2020 Ethics Case #1 Study Guide – Data Access, Analysis and Reporting within a Research Group

When Dr. John Thomas (an M.D./Ph.D.) joined Dr. Rick Peterson's lab as a clinical fellow, Dr. Peterson told him about an exciting new compound they were studying that showed promise for treating schizophrenia. The lab was currently completing a Phase 1 clinical trial under the leadership of Dr. Sally Simpson, a staff clinician in Dr. Peterson's lab who served as Lead Investigator (LI) and Medically Accountable Investigator (MAI) on the study with Dr. Peterson as Principal Investigator (PI). Dr. Simpson had just gone on early maternity leave unexpectedly due to complications, and the project needed someone to take over. Dr. Peterson suggested that Dr. Thomas take over the project and start planning the Phase 2 trial because Dr. Simpson wasn't expected to return for at least six months and Dr. Peterson was eager to keep the project moving. While Dr. Thomas found the science and experimental findings very interesting, he felt uneasy about taking over the project of another investigator who would be returning to the work. Dr. Peterson told him not to worry about it because as a staff clinician, Dr. Simpson would always have projects to work on and it didn't matter if she stayed with any one study through completion because she wasn't 'ambitious in that way'.

1. How can disruptions in workflow due to unexpected absences be dealt with?
   *Decision-making during a crisis can sometimes be easier when there are written agreements regarding work responsibilities during extended leave, such as Dr. Simpson's maternity leave.*
2. Are there other ways Dr. Peterson could have approached this?
   *The head of the lab is ultimately responsible for management of projects within the lab, but that is generally best done with input from those involved with getting the project completed. It is essential that the roles of different members in the lab, including the staff clinician, are clearly defined. Dr. Peterson might have been able to discuss coverage with Dr. Simpson before she went out but if she was unavailable to discuss it due to the suddenness of her departure, Dr. Peterson should make decisions about the project, keeping in mind the needs of the lab and the affected team members.*
3. What if the Phase 1 trial had been funded by a bench-to-bedside grant (or other outside funding mechanism) obtained by Dr. Simpson? What if Dr. Simpson had served as PI on the study within Dr. Peterson's lab?
   *While Staff Clinicians can apply for funding with the permission of their PI, the PI will control any funds obtained. In a respectful work environment, Dr. Peterson would acknowledge Dr. Simpson's role in obtaining funding for this project by allowing her more control over the project than she would typically have, especially if he had allowed her to serve as PI on the protocol. If it is necessary to bring in another investigator such as Dr. Thomas, Dr. Peterson should work to facilitate a cooperative arrangement between Drs. Simpson and Thomas, with clear definitions of their respective roles on the project.*
4. How could Dr. Simpson handle the situation differently?
   *Ideally, Dr. Simpson would formulate a plan with Dr. Peterson for coverage during her maternity leave well before the leave is expected to occur. In this situation, she left suddenly without a fully formed plan in place. She should reach out to Dr. Peterson as soon as she is able. Pregnancy and childbirth are protected under gender/sex discrimination regulations and are a qualifying medical condition under the American with Disabilities Act (ADA) that could lead to a Reasonable Accommodation (RA). Dr. Simpson may consider requesting a RA due to her medical condition, either before or after the pregnancy. She may also request job-protected leave without pay under the Family Medical Leave Act (FMLA). If she is unhappy with Dr. Peterson's handling of the issue and unable to work it out with him, she could discuss it with other trusted sources, including the laboratory chief, the Scientific Director, or the NIH Ombudsman, Civil, or Employee Assistance Program offices.*

