

IRB/Scientific Integrity Committee Report

by John H. Mueller, University of Calgary & Richard M. O'Brien, Hofstra University

This column is a product of Division One's new committee on "IRB/Scientific integrity," chaired by John Mueller. The committee has the following mandate: To probe the impact of IRBs on science, scientists, and society, as well as academic freedom, junk science, and other trends that may threaten the integrity of the scientific enterprise. This column is to follow up our column in the previous issue of TGP (Winter-Spring, 2007), we noted several items relevant to the mandate of our committee. This column will include a follow-up to the recent APA convention as well as other items.

1. Symposium The first item of note with regard to IRBs would be a symposium sponsored by Division One at the APA convention in San Francisco, August 19, 2007, sponsored by the President of Division One, Harold Takooshian, entitled Human Subject Protection, Academic Freedom and the First Amendment: Can't We Have It All?

For 60 years the role of Division One has been to identify pervasive topics and issues that transcend specialties. Today it is hard to identify an issue that has broader impact than the ever-expanding presence of Institutional Review Boards (IRBs). At their outset some 30 years ago, research ethics committees had the mandate to decide whether the public is at more than everyday risk from your project, and it was understood that this would be a rare event in psychological research. However, the domain of such reviews has expanded greatly, with little evidence of need or effectiveness. Furthermore, forums to meaningfully discuss concerns with this enterprise are very limited, compared to the ubiquitous and increasingly obligatory workshops that focus entirely on how to comply with the progressively more complex regulations.

Our symposium brought together presenters to comment on the damages that have arisen from uncritical compliance with IRBs. We feel that it is time to reject the claim that researchers are to blame for problems with IRBs. Instead it is the ethics enterprise itself that must be the focus of examination, and with the tools appropriate to any research enterprise, specifically empirical evidence as opposed to legal and philosophical creations. Only in this way can we be sure that research subjects are really safer with IRBs than without IRBs.

The presenters and paper titles were as follows, with author contact information to request complete copies of their presentation:

1. Michael H. Birnbaum, California State University-Fullerton: When Is Ethical Review Itself Unethical? <mbirnbaum@fullerton.edu>
2. John J. Furedy, University of Toronto: IRBs as Bioethical Industrial Waste for Both Research and Society. <furedy@psych.utoronto.ca>
3. Richard M. O'Brien and Kurt Salzinger, Hofstra University: IRB Prior Approval: Unnecessary, Counterproductive and Unethical to Academic Freedom. <psyrmo@hofstra.edu>

The speakers in Division One's symposium covered a number of topics arranged about six basic issues:

1. The lack of empirical support for the entire prior review process.

2. The drift of IRB evaluations from protecting human subjects to micromanagement of all aspects of the research enterprise.
3. The first amendment/academic freedom challenge of having non government funded research evaluated according to government directives.
4. The lack of either appeal provisions from the decisions of IRBs and Compliance Officers or any accountability for their capricious actions.
5. The potential for abuse in the entire research ethics program.
6. The deficiencies of the available training materials.

All of the speakers stressed the need for APA support in opposing these IRB actions and suggested various approaches to respond to arbitrary IRB decisions.

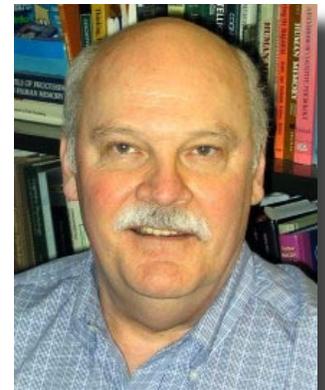
The Sunday morning symposium was well attended and well received. Although some people seemed disheartened by the state of the field, others hoped this was another step on the road to correcting what is obviously a troubling situation.

2. The Presidential Program on IRBs at APA

Later that day, APA presented an invited symposium entitled: The Presidential Program-Psychologists and Institutional Review Boards: Working Collaboratively to Protect Research Participants, chaired by Thomas Eisenberg of Virginia Commonwealth University. Although the tone of this symposium was very different from our morning session, some of the same issues were raised. Dr. Eisenberg spoke of the problems with expedited reviews that really weren't expedited and the general unhappiness with the process. Representing OHRP in Washington, Ivor Pritchard noted the necessity of providing some research on the effects of IRBs. He reported that DHHS had issued a call for research proposals to examine the effects of IRBs. Attendance at the Presidential Symposium was somewhat sparse: N=20 (including a rather annoying professional photographer who took many pictures of each speaker).

Earlier in the convention, Dr. Pritchard had presented on IRB issues under the somewhat paternalistic title: What Should Psychologists Think About IRB Decisions? He placed the responsibility for the inconsistency in IRB decisions on personality differences in the members of the different boards. One can only hope that some of the papers in the Division One symposium helped him to see that the problem is systemic, in that the boards have unlimited power which leads to capricious decisions.

