

## The American Research University and Institutional Biosafety Committees

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On November 17, 1944, President Franklin D. Roosevelt sent to the Office of Scientific Research and Development, directed by Vannevar Bush, a series of questions about the future of scientific research and development after World War II. Among the questions he asked was, "With particular reference to the war of science against disease, what can be done now to organize a program for continuing in the future the work which has been done in medicine and related sciences?" President Roosevelt observed, "New frontiers of the mind are before us, and if they are pioneered with the same vision, boldness, and drive with which we have waged this war, we can create a fuller and more fruitful employment and a fuller and more fruitful life." In July 1945, Vannevar Bush responded to the President's request with a report entitled *Science: The Endless Frontier*. Among the very important recommendations made by Vannevar Bush was the identification that basic or fundamental research should be carried out in America's universities, while industry would focus on applied research and development. This reliance upon the university accelerated a trajectory that made American universities the leading research universities in the world.

Unlike research institutes in Western Europe or the focus of research in industry in Japan, the American university combined education and training with research. Many of the most important ideas in biomedical research come from young PhD, MD, and post-doctoral students. These same students are the workhorses of the research enterprise.

Combining research and education was a master stroke which brought students to America from all over the world. In contrast to other countries, the United States developed a peer review process, in which the best ideas were funded by agencies such as the National Institutes of Health (NIH) and the National Science Foundation, rather than the European practice of providing money to senior professors who then directed the research. An essential feature of this method in the United States was the decentralization of the research enterprise, fostering a diversity of approaches, innovative ideas, and environments enriched by the interaction between the researchers and their students.

A central feature of this decentralization was the

trust placed in the University to oversee the actual conduct of research. The university and its investigators were trusted to use monies granted from the federal government to carry out research in an appropriate and cost-effective manner. Investigators were trusted to record scientific data and to report it accurately and appropriately in scientific journals. The peer review process used for grants became a central feature in the determination of publication. The institution was also trusted to organize institutional review boards to assess the ethical and scientific appropriateness of human participation in scientific research. The system was by no means flawless and from time to time significant problems arose regarding informed consent, conflict of interest, and some unsafe practices. However, the solution applied to these challenges again was based upon a level of trust attested through accreditation processes, which themselves were conducted by scientific and ethical peers. A similar approach was taken for the use of animals in research, with the creation of institutional animal care committees and an accreditation process.

Institutional biosafety committees (IBCs) came into being when scientists and the public, including policy-makers, were challenged by the emergence of recombinant DNA as a potential therapeutic device. Although some aspects of unapproved DNA applications to humans were forbidden by law and in some cases involved criminal penalties, the overall oversight for DNA research was through the trust placed in IBCs. More recently, the IBCs have been responsible for even broader issues of safety including select agents and other biological and chemical risks on the campus. As with other aspects of this endeavor, the system has not always been perfect and, particularly as a consequence of whistle-blowers, deviations from policy have been identified and have led to sanctions by agencies of the federal government. Although examples of scientific misconduct have been identified, they still remain relatively rare events given the size and scope of the scientific undertaking. In general, however, the system of trust placed in the University, its scientists, and its committees has been remarkably successful.

In the spirit of this delegated responsibility of trust, The University of Texas System (UT System) organized, in

collaboration with the NIH, an educational conference on the role of the IBCs in the UT System entitled, "IBC 101." This conference, held August 18-19, 2005, was originally designed for UT System institutions, but over 30 institutions from 12 states attended the meeting. It was not only instructive but also led to the development of a template which IBCs could use as a self-assessment tool to evaluate their own performance, as well as for training and education. Participants found the experience so useful that a subsequent conference, "IBC 201," was held in September 2008, in collaboration with the NIH, the Centers for Disease Control and Prevention (CDC), and the U.S. Department of Agriculture. At this conference, the template was updated.

The NIH and the CDC convened the first national meeting for IBC participants in June 2009. This meeting brought together over 250 individuals who discussed an intense and comprehensive approach to the challenges posed by the responsibilities of IBCs. As a result of this meeting, the NIH has made available a self-assessment template for IBCs that is, in part, based on the UT System model and further adapted for use across the country.

IBC's continue to be essential components in the maintenance of trust which has made American research universities and other research institutions the best in the world. They deserve greater recognition within their institutions for the role they play, as well as clearer articulation of institutional support at the very highest levels. In many cases they continue to be under-resourced in both personnel and financing for the magnitude of the responsibility they must fulfill. In this regard, the NIH has indicated a program of site visits which can be used not only to assess the state of IBC's effectiveness on campus, but also can be effectively used as an educational tool for institutional leaders to educate them on the importance of properly supported and properly functioning IBCs.

A major challenge and opportunity for IBCs is an enhanced set of interactions with other institutional entities such as the institutional review boards, the institutional animal care and use committee, and other comparable committees. Enhanced communication and coordination among these entities can facilitate the improved operations of each. The involvement of human participants and animals in studies involving select agents or DNA is a joint responsibility of multiple committees

which can coordinate these activities more effectively in many cases. At the same time, these entities have major educational responsibilities within the institution. Coordinating these educational activities to make them efficient and effective, particularly for time-pressured investigators and their staff, can be an important contribution to effectiveness and efficiency. We have found the self-assessment tool to be a useful vehicle to understand internal operations.

As a keynote speaker at the 2009 IBC meeting, it was Kenneth Shine's privilege to salute the dedication and expertise reflected in the participants and in those who work to promote institutional biosafety. It is essential that the scientific community understand the importance of this activity and the trust which society has placed in it. The IBCs have helped to allow American science to operate in the decentralized university-based role that continues to lead to opportunities for individuality, creativity, and local initiative. Preserving trust, through the IBCs and other institutional committees with similar responsibilities, is an essential feature if American science is to prosper and the American research university is to be preserved.

## Acknowledgment

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## References

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