While Dr. Thomas still felt unclear about Dr. Simpson's future role on the protocol, he was excited about the opportunity to work with this compound and agreed to Dr. Peterson's plan. He learned all he could about the

compound and the Phase 1 trial and took over the day-to-day supervision of data gathering and safety monitoring, reporting back to Dr. Peterson regularly. At Dr. Peterson's suggestion, Dr. Thomas occasionally emailed Dr. Simpson about potential side effects/adverse events in the participants since she had the most experience with the compound. He then began writing up the Phase 2 protocol, which was generally very straight-forward, but after his extensive review of the preclinical data, Dr. Thomas added a novel assessment of cognitive function to the standard clinical measures of psychosis. Again at Dr. Peterson's suggestion, he sent the protocol to Dr. Simpson, who was still on leave recovering from her complicated pregnancy and caring for her premature son, for input. Dr. Simpson reviewed the protocol, raised several helpful points, and suggested that a novel assessment of mood also be included.

5. Is it appropriate for Dr. Peterson to repeatedly suggest Dr. Thomas involve Dr. Simpson in ongoing work while she is on leave? What issues should be considered in a situation like this?
   *This is an issue that should be negotiated with Dr. Simpson. While it can be very helpful to continue to be kept abreast of the progress of the project and Dr. Simpson's advice on some matters could be very helpful to Dr. Thomas, care should be taken that it doesn't evolve into Dr. Simpson actually performing a significant amount of work while on leave; for example, writing sections of the new protocol rather than simply commenting on specific issues and questions. The boundary between doing uncompensated work and offering informal guidance on a project to which one expects to return can be difficult to define. Exploring options to return to work on a part-time basis including telework may be appropriate in some situations.*
6. What other actions might Dr. Thomas take in this situation?
   *Dr. Thomas should clarify with Dr. Peterson and with Dr. Simpson how they will work together moving forward on this protocol and who will be responsible for what. If he finds disparities in the expectations of Dr. Peterson and Dr. Simpson, he also should try to resolve these before beginning work on the project. Trainees may feel most comfortable seeking advice from their IC Training Director, laboratory/branch chief, or the NIH Office of Intramural Training and Education (OITE). If they are unable to get help from these sources, they may also contact their Scientific Director or offices of the NIH Ombudsman, NIH Civil Program, or NIH Employee Assistance Program which offer confidential help. Concerns about a workplace situation can also be reported anonymously to the Civil Program, either by phone or online. Trainees and other employees are encouraged to check the matrix of relevant NIH Workforce Resources for NIH programs that may be useful in circumstances requiring workplace flexibility, such as is discussed in this case study.*

Dr. Simpson returned to the lab after about 6 months and opted for a flexible work schedule to accommodate childcare responsibilities she shared with her husband. She worked 10-hour days in the office on Mondays and Tuesdays (days her husband was responsible for childcare issues) and 20 hours flexibly the rest of the week, some of which could be unscheduled telework, in order to be available for any emergencies that might arise with her young son. Dr. Simpson told Dr. Peterson she wished to resume her work with the compound she had already spent so much time and effort developing but Dr. Peterson told her that Dr. Thomas needed to stay on that project because he was going to be applying for faculty positions and needed to demonstrate his ability to see a big project through the many phases required for developing a new treatment. Dr. Peterson also told her he thought the project needed someone who would be reliably in the office every day in order for it to continue running smoothly. He did, however, encourage her to continue to help Dr. Thomas with the protocol and told her she would be included on any publications from the project. Dr. Peterson assigned Dr. Simpson to another protocol that he felt was more suited to her irregular schedule. Dr. Simpson saw little difference in the needs of the two protocols except that her new protocol was decidedly less likely to result in high-impact results.

