

# GUEST ARTICLE: IBCS, IRBS, AND IACUCS: CREATING A STRONGER FOUNDATION FOR THE OVERSIGHT OF RECOMBINANT DNA RESEARCH

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Institutional Biosafety Committees (IBCs) are the cornerstone of institutional systems of oversight of recombinant DNA research. When this form of research involves animals or humans, IACUCs or IRBs, as appropriate, also have important purview. While each of these committees can fulfill its responsibilities independently, oversight of research involving recombinant DNA is enhanced when they are joined together and provide a common foundation on which to stand. More often than not, though, this does not occur, in part because IBCs are not well understood by their sister committees. Thus, a key objective of this article is to describe the important function IBCs serve and to underscore the value of having IBCs, IRBs, and IACUCs work together.

**History of NIH Oversight** - To understand the role of IBCs, it may help to hearken back to their origin. IBCs were formed some 25 years ago when our current system of oversight of recombinant DNA research was established. At the time, recombinant DNA was a nascent and poorly understood technology, and the public was apprehensive about its impact on human health and the environment. In response, scientists developing this field convened the landmark Asilomar Conference and over the course of three days initiated what was to become an enduring system of institutional and federal oversight guided by the NIH. A key tool in this system was the Recombinant DNA Advisory Committee (RAC), which met at the end of Asilomar and created the first venue for discussing these concerns publicly. In the following year, the RAC hammered out the initial version of the *NIH Guidelines for Research Involving Recombinant DNA Molecules*. The *NIH Guidelines*

is a "living" document that details biosafety practices for institutions and investigators to follow, consonant with current scientific understanding. A salient and valued characteristic of this system is its transparency, which has served to inform the public and to provide assurance of adequate oversight.

**Role of IBCs** - Under the *NIH Guidelines*, IBCs are responsible for local oversight of recombinant DNA research. In that capacity, IBCs review proposed experimentation to ensure that it is conducted in a manner consistent with the biosafety practices outlined in the *NIH Guidelines*. Equally important, IBCs assess the adequacy of facilities, institutional procedures, and investigator training and expertise. When human gene transfer trials were first proposed just over a decade ago, IBCs assumed additional responsibilities (under Appendix M of the *NIH Guidelines*) for reviewing clinical protocols to ensure the safety and proper design of this research, including the receipt and analysis of adverse event reports and findings from animal studies germane to the design and conduct of human studies. Finally, many institutions have assigned these committees additional authority, which may include the oversight of research involving other biohazardous materials, such as carcinogens and infectious agents. An interesting feature of IBCs is that, like the RAC, they allow for public participation in this review, in this instance through the inclusion of at least two non-institutional members representing community interests.

**IBCs and their sister committees** - IRBs review the ethics of research involving human subjects, and IACUCs ensure the welfare of animals used in research. In recombinant DNA research, IBCs are the "bridge" committees that review the science, safety, and ethics of experimentation from the bench, through animal

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models, to the clinic. IBCs can thus provide important information and longitudinal perspectives to their sister committees on this line of research. IRBs and IACUCs have unique expertise to share with IBCs, as well. Greater communication between these committees enhances the efficiency of data gathering and analysis and improves the quality and consistency of each committee's review. It also promotes the development of a common infrastructure, such as shared information and administrative resources, which solidifies the bases on which these committees operate.

However, systems are not in place at many institutions to facilitate effective and systematic communication between IBCs and their sister committees. Furthermore, IRBs and IACUCs often do not have a clear idea what the IBC does to fulfill the requirements of the *NIH Guidelines*. With ARENA's help, this is a situation that the NIH Office of Biotechnology Activities is working to rectify.

**OBA and ARENA** - For the past couple years, the Office of Biotechnology Activities (OBA) has worked with ARENA and its sister organization PRIM&R to enhance our communications with the IRB and IACUC communities. At the December 2001 and November 2002 PRIM&R and ARENA meetings, OBA staff led workshops on a number of topics related to IBCs and the *NIH Guidelines*, giving OBA an important opportunity to convey information about the process of

review for human gene transfer trials and to discuss how IRBs can benefit from the NIH process of oversight.

In December 2001, OBA sponsored a policy conference to examine the roles and responsibilities of IBCs in light of the changing landscape in which human gene transfer research is being conducted. One outcome of this conference was a clear call for more professional development opportunities for IBCs, which lack a constituency organization specifically focused on their educational needs. OBA, ARENA, and the American Biological Safety Association are organizing such an event to take place February 20-22, 2003. The conference will include workshops to explore IBC relationships with both IRBs and IACUCs.

**Standing strong together** - ARENA is helping OBA form stronger ties between IRBs, IACUCs and IBCs for the purpose of enhancing the oversight of recombinant DNA research. OBA looks forward to continuing its efforts with ARENA, as a key partner, to create a firmer foundation on which institutional oversight of recombinant DNA research can stand.

To learn more about IBCs and the February 2003 conference, connect to the IBC page on OBA's Web site at: [www4.od.nih.gov/oba/IBC/IBCindexpg.htm](http://www4.od.nih.gov/oba/IBC/IBCindexpg.htm). To receive bulletins on OBA's activities, subscribe to our listserv, OBA\_NEWS, by sending a message "subscribe oba\_news to: listserv@list.nih.gov."

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