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MEMORANDUM

TO: Attendees of Institutional Biosafety Committee (IBC) 101 preconference course
FROM: Ted Myatt, Sc.D., R.B.P.
DATE: April 28, 2010
RE: Questions and Answers and other Topics

As I mentioned in our session on April 21 in Dallas, below are questions raised by the group and hopefully some straightforward and informative answers. I appreciate your attendance and hope that you found the course to be useful and relevant for your institution. If there are other questions that you have regarding IBCs, program audits, or software solutions, please feel free to contact me at any time at 800-835-5343 or tmyatt@eheinc.com.

Q. In terms of the interactions between other research review committees (e.g., IACUC and IRB), which committee defers?

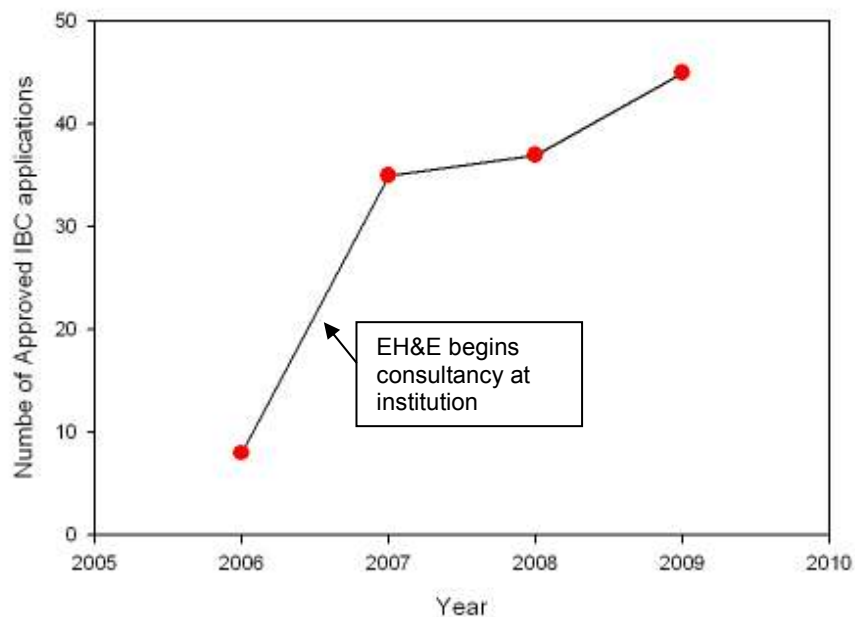
A. Generally speaking, IACUC's and IRB's will defer to IBC recommendations or stipulations in matters related to the study product and biosafety. This occurs because IBC's should be the study product experts for products that involve rDNA and/or infectious agents whereas IACUCs and IRBs may not have experts in these fields.

Q. One compliance challenge that was discussed was how to ensure review of all applicable research. Can you describe this issue more fully?

A. IBC's have been particularly challenged with ensuring review because in most academic settings, there is little to stop researchers from purchasing or borrowing new rDNA materials or infectious agents prior to approval. In the IACUC world, approval is necessary prior to the

allowing access to animal facilities or purchase of animals. No such “gate keeper” exists in the IBC world.

Institutions must rely on proactive biosafety officers and connections between other research committees and the grants and contracts office as methods to ensure review. In many institutions these connections are not in place and the resources may not be available to the biosafety officer to be proactive. As an example of this issue, the graph below (which is quite typical of institutions we have consulted with) shows the number of research protocols approved by year before and after we have been involved at the institution. Clearly, the volume of research did not quadruple between 2006 and 2007 – the increased focus and resources directed to the biological safety office and the IBC identified research that was “flying under the radar.” Unapproved research is not only a compliance risk in terms of the NIH, but a safety risk. Without approval, it is likely that the staff are not being trained appropriately to handle the agents in use. When (not if) exposures occur, the first question the NIH will ask is what the staff have been trained on.



Q. What interaction does the US Food and Drug Administration (FDA) have with the NIH Office of Biotechnology Activities (OBA) in terms of clinical trials?

A. There does not seem to be coordination between the FDA and the NIH OBA. The materials that are required to be supplied to the NIH (as described in Appendix M of the NIH Guidelines),

is different that the materials required by the FDA. It is important to understand that materials submitted to the NIH OBA may be discussed by a Recombinant DNA Advisory Committee (RAC) meeting which is open to the public. Therefore, trade secrets and confidential materials should not be included in the NIH OBA package.

Q. How aggressive is the NIH in terms of site visits?

A. While data is not available on the number of inspections the NIH conducts on an annual basis, they have increased their efforts in recent years. The NIH site visit program was established around 2005 and more recently the NIH has contracted with an outside firm to provide support for the inspection process. It is interesting to note that the establishment of the site visit program roughly corresponds to with rapid rise in the number of registered IBCs in recent years.

Q. Are IBC's required to conduct something similar to IACUC annual review process?

A. No. However, IBCs are to "periodically" review all rDNA research conducted at the institution to ensure compliance with the NIH Guidelines. The best practice to accomplish this is conducting an annual review of all protocols. Additionally, the IBC is required to submit an annual report to the NIH that includes i) a roster of all IBC members clearly indicating the Chair, contact person, Biological Safety Officer (if applicable), plant expert (if applicable), animal expert (if applicable), human gene therapy expertise or ad hoc consultant (if applicable); and (ii) biographical sketches of all Institutional Biosafety Committee members (including community members).

Q. How is the NIH Guidelines evolving?

A. The NIH Guidelines has been changed substantially over the years. Last year, additional requirements were included for research involving certain strains of influenza virus. On April 22, a notice of a proposed change to the NIH Guidelines was published in the Federal Register (<http://oba.od.nih.gov/oba/RAC/2010-9258.pdf>). This is a substantial revision that may allow the IBC to lower containment for certain experiments involving replication deficient viruses. It is imperative, that the IBC chair and/or biosafety officer be aware of these changes and convey them to the IBC members and the research community.

Q. What does the NIH review as part of their site visit program?

A. *The NIH reviews materials such as IBC policies and procedures, IBC forms and approvals, training materials. During their site visit they use a checklist similar to their self-assessment tool available at: http://oba.od.nih.gov/rdna_ibc/ibc.html. The tool can be used to provide a self audit.*

I have found that in most cases, an outside audit/gap analysis provides a superior review of the program and can also be used to identify ways to create efficiencies and ensure that the institutions are following best practices. An outside audit can also look more broadly at the entire EH&S program and research committees (e.g. IRB and IACUC) for appropriate staffing levels (benchmarked to similar size institutions) and best practices.

Efficiencies can also be created through the use of a online IBC submission system. There are many available systems. There are pros and cons with each. I had a hand in creating a research protocol submission system, which we developed for the EH&S programs EH&E manage. A demo of this system, which is build on Microsoft SharePoint along with our information is here: <http://www.eheinc.com/ibc.htm>