7. Does Dr. Simpson have a 'right' to return to the project she was working on prior to her leave?

8. Would it matter if Dr. Simpson had taken the lead on the early development of the compound?
9. What issues arise when 'ownership/leadership' of a project has changed hands?
   *As PI, Dr. Peterson has the responsibility to run the lab. In addition to making sure projects move forward in a timely manner, running a lab also involves fostering an environment in which lab members feel valued for their contributions and their roles are clear. Dr. Simpson may not have a right to return to this project but since she contributed significantly to the intellectual development of the project, Dr. Peterson should recognize that contribution and foster her continued engagement in the work of the lab by allowing her continued significant participation. That might mean returning to a leadership role on this project or it might mean significant involvement as a co-investigator. NIH policies require that a person returning from extended medical leave that cannot be returned to their prior position must be returned to an equivalent position, with the same pay and same status. If Dr. Simpson is unable to work out a satisfactory arrangement with Dr. Peterson, this is also an issue she could take to the trusted sources mentioned for Questions 4 and 6.*

Dr. Thomas struggled to get FDA approval for his phase II protocol. Dr. Simpson, who had extensive experience getting FDA approval for protocols, helped him navigate several rounds of queries and get the approvals from both the FDA and IRB so he could start enrolling participants. Dr. Thomas finally began enrolling participants, but recruitment was slow, and it was difficult to maintain adherence through the one-year follow-up visit, which is far longer than typical Phase 2 studies. Dr. Peterson wanted the longer follow-up because it would allow for a more clinically relevant assessment of the drug and because long follow-up phases are possible at NIH where it's part of the mission to do long-term studies that are not feasible in other settings.

In the third year of his clinical fellowship, Dr. Thomas had a motorcycle accident, badly breaking several bones and requiring an extensive leave of absence. Dr. Peterson tapped Dr. Simpson to fill in while Dr. Thomas was recuperating, which she was easily able to do since she already knew the protocol well and had covered for Dr. Thomas for 10 days when his mother unexpectedly passed away. Recruitment picked up with Dr. Simpson in charge because she had relationships with community psychiatrists who felt comfortable referring their patients knowing she was running the study. When Dr. Thomas was ready to return to work about 6 months later, Dr. Simpson again asked to stay on the project and let Dr. Thomas manage another project for the remainder of his clinical fellowship. Dr. Peterson again said that it was important for Dr. Thomas's job prospects to remain in charge of the project he had started with, while Dr. Simpson already had a stable job and didn't need this project for her CV or advancement.

10. What do you think of Dr Peterson's decision-making process regarding management of this project?
11. What assumptions is Dr. Peterson making about Dr. Simpson's career, including her future plans? Is this appropriate? Might it reflect bias?

*While Dr. Peterson had previously prioritized moving the project forward when he replaced Dr. Simpson with Dr. Thomas after Dr. Simpson's early maternity leave, he is now prioritizing Dr. Thomas' career needs over moving the project forward as it is clearly running better under Dr. Simpson's leadership. He is also weighing the career needs of Dr. Simpson and Dr. Thomas differently and we are not given a clear justification for this. While post-docs and clinical fellows such as Dr. Thomas by definition have a limited time in which to show productivity and move on to a new job, staff clinicians are generally in a more stable position, although this should not imply they do not also wish to advance in their careers. Drs. Peterson and Simpson should be discussing Dr. Simpson's role in the lab and her plans for her future explicitly. Some may feel that there is disparate treatment of Drs. Simpson and Thomas that could represent a pattern of gender/sex discrimination. The PI must have a legitimate, non-discriminatory business reason for assigning work; career advancement for Dr. Thomas is not a legitimate business reason.*

With the papers from his Ph.D. research and one publication from the Phase 1 data, which Dr. Peterson had allowed him to write up as first author, Dr. Thomas applied for jobs and was offered a soft money position as an Assistant Professor at a large research university. He negotiated some start-up funds but needed to apply for grant money as soon as he started. He asked Dr. Peterson to unblind the trial's treatment-arm data for participants who had completed the protocol to date (about half of the planned cohort) so he could analyze the study and use it as preliminary data for grant applications.

