation.

If Dr. Fathi has no objections to the content of the publication, their actions will likely depend more on the details of what happened and their professional relationships with the other scientists involved. Questions to consider would include: Were honest mistakes made or was the bad behavior intentional or agenda driven? Was this an isolated incident or part of a pattern of behavior?

The question of whether code developed for the CRADA was used in the paper without Dr. Fathi's consent for a non-CRADA project is an important one, and if so, would constitute a breach of CRADA terms.

3. Can Dr. Johansson remain the first author but not list their NIH affiliation?

No - given that the publication acknowledges NIH support and their supervisor, Dr. Fathi, is second last author, it would be inappropriate for Dr. Johansson not to include their NIH affiliation.

4. Should the NIH contest the patents that are being applied for?

As noted above, if NIH scientists made inventive contributions to the inventions being protected, then NIH is entitled to some share of any intellectual property arising from the

project. And so yes, NIH should contest the patents if it is confirmed that no deserving NIH inventor has been included on the patents filed.

Since the subject matter of the publication is apparently outside the scope of the CRADA, a possible way forward would be for all parties to agree to a CRADA amendment that expands its scope to include the additional project. Inventorships would need to be fixed as well, but then all the intellectual property would at least fall under the CRADA.

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?

This situation could have been prevented if all parties were clear on what the scope of the CRADA project was and what the terms of the CRADA were. Additionally, there should have been transparency on where the CRADA data were being used. Also, regardless of any agreement, responsible publication practices require drafts of manuscripts are shared with all authors prior to submitting them to journals.

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?

Yes, assuming Dr. Johansson acted inappropriately on account of ignorance, it would seem that Dr. Fathi should have done a better job of mentoring Dr. Johansson on how CRADAs work and what is and is not allowable.

[End of case study]

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Sourcebook chapter on Publication and Abstract Clearance:
<https://oir.nih.gov/sourcebook/submitting-research-publications/publication-abstract-clearance>

Sourcebook chapter on Foreign Interference:
<https://oir.nih.gov/sourcebook/personnel/policies-recruitment-processes/guide-nih-intramural-principal-investigators-navigate-international>

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/>