

Ask the Ethicist: Retrospective Chart Review

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Q: *I planned a retrospective chart review to prepare a paper on the correlation of certain genetic markers to the development of macular degeneration. My practice administrator refused access to the records for this purpose without getting approval from an institutional review board (IRB). Why would I ever need an IRB to research data from my own patients' charts?*

A: Federal regulations state that any activity that is a systematic investigation designed or developed to add to "generalizable medical knowledge" (e.g., papers, posters, courses or presentations to be given at professional meetings or for publication) is considered research. The Department of Health and Human Services (HHS) and the Office of Human Research Protection (OHRP) have oversight over all research involving human subjects. All research, retrospective or otherwise, that will contribute to professional knowledge must have IRB oversight.

There are exemptions to the regulations, and ophthalmologists are advised to review the OHRP's website at www.hhs.gov/ohrp to familiarize themselves with these regulations.

In addition to federal requirements for IRB oversight, sponsoring organizations to which you plan to present the research data or in whose journal you hope to publish the data will likely require IRB approval or a written exemption for the study from an IRB. IRB approval and written exemptions cannot be granted retrospectively so, if in doubt, always inquire and get the approval—or, if available, the exemption—first.

With respect to enforcement, the HHS and OHRP have an inspection and enforcement wing, and individuals found to have violated the regulations could be subjected to an audit, among other actions. If research is performed using federal funding and the investigator fails to get IRB approval, the federal government has the authority to impose a sanction on the individual. Ultimately, a researcher can be disqualified from participating in any federally funded research.

In the private sector, an individual who fails to get IRB approval for a study (when required) will run afoul of the publisher's or meeting sponsor's requirements. Enforcement in this arena generally results in nonpublication and enforced nonparticipation.

If a private practitioner performs a retrospective chart review for the particular purpose of gathering information for internal use (e.g., quality assurance or to spot patterns of eye disease in the surrounding community), oversight by a review board would not be necessary.

For more information or to submit a question for this column, contact the Ethics Committee staff at ethics@aao.org. To read the Code of Ethics, visit www.aao.org/about and click "Ethics" and "Code of Ethics."