12. Is this an appropriate reason to unblind an ongoing protocol? Why might Dr. Peterson refuse to unblind?
    *Clinical trials designed to demonstrate efficacy of a new compound must include detailed analysis plans prior to starting the trial. This is important to prevent cherry picking of results that could lead to inappropriate conclusions. Under some circumstances, especially for protocols that do not aim to demonstrate efficacy of a treatment, a protocol may include explicit provisions for interim analyses that could accommodate early exploratory analyses to allow for presentations at meetings or preliminary data for grant applications, however, such analyses cannot be used to alter the enrollment and analysis plan of the ongoing trial. If there is no provision in the protocol for interim analyses by the investigators, Dr. Peterson should refuse this request. Unblinding a trial early is often done by a DSMB to look for safety and efficacy reasons to stop a trial early but results are not shared with investigators unless action must be taken, thus mitigating the risk of compromising the integrity of the study by biasing the clinicians interacting with the participants. These analyses typically begin with unblinding participants by group without identifying the groups unless significant results warrant group identification. As Dr. Thomas is no longer working on the study, his interim analysis would not necessarily compromise the integrity of the study, but he would have to keep the results from Dr. Simpson and Dr. Peterson, himself, in order to avoid a problem. This would create its own set of difficulties since both these investigators have an intellectual stake in the study results.*
13. Would the situation be any different if this protocol was a preclinical study investigating the impact of the compound in a preclinical model?
    *While blinding does not always take place in preclinical studies, it can be useful for many of the same reasons as in clinical studies such as minimizing bias in assessing outcome measures. A blinded preclinical study should also specify when and for what purposes an ingoing trial can be unblinded.*

Dr. Peterson agreed to unblind the completed participants, and Dr. Thomas analyzed the unblinded data quickly and began writing grants. He discovered that the compound appeared to have marginal efficacy for the primary outcome of psychotic symptoms, no effect on the cognitive functions he had hypothesized would benefit, but a strong effect on some aspects of mood that was already significant at the one-month follow-up in this initial cohort sample. The mood measures had been added at Dr. Simpson's suggestion. He formulated his next hypotheses around these mood findings and started writing up a manuscript as well, since the findings were very interesting, even if preliminary, and having a paper would help his chances of securing grant funding.

Dr. Simpson found out about Dr. Thomas's analysis and results when he sent around a manuscript with himself as first author, Dr. Peterson as senior author, and Dr. Simpson as second author. Dr. Simpson complained to Dr. Peterson that the mood assessment was her contribution to the protocol and that she had planned to present the data at a conference and serve as first author. She also thought it was premature to publish the data as a paper, since the study was ongoing and had not yet met its planned enrollment numbers. Dr. Peterson mentioned that Dr. Thomas was submitting a grant to follow up on the mood findings. Dr. Simpson was not happy, as she had planned to follow up on this hypothesis if the data looked promising.

14. Who should control use of the data in this situation?

*As PI of the lab conducting the research, Dr. Peterson controls the use of the data. With multiple investigators having contributed significantly to the project, he should consider discussing data use plans with all those who have an intellectual stake in the data.*

15. Is it appropriate to publish an interim analysis of an ongoing study? To include it in a grant application or present it at a conference?
    *As the data are not complete, any publication should be explicitly clear about this point. In this case, the trial is likely to be used in support of an FDA indication for the drug, making it more problematic to have broken the blind for an interim analysis. In some situations, it might be acceptable to publish an interim analysis as pilot or preliminary data, but there is a risk that readers may not appropriately interpret a promising but preliminary result. Presentations at conferences, especially as posters, are expected to often be preliminary and in need of further confirmation. A conference audience and grant reviewers are generally comprised of other researchers who should be aware of the dangers of overinterpreting preliminary results while a journal audience may also include practitioners, less sophisticated in evaluating data and eager to find anything that might help their most challenging patients. It is also possible that patients in the ongoing trial may learn of the publication which might affect their willingness to continue to participate or bias their expectations, further compromising the integrity of the study. In general, publishing issues should be discussed at the start of a project, although plans may change as the project moves forward. Changes in agreed upon publishing strategies should be discussed with all stakeholders.*

After two more years, the protocol completed its final one-year follow-up visit. With the assistance of the current clinical fellow, Dr. Simpson analyzed the data and found that the compound significantly improved psychotic symptoms, mood, and cognition after a year of treatment. She drafted the findings for the three outcomes, with herself as first author, Dr. Peterson as senior author, the current clinical fellow as second author, and Dr. Thomas in the middle of the author list. Dr. Thomas, now three years into his new position and struggling to secure grant funding, was upset that Dr. Simpson had included all the data in one manuscript and thought the cognitive findings warranted their own paper which he wanted to write. He complained to Dr. Peterson.

