

## Ask the Ethicist: Do I Need an IRB to Publish Research?

**Question:** I performed more than 150 modified trabeculectomies over the past 3 years and compared my outcomes of two techniques. I presented this data at my state society meeting and then submitted my findings for publication. The abstract was rejected because I did not have institutional review board (IRB) approval. Why do I need an IRB approval for a retrospective review of my own charts?

**Answer:** If you intend to publish the results of your research, you are required to obtain either IRB approval or confirmation of exempt status. The National Institutes of Health define research as "...a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Your attempt to publish your research indicate that your results were intended to contribute to "generalizable knowledge" in this area of study. Most, if not all, peer-reviewed journals require this approval for publication of research results. If you are not affiliated with an academic institution and you are unable to work with a university IRB, there are several private/regional IRBs available.

Why IRB review is needed. IRB oversight is required in order to verify that the participants have provided permission for their personal health information to be used for research. individually identifiable information to be used for research purposes – the purpose is to ensure the privacy of individuals being studied. The review may involve, among other activities, the following: patient interviews or questionnaires, follow-up with patients to determine the effectiveness of a program or a treatment, chart review, analysis of clinical and administrative data, or mailed questionnaires.

Exempt status is an option. You may be able to obtain exempt status if your research falls into a specific category, such as the collection or study of existing data, documents, records, and pathological or diagnostic specimens. The term "existing data" means that all of the data, documents, records, or specimens used in the research are in existence prior to IRB review and were collected for other purposes. These may be deemed exempt if the sources are publicly available or if the information is recorded such that subjects are unidentifiable. Even if you believe your research falls into one of these exempt categories, it would be wise to obtain the exemption first and then perform the retrospective chart review.

For more information, read Rule 3 of the Code of Ethics, "Research and Innovation," at <a href="mailto:ao.org/ethics-detail/code-of-ethics#clinical">ao.org/ethics-detail/code-of-ethics#clinical</a>

To submit a question to the Ethics Committee, email ethics@aao.org.