RCR Casebook: Data Acquisition and Management

This role play involves an assistant professor who places his/her data on NIH's database of genotypes and phenotypes (dbGaP); a leading researcher who violates the one-year embargo or use of the data and published an article using the assistant professor's data before s/he had the opportunity to do so; and an NIH official who is in charge of the dbGaP database. Roles • Assistant Professor • Lead Author • NIH Official (Trusted Other) Scenarios • Scenario One: Assistant Professor discussion with Lead Author • Scenario Two: Assistant Professor discussion with NIH Official (Trusted Other) *This role play is based on a published case. ²³	 Detailed role descriptions and prompts are provided to guide the role play. This is not a strict script. Encourage role players to familiarize themselves with their characters
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"Consistent with the NIH mission to improve public health through research, the NIH believes that the full value of GWAS [Genome-wide Association Studies] to the public can be realized only if the genotype and phenotype datasets are made available as rapidly as possible to a wide range of scientific investigators."

Role Play: Assistant Professor Role Guide

Character Description: Assistant Professor

You are an assistant professor who has prepared extensively for a career as a geneticist. You have spent recent time sequencing data and are exploring it to search for genetic bases of addiction. The research is funded with an NIH grant. In accordance with the grant's requirements, you have placed your data in the NIH database of genotypes and phenotypes (dbGaP), which enables other qualified scientists to eventually use your data as well. This data-sharing arrangement is designed to hasten discoveries. The initial researcher who gathers and shares the data is motivated to work diligently to publish the findings, and other researchers are also able to work with the data and may begin to publish them as soon as the embargo period of one year has ended.

You value the NIH database. Sharing data enables multiple researchers to analyze and publish studies based on each other's work. Thus, you know that you will foster more research on your data than you yourself would actually have time or resources to do. You will be cited by those who use your data. They have to get permission from NIH to use your data and must sign an agreement pledging not to submit any paper before the end of an embargo of one year.

Your project has gone well, and you are excited to be preparing an article for publication. This has been a huge and important project, and you hope that it will be the accomplishment for which you will be tenured and promoted. As you are putting the final touches on your manuscript, you go online to look at genetics papers published in the journal to which you plan to submit your article. To your horror, you find an "online first" paper based on the data you have gathered! Someone has obviously broken the embargo on your data.

Role Play: Lead Author Role Guide

Character Description: Lead Author

You are the researcher who published the data before the embargo had ended. You and your colleagues signed a promise not to publish until the embargo period was over, yet your paper was published 1 week before the end of the embargo. As of yet, no one other than you knows whether the violation of the embargo was intentional or simply an oversight. It is also unclear who, on your team, was most responsible for this breach whether intentional or not. In any event, you are not too pleased to hear from the Assistant Professor who provided the data. You are non-committal. You are not rude, but you are not helpful either. In short, you stonewall the Assistant Professor. You are certainly not interested in retracting a paper that involved a lot of original data analysis by your team. You are not even convinced the assistant professor has sufficient knowledge to fully analyze his/her own data.

Role Play: NIH Official Role Guide

Character Description: NIH Official

You are the Program Officer who directs the National Human Genome Research Institute. As the official in charge of the dbGaP database, you feel some responsibility for what happened.

Scenario One

The Assistant Professor picks up the phone and calls the Lead Author and demands that the author immediately—today—contact the journal and have the paper retracted.

Prompt

Lead Author: "We certainly never meant to violate an embargo period. I'm sorry. But we put in a lot of work analyzing that data. You did not do the analysis, we did—it was very sophisticated work done by one of the best biostatisticians in the nation. There is no way we're going to retract the paper—that's what you do with falsified data. Our data are great—even if we did lose track of our publication timeline."

Assistant Professor: How do you respond?

Questions to Consider

- 1. After talking in circles for some time it becomes clear that the lead author is not going to retract the paper. What should you do?
- 2. At this point you have contacted the official in charge of the dbGaP database as well as the journal that the manuscript was published to and they are in the process of the investigating the issue. The one-year embargo is now over and this makes you anxious to get your article published. Should you go ahead and submit your article for publication?

Scenario Two

After an unproductive phone conversation with the Lead Author, the Assistant Professor phones his/her NIH Program Officer. The Assistant Professor identifies herself and explains the problem to the NIH Official.

Prompt

Assistant Professor: "You need to change your policy on data sharing. I want you to pull down my data, and to change your policy. This should never happen again."

NIH Official: How do you respond?

Question to Consider

1. The NIH Official makes reference to the data sharing agreement that you signed and reminds you that it is legally binding. What would you say to the NIH Official?

Take Away Points

Breaching a data use embargo period is a violation NIH takes seriously. Upon realizing a breach
of this nature, you should immediately contact your program official. With issues related to
publication, time is of the essence. The sooner your program official can begin their
investigation, the sooner they can put a hold to the publication of the embargo violator's work.
The program officer can also provide guidance on whether to move forward with publishing
your manuscripts that are based on the data in question.

References

DuBois, J., Sieber, J., Bante, H., & Partin, K. (n.d.). RCR Casebook: Stories about Researchers Worth Discussing. Retrieved November 7, 2019, from https://ori.hhs.gov/rcr-casebook-stories-aboutresearchers-worth-discussing.