16. How should decisions about publishing and authorship be handled after a post-doc has left the lab?
    *In long running projects, it can be easy to forget the important intellectual contributions of those who were involved early in the project but then moved on. However, significant intellectual contributions to the inception of a project do warrant inclusion on subsequent publications. As head of the lab, Dr. Peterson should ensure that all those who have made significant contributions are offered authorship on the papers. An authorship plan should have been in place before Dr. Thomas left and should be followed if it exists. Information about NIH authorship and publication standards can be found in the Sourcebook Conduct of Research Guidelines.*
17. Is it reasonable to publish results separately in order to provide first-authorship opportunities for more study team members? What considerations should go into deciding what data get published together vs. separately?
    *A manuscript should provide a complete story of a result. Many projects contain large numbers of assessments, sometimes making publication of all results in a single paper impractical. In some situations, publication of all results for a facet of the study could be reasonable, with acknowledgement that the data are part of a larger study that also included x-y-z. While this study could likely be presented coherently in a single manuscript, the realities of needing to generate publication records for individual investigators could warrant producing multiple publications addressing the psychotic, mood and cognitive results separately. It would be inappropriate, however, to publish each individual measure separately (i.e., one paper for each of two different mood assessments used, etc.).*

2020 Ethics Case #2 (with Facilitator Notes) – Moving On

Dr. Pat Suarez has been a highly productive postdoc with Dr. Jones at the NIH for three years. Though excited to begin a second postdoc at the University of GreatState (UofG) in a week's time, Pat is torn. He just received data back for samples he had submitted to the NIH Sequencing Core. The data are from patients with the disease that the Jones lab studies, and the results are expected to provide insights into why some patients are unresponsive to treatment.

Pat offered to undertake the bioinformatics analysis of the data even though he was formally leaving the lab, but Dr. Jones was resistant. He gave as his reason that Pat should immerse himself in the work of his new lab, but he also had in mind that the analysis would be a good first project for the new computationally-trained postdoc scheduled to join the lab in a few days. Dr. Jones reminds Pat of all he has accomplished in three years and assures Pat that he would be co-first author on the primary publication from the project.

Though Pat highly respects Dr. Jones, he decides that Jones couldn't possibly be unhappy if he was able to rapidly analyze the sequencing data after leaving the lab (working evenings and weekends). On his way into lab on his last day, Pat stops to purchase a high capacity flash drive at his favorite computer supply store and copies the data files. He finally finishes late in the evening, grabs the three lab notebooks he's filled over the years and heads for the door.

1. Who owns the data generated by an NIH lab or research group?
2. Does Pat have the authority to take copies of the sequencing data with him? What about the lab notebooks?
3. How could this situation have been better managed by Dr. Jones?

A few days later Pat starts work in his new lab. His new PI had purchased a laptop for him, which Pat configures for use on UofG's network. He is eager to get a start on analyzing the data from the Jones lab before getting too busy with new work. When Pat gets home, he immediately loads the data from the flash drive to his new laptop and gets to work.

4. Apart from the right or wrong of taking a copy of the data, how have Pat's actions put the security of the data at risk?
5. It is not uncommon for trainees (as well as other NIH scientists) to finish up projects after leaving the NIH. For someone in Pat's situation (i.e., leaving NIH for another training position), what is the appropriate arrangement consistent with NIH data use policy?
6. What additional or different considerations would there be if Pat were leaving NIH to accept a position as independent investigator at a university? Or what if Pat were starting a job in industry?

