

Academic Affairs

The following article by Dr. Joe Breault, Chair of the OCF IRB, describes a sentinel event at OCF as well as a rededication of our institution. The rededication is our further commitment to patient safety and quality of care. I can think of no more important issue at an academic medical center than clinical research.

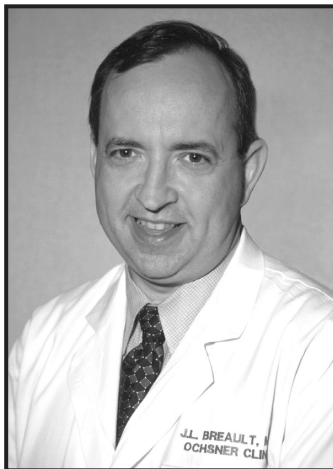
As I have described in prior columns, patients who volunteer themselves for clinical trials and research deserve our respect, gratitude, and most importantly our protection. Even though they hope to gain clinically from their participation, there is no guarantee of that. What is guaranteed is that their participation will add to our medical knowledge and have an impact on other patients and their clinical care.

I applaud the patients for their willingness to participate. I applaud Dr. Breault and the volunteer members of the IRB for their dedication. I applaud OCF for making this commitment to our patients and to further advancing our armamentarium of therapeutic interventions.



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The Institutional Review Board



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Institutional Review Board*

Institutional Review Boards (IRBs) are charged with protecting human research subjects. The IRB's role in reviewing research is to ensure that the benefits of research outweigh the risks, subject selection is equitable, data are used confidentially, informed consents are properly written for the layperson, there is no coercion, and proper documentation of consent occurs.

Recent stories in the media that exposed terrible lapses in research oversight resulting in deaths and horrendous stories of patients not being fully informed have changed the research climate. Regulatory agencies have responded to public outcries. There are increased federal audits of IRBs and increased penalties to institutions that do not assure an environment for IRBs to fully function and comply with

all the regulatory requirements that are designed to ensure the protection of human subjects.

A review of the Food and Drug Administration's public warning letters and the Office of Human Research Protection's (OHRP's) determination letters on their web sites reads like a Who's Who of American Medicine. Regulatory oversight has skyrocketed recently, much of it justified. Ochsner was not spared, and following an FDA audit and follow-up warning letter citing IRB deficiencies, it became apparent that changes were needed.

IRB Re-Engineering

Rather than just patching a few holes, Ochsner has completely re-engineered its IRB. Our goal was not only to meet the immediate demand of regulators, but also to reshape our IRB structure and process in order to meet the challenges of the quickly changing regulatory environment of human subject protection.

First, the Ochsner IRB was made independent of the Office of Research Administration and the Research Compliance Office. While Research Administration promotes research and performs oversight, the IRB focuses exclusively on human subject protection while meticulously following federal regulations designed to ensure it.

Second, a major training effort was undertaken. The research compliance officers and the new IRB Chairman were sent to the Western IRB (WIRB) in Olympia, WA for training in theory, structures, and procedures. A WIRB team was also sent to Ochsner to train IRB members, Principal Investigators, and Clinical Research Coordinators.

Third, in addition to a new IRB Chairman with 60% time for the IRB, the IRB office staff was tripled and office space was dramatically expanded to accommodate the larger staff and space for an IRB record review room and library.

Finally, with the help of WIRB, the entire structure and process of the IRB was revamped. New standard operating procedures and guidelines were put in place and have now been approved by both FDA and OHRP who have said their initial concerns have been resolved. The number of IRB Panels has been increased from one to three. All studies are being re-reviewed in light of the earlier regulatory agency concerns, and as of this writing about half have been completed.

Ethical Standards

The ethical standards Ochsner uses are contained in the Belmont Report*. The key ethical principles in the report are respect for persons, beneficence, and justice. Applications of the general principles to the conduct of research led to the requirements of informed consent, risk/benefit assessment, and the equitable selection of research subjects. Ochsner's federalwide assurance voluntarily commits the institution to apply the same ethical standards and procedural safeguards that are mandated for federally funded or FDA-regulated studies to all research done at Ochsner.

Data Privacy

For many studies, harm might come as side effects of drugs or devices, but benefits may outweigh possible risks. Some researchers mistakenly think that studies without drugs or devices, e.g., retrospective chart review, carry no risk to patients. Harm that can be done by accessing secondary data are psychological and financial risks resulting from improper disclosure of personally identifiable health information. These include potential denial of health insurance coverage, difficulty obtaining employment, embarrassment, loss of reputation, legal liability, or anxiety about what the recipient of an unauthorized disclosure of information might do with it†. Because of these risks, confidentiality in the use of data is important. At a minimum, data confidentiality requires:

- Not abstracting personal identifiers such as names, addresses, telephone numbers, e-mail addresses, or Social Security numbers except when essential
- Removing coded personal identifiers such as clinic or hospital numbers at the earliest stage of the research compatible with the study goals, such as after linking data from various sources together
- If coded personal identifiers must remain to combine with future data, encrypting them and not using the plain clinic or hospital numbers
- The data files should be kept in a secure environment such as a locked cabinet or a properly secured computer file with password protection.

For more information:

* <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm>

† <http://books.nap.edu/books/0309071879/html/29.html>

Federalwide Assurance

Every institution conducting research with human subjects is required to have an assurance filed with OHRP that lists the IRBs used by the institution and sets forth the ethical norms the institution will use in its conduct of research. In addition to the three Ochsner IRB panels, Ochsner now lists the WIRB panels on its assurance. Participating in a pilot project with the National Cancer Institute, Ochsner has also listed the Central IRB (CIRB) from the National Cancer Institute on its federalwide assurance. Certain national oncology studies will have IRB review performed by the CIRB, and the Ochsner IRB will provide administrative oversight to assure that no local conditions require modification to the study or its informed consent.

The IRB Meeting—An Open, Honest Discussion

The key role of the IRB is the review of a study both initially and on a continuing basis at intervals set at the prior review. Each IRB panel must have a member that is not affiliated with Ochsner, and a non-scientist must be present to have a quorum. Ochsner's IRB panels combine lay people, legal professionals, physicians, and other scientists. There must be a free, open, and honest discussion by people of varying backgrounds to come to a reasonable decision about whether a study's protocol should be approved or modified or disapproved. This is the central mechanism for the protection of human subjects.

The Larger Human Subject Protection Community

The IRB re-engineering is occurring in a larger context of heightened concern throughout America about human research protections. The Health Insurance Portability and Accountability Act (HIPAA) is highlighting the data privacy issues. Ochsner's collaboration with WIRB and CIRB, noted above, reflects the current national research environment.

Ochsner IRB staff and some members participate in the Public Responsibility in Medicine and Research (PRIM&R, www.primr.org) and Applied Research Ethics National Association (ARENA, www.arena.org). All IRB members receive a subscription to *IRB Ethics & Human Research* to keep abreast of national trends. Other relevant journals and materials are being gathered into the IRB Library with the help of the Ochsner Medical Librarian.

Ochsner has also been invited to participate in an IRB Benchmarking Consortium organized by the Center for Bioethics at the University of Pennsylvania. This effort is designed to improve IRB functioning through the development and use of reliable benchmarks for understanding what works, for assessing systemic changes, and for tracking improvement efforts over time.

Conclusion

Ochsner Clinic Foundation has made a leading-edge commitment to protecting human research subjects. Our re-engineered IRB will insure a safe and solid research base, which will contribute to the care our patients receive and set a precedent in the research community during these times of wide-ranging improvements in research oversight and protections. ☞