3. Torture and interrogation The question of participation by APA members in interrogations of prisoners was the subject of considerable discussion in San Francisco, both informal and formal. As per an APA press release at <<http://www.apa.org/releases/councilres0807.html>>, the Council of Representatives



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moved to limit the type of interrogations that APA members may participate in:

"The resolution, passed at the APA's annual convention in San Francisco, unequivocally condemns and strictly prohibits psychologists from direct or indirect participation in a list of 19 unethical interrogation techniques ..." This resolution extends the long-standing position opposing torture to include interrogations involving "cruel, inhuman or degrading treatment," but stops short of prohibiting member participation in interrogation per se.

4. Censorship and IRBs A special issue of the Northwestern University Law Review has just been made available on-line at <http://www.law.northwestern.edu/journals/lawreview/issues/101.2.html>, summarizing contributions at a symposium on Censorship and Institutional Review Boards held at Northwestern, April 7, 2006, sponsored by the Law Schools of Northwestern University and the University of Chicago. The participants included legal scholars and social science researchers, who addressed the constitutionality of IRB prior restraint and, given the varied nature of the participants, the papers contain a wide variety of perspectives.



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5. IRB Blog Zach Schrag, a Professor of History at George Mason University, has started a blog to provide analysis and commentary on issues associated with IRBs, which is maintained and regularly updated at <http://institutionalreviewblog.blogspot.com/>. As with the NWU Law Review special issue noted above, this highlights the multi-disciplinary impact that IRB "creep" has had on academic scholarship in the social sciences and humanities beyond psychology and underscores a conclusion that correcting the problems that affect psychology is going to require a broad-based effort. Defending academic freedom against the top-down IRB/ethics industry often seems a daunting task, but it seems that a growing number of scholars across an array of fields in the social sciences and humanities are unwilling to accept continued loss of freedom of inquiry. Broad-based efforts seem critical, given a divide-and-conquer history of regulation.

6. Monitoring the Monitors Occasionally the question is raised as to how to appeal the decision of an IRB. Of course, one can make an appeal back to the IRB, but if this is not successful, then what? The general problem here is that the IRBs are their own adjudicators, and the same is true of the regulators. This has long been recognized as a problem, going back at least to Plato (Republic): "Who will watch the watchmen?" The concern is addressed sometimes by a system of checks and balances, as in the "separation of powers," but that is lacking here.

One suggestion we have heard is that APA could function somehow as an ombudsman, perhaps by broadening the work of the present Ethics Committee of APA or by adding some new office. Not to reject this out of hand, but the mechanics of how this would work are not clear. Perhaps more importantly, that would not be a general solution because it would not accommodate the multiplicity of disciplines that the accountability concern covers. An alternative solution (noted in an earlier col-

umn) would be to recognize that research is a job requirement for academics, and thus incorporate IRB decisions into the Collective Bargaining Agreement between the campus faculty union and the administration. This would cover the several disciplines on a campus, but would have to be accomplished one campus at a time, and would leave out the many institutions without a faculty union.

It is not clear to us that there exists a general solution to this concern at this time. In Canada, SAFS, the Society for Academic Freedom and Scholarship <http://www.safs.ca>, does occasionally address research ethics issues, but not systematically and does not handle appeals. Another example of this type of organization would be FIRE, the Foundation for Individual Rights in Education <http://www.thefire.org/>, which has worked to deal with campus speech codes for students. The AAUP, the American Association for University Professors <http://www.aaup.org>, has considered the impact of IRBs generally, but the potential extent of regular appeals may be beyond their capabilities. It also seems unlikely that appeal adjudication would be an acceptable function of a research ethics accreditation agency.

The development of some genuine appeals process seems a commendable objective, and should enough parties agree to that perhaps a solution can be achieved. Anything to introduce accountability into the present scheme would be desirable. We would like to hear of other suggestions in this regard.

8. Legality Jack Katz, a sociologist at UCLA, has an article forthcoming in the *Law & Society Review*, 2007 <http://www.blackwellpublishing.com/journal.asp?ref=0023-9216>, "Toward a Natural History of Ethical Censorship". In this article, he examines the prospects of a "legality" based challenge to the IRB process, along the lines of the first amendment questions raised in the NWU special issue above.

9. Tuskegee Richard Shweder, a cultural anthropologist at the U. of Chicago, has published an analysis of the infamous Tuskegee syphilis research project in Alabama <http://www.spiked-online.com/Articles/0000000CA34A.htm>. Although a few years old, the article seems not widely known, and it is interesting as an example of how IRB history can involve elements of caricature and urban myth. That the analysis is not in a mainstream journal perhaps speaks further to the limitations on the opportunity to make critical commentary about the research ethics industry.

The authors welcome communications about research ethics and scientific integrity, reports of particularly outrageous IRB or Administration Compliance Officer conduct, and suggestions for future columns. This Committee will be continuing its work during the coming year, with Richard O'Brien as chair. We would be happy to hear suggestions as to how the committee should proceed, such as a resolution from Division One to the APA Council, and, of course, volunteers are welcome! Please send correspondence to: John Mueller, Applied Psychology Division, University of Calgary, Calgary, Alberta, T2N 1N4, mueller@ucalgary.ca.