Over the next few weeks and on his own time, Pat analyzes the sequencing data he brought from the Jones lab. He is pleased because he had been taught to use some sophisticated, home-grown bioinformatics tools in his new lab at UofG and they have proved very useful for analyzing the Jones lab data. He has found some exciting results, and when he emails his analysis to Dr. Jones he feels sure that Dr. Jones will be impressed.

But Dr. Jones is NOT happy. He tells Pat that a new computationally trained postdoc in his lab had been doing some nice analysis of the same data set with the understanding that it was HER project. And he is very concerned about Pat using software tools developed at his UofG lab. Pat is dismayed.

7. Should Dr. Jones be upset? What are his interests and obligations in this situation?

Facilitator Notes

**Moving On**

1. Who owns the data generated by an NIH lab or research group?

As stated in the "NIH Conduct of Research" guidelines (https://oir.nih.gov/sites/default/files/uploads/sourcebook/documents/ethical_conduct/guidelines-conduct_research.pdf) "All intramural research records remain the property of the NIH". Responsibility and stewardship of the data resides with the PI.

2. Does Pat have the authority to take copies of the sequencing data with him? What about the lab notebooks?

In a research setting, only the PI has the authority to grant departing lab members (or any outsider) access to data. It is common, however, for departing scientists to receive permission to copy or access data in order to complete projects.

Laboratory notebooks are considered part of the research record and physical volumes fairly universally remain with the laboratory when scientists depart. Again, material in lab notebooks can be copied, with PI permission.

3. How could this situation have been better managed by Dr. Jones?

When a trainee (or any scientist) leaves a research group, it is critical that there be a clear understanding of expectations related to unfinished projects. It may be necessary to have multiple conversations surrounding relevant issues, and it is good practice to put agreed-upon points in writing.

In the current case, Pat is apparently heavily invested in the sequencing project. How Jones handles the situation depends in part on expectations established at the project onset – e.g., was the plan for Pat to do the bioinformatics analysis before leaving, but unavoidable delays in the project meant he ran out of time? Or, was it never the plan that Pat would do that work?

There are lots of good reasons why Jones might prefer to keep the bioinformatics analysis in house. But he should be sensitive to Pat's attachment to the project – and to Pat's clearly high levels of competence and ambition. Jones probably would have done well to be clearer with Pat about his plans for project completion. If Pat understood that a new postdoc was going to take over the analysis, he may have been less inclined to undertake it himself.

Two mentoring tools that can be helpful for enhancing expectations and avoiding misunderstanding in a research group are the so-called laboratory "compact" and the Individual Development Plan (IDP). IDPs are a requirement for trainees in the IRP; compacts are strongly encouraged as a practice that promotes the Responsible Conduct of Research (RCR). A compact, which should first be discussed when a trainee joins a research group, is useful for establishing expectations surrounding a full range of practices and behaviors in a particular research environment. An IDP serves as a plan, agreed upon by mentor and trainee,

for the scientific and professional development activities of the trainee. Ideally an IDP is updated regularly – at least once a year.

Example compacts:
https://oir.nih.gov/sites/default/files/uploads/sourcebook/documents/ethical_conduct/lab_compact_examples.pdf

NIH IRP IDP Policy:
https://oir.nih.gov/sites/default/files/uploads/sourcebook/documents/mentoring/individual-development_plan.pdf

4. Apart from the right or wrong of taking a copy of the data, how have Pat's actions put the security of the data at risk?

Pat has violated a number of NIH policies related to data management.

i. By copying his data onto a personal flash drive he violates the policy that only Government Furnished Equipment (GFE) may be connected to the NIH network and IT equipment (https://policymanual.nih.gov/manage/chapter/view/2814).
ii. The sequencing data comes from patient samples. This raises the possibility that the data contain PII. If so, external devices (such as flash drives), must be not only GFE, but encrypted.
iii. Pat copies the data from his flash drive to a new (non-GFE) laptop connected to the UofG network, potentially making it accessible to other parties. The violation is even more egregious if the data includes PII.

