

## ◆ *Ethics Clinic*

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These are exciting yet challenging times in the world of scientific-journal publishing. Technology and research trends have pushed the publication field in new directions. Combined with increasing demands for instant access and more transparency in data collection and reporting, new ethical quandaries are arising regularly. In this year's Ethics Clinic, participants considered two real-life cases, using a moderated roundtable discussion format followed by whole-group comments.

Case One, Access to Data: A university-based principal investigator (PI) published a paper using data from a multisite study sponsored by a pharmaceutical company. He wished to reanalyze the data, but the sponsor fought to restrict access, ultimately only providing the database from the PI's site. His new analysis resulted in "significant change in the interpretation of the findings". He was not, however, able to obtain a retraction due to author disputes. The editor of the journal requested but was denied access to the data.

Many of the Ethics Clinic's participants stated that their journals ask specific questions about access to data, rights of analy-

ses, and rights of publication at the outset. Most participants felt that reviewers could ask to see raw data but that journal editors had no rights to view these data themselves. Nonetheless, journals can require data access as part of their submission policy. There were mixed feelings about the journal's ability to retract the article without the consent of all the authors. In this case, the journal was limited to an "expression of concern". If such action is taken, journal policies to alert current and future readers vary from simple statements to removal of online content. Ideally, data management and access rights will be established before the study onset, and there will be contingencies for access to data and flexibility as study needs change. Sponsors, however, may not be willing to provide such open access.

In summary, prevention of the problem was the main theme of discussion. Journal editors may ask questions about access and rights of publication for authors and their financial sponsors.

Case Two, Dual-Use Research of Concern (DURC): A researcher published results about a more effective inhaled aerosol intended for the treatment of lung disease. However, it could also be used for bioweapons, such as anthrax and botulism. Thus, his research was defined as DURC by the National Science Advisory Board for Biosecurity (NSABB, [www.biosecurityboard.gov](http://www.biosecurityboard.gov)), as it could be "misapplied by others to pose a threat...."

DURC describes research that began with a benign scientific goal but could be co-opted for sinister purposes. Most research could have dual use, but what

pushes that research into a subject of concern? Few attendees were aware of efforts to predict what research qualifies as DURC, what to do if it does qualify as such, or who should be monitoring for it. Participants speculated about how DURC could change our current practices, such as addressing DURC within the internal review process or in grant applications. Many felt that monitoring was beyond the job of journal editors.

Two attendees conveyed stories of 11th-hour government intervention regarding manuscripts flagged during the embargo process. Journals in controversial fields have established procedures for handling DURC, including review committees that search submitted material for potential DURC and have contingencies for dealing with it. Some have authors check a box that indicates that their research poses a risk, in which case the journal will investigate and review the risk:benefit ratio of publication, using NSABB guidance as needed.

In summary, many people working in the field are not actively considering what research falls in the category of DURC. Scientific journals may wish to consider how they will screen for and ultimately handle potential cases of DURC.

Overall, the main theme of the Ethics Clinic was preventing ethical dilemmas, a responsibility of both authors and editors. By carefully reviewing ethical cases, journals can be more prepared to balance new manuscripts and user demands with the aims and scopes of their journals. 