WILDERNESS & ENVIRONMENTAL MEDICINE (2018) **29,** 149–150

EDITOR'S NOTE

Ethics Authorization for Research Reporting

One of the fundamental requirements to publish research is the reasonable assurance that the work was conducted ethically. This is usually met by having project plans reviewed in advance by an appropriate institutional review board, either for human or animal studies. Different titles are used, but the intent is the same: to prospectively evaluate research plans to ensure that they conform to institutional and overarching ethics guidelines.

There is ongoing effort to harmonize ethics guidelines internationally to ensure adequate protection for all research subjects. Although this goal is laudable, it is also extremely ambitious. Regulations and guidelines must be flexible because they cover a wide and creative range of research initiatives. Additionally, even though institutions may adhere to the same overarching principles, individual review boards will develop their own personality over time. There will be a number of reasons for this, with one of the most important being the type of research conducted at the institution. Acceptance of a given approach develops through experience, particularly positive experience, and tolerance can reach the point at which work sanctioned at one institution would not be allowed by another. Given legal and cultural differences, particularly across international boundaries, the personality of ethical reviews can be quite different.

Institutional review boards frequently apply different levels of scrutiny to research protocols. Complex and/or potentially higher risk projects will require full board review, with group discussion to evaluate the plan. Projects perceived to constitute very low-risk efforts can be reviewed in a more limited fashion and approved as expedited protocols. Some research will also be designated as exempt, not requiring further review. An example would be research projects developed from data available in the public domain.

The designation of exempt research is confusing to many individuals new to research. A common misunderstanding is how work is determined to be exempt. There is some irony to the fact that a research protocol must be evaluated by the appropriate ethics review board to be classified as exempt from review. It is not a determination made by the investigators. A key feature is that once a research protocol is classified as exempt, it does not require re-review, which is typically required annually for nonexempt protocols. Another common misunderstanding is the breadth of the exemption status: It only remains valid if no changes are made to the research protocol. If any changes are made, the protocol must be reviewed again and will either retain or lose the exempt status.

Institutional review boards collect summary information on research activities as part of the periodic re-review of approved research protocols, whether the approval was made by the full board or expedited. One of the standard questions is whether any changes have been made to the protocol since the last review. This encourages care on the part of investigators to protect the approved status of the work. However, because review boards are generally extremely limited in their ability to evaluate the actual work done or data collected, it is possible for unapproved elements to creep into research efforts.

Although coordination of research ethics and research oversight is the idealized goal, this reality is not likely to be achieved in the foreseeable future. One simple fact is that the obligation to maintain institutional review boards is not universal. They are also not a requirement of good practice. Legitimate and ethical work can be conducted without external oversight. For example, it is possible that none of a team of competent and ethical investigators is affiliated with an institution with a review board, or that the effort that produces meaningful findings was not originally intended as research. Although some journals categorically reject manuscripts that do not include institutional authorization, this can penalize some good investigators. The alternative approach is to promote institutional ethics approval as a standard, but to consider work without such approval on a case-by-case basis. Authors without documented preauthorization would have to provide a fair accounting of ethical procedures in manuscripts and should expect more critical evaluations, but publication can still be possible. Such flexibility can help to encourage open scientific communication.

Peer-review plays an important role in ensuring ethical research practice. Although reviewers are primarily

tasked with evaluating scientific content, they should also consider the ethics of the work. This is oversight independent of other efforts, essentially a double-check of the research ethics.

Authors are asked to provide a statement of ethics approval or determination of exemption. There is no standard language for this statement, but it should include the name of the review board(s) and institution(s) providing approval or exemption. For human studies, there should also be a statement on how research subjects provided consent to participate. This should fairly describe the nature of consent. For example, it is less relevant that participants "signed consent forms" than it is that they "provided written informed consent" (if this is true). Some studies must involve misdirection of research subjects to achieve the study goal, specifically those in which knowing the true objectives could alter performance. If misdirection is employed it must be stated, along with an explanation of how the misdirection was corrected upon completion of the study.

Peer-reviewed journals play an important role not only as a repository of our research efforts but also in the evaluation and crafting of our best efforts and the exclusion of what is not valid. The collaboration of oversight authorities, authors, reviewers, and editors helps to ensure a robust research record.

Neal W. Pollock, PhD
Editor-in-Chief