5. It is not uncommon for trainees (as well as other NIH scientists) to finish up projects after leaving the NIH. For someone in Pat's situation (i.e., leaving NIH for another training position), what is the appropriate arrangement consistent with NIH data use policy?

The most appropriate arrangement depends on the particulars of the case. For a trainee who will be mostly writing and performing light analysis using commercial software for (e.g., Excel), it is often acceptable for a trainee to safely transfer needed data to a personal device. However, often a better solution, especially when the data needs to be accessed by multiple individuals, is to put the data on Box, NIH's currently approved solution for sharing data with non-NIH parties. A cloud solution may also be an option, especially if the cloud environment provides computational tools as well as data. In these cases the trainee effectively becomes a collaborator, albeit one not connected with an institution.

When an exiting trainee needs to access resources on the NIH network, Biowulf for example, or IC-based storage or NIH-licensed software, then GFE equipment is usually required. In these cases the preferred arrangement is for that individual to convert to Special Volunteer (SV) status and be allowed to take their GFE equipment with them. As a SV, the scientist has a PIV card and retains access to the NIH network. Once the planned work is complete, the equipment is returned to NIH and the SV appointment is terminated.

A complication arises when the departing individual is relocating to another country (e.g., a visiting fellow returning to his/her home country). NIH policy prohibits such individuals

from having a PIV card, meaning they cannot access the NIH network and should not have GFE. In these cases, the (current) NIH-approved solution for data sharing is to use the Box platform. (Such "solutions" can change frequently, however.)

6. What additional or different considerations would there be if Pat were leaving NIH to accept a position as independent investigator at a university and planned to continue the project with patient data collected in the Jones lab? Or, what if Pat were starting a job in industry (unrelated to his research in Jones' lab) and wanted to finish writing up his work from the Jones lab on his own time?

If Pat were leaving to establish his own research group at a university, it would be very important that he and Dr. Jones agree on exactly what project(s) he could take from the Jones lab. If he plans to continue working with human data generated in the Jones lab, it would be important that a Data Transfer Agreement (DTA) be established between the NIH (Dr. Jones' IC) and the UofG. A DTA is a "light" version of a Material Transfer Agreement (MTA), which is used when material, with or without accompanying data, is transferred. (For non-human data, a DTA is typically not necessary.) If collaborations are to continue, it is good practice to establish a formal Collaboration Agreement to insure that both parties understand their roles and responsibilities.

If Pat were leaving the NIH for a job in industry and planned to finish up the project from the Jones lab on his own time, the solutions discussed for Q5, as described above, would apply.

7. Should Dr. Jones be upset? What are his interests, obligations, and concerns in this situation?

Dr. Jones has a right to be angry, as Pat violated his trust by taking the sequencing data with him and continuing with the project when he was told not to. (Pat may not have known about the new postdoc Jones hired to do the bioinformatics anlaysis, but that shouldn't matter; Pat should have respected Jones's decision.) Pat's actions have put Dr. Jones in a very difficult position.

Dr. Jones has an obligation to support the postdoc assigned to analyze the data that Pat took with him. What is not clear from the narrative is how Pat's analysis compares to the analysis done by Jones's new postdoc. If Pat's analysis is markedly superior, Jones will be in an especially difficult position: he wants to publish the highest quality science but he doesn't want to condone Pat's poor (if well-intentioned) behavior or be accused of not supporting the postdoc whose project Pat stole.

Jones may also be concerned with the fact that Pat utilized bioinformatics tools developed in another lab. Jones may not be in a position to fully understand and vet the tools, and he could be put in an awkward position if the PI of Pat's new lab discovered that Pat had used his lab's tools in a potentially unauthorized manner. Depending on the nature of the tools and involvement of the UofG lab staff in training and helping Pat with the tools, Pat's new PI might even argue for authorship.