

Pre-CONFERENCE AGENDA

National Institutes of Health - Office of Biotechnology Activities EFFECTIVE IBCs

Effective IBCs: *An Introduction to the NIH Guidelines and the Oversight of Recombinant DNA Research*

Effective IBCs is a half day workshop on the history, function, and administration of Institutional Biosafety Committees delivered by expert staff from the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA).

Effective IBCs will promote the professional development of those associated with IBCs, by providing an opportunity to:

- Learn about the NIH OBA and the history of IBCs
- Learn about the content of the *NIH Guidelines for Research Involving Recombinant DNA Molecules*
- Understand the range of responsibilities that IBCs have under the *NIH Guidelines*
- Network with colleagues to share ideas about best practices, resources, innovative approaches, and possible collaborations.

Effective IBCs is intended for IBC members and staff and others who have an interest in the oversight of recombinant DNA research, including research administrators, biosafety officers, regulatory affairs officers, and the members and staff of other institutional oversight committees such as Institutional Animal Care and Use Committees and Institutional Review Boards.

There is a separate Registration fee for this course.

Effective Institutional Biosafety Committees

FACULTY

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Pre-conference Agenda

1:00 - 1:15 PM

Welcome and Introduction

1:15 - 1:45 PM

Introduction to the National Institutes of Health Office of Biotechnology Activities and to the History of the NIH System of Recombinant DNA Oversight

A discussion of the responsibilities and activities of the NIH Office of Biotechnology Activities. An overview of the origins of the current system of oversight and its scientific and philosophical basis.

1:45 - 2:30 AM

Overview of the Current *NIH Guidelines for Research Involving Recombinant DNA Molecules*

A discussion of the key elements of the *NIH Guidelines* and their application to basic and clinical recombinant DNA research. An overview of sections of the *NIH Guidelines*.

2:30 - 3:00 PM

Requirements for IBCs in the *NIH Guidelines*

The need for, and expected characteristics of, IBCs. Registering an IBC with NIH OBA. General responsibilities of IBCs in the review of research involving recombinant DNA.

3:00 - 3:15 PM

Questions and Open Discussion

An opportunity to ask questions and exchange information and ideas.

3:15 - 3:30 PM

Break

3:30 - 4:15 PM

Role of the Recombinant DNA Advisory Committee and the Protocol Review Process

An overview of the RAC and its major responsibilities as a key federal advisory committee. A discussion of the requirements of Appendix M and protocol submission to NIH.

4:15 - 4:45 AM

The NIH Site Visit Program

What to expect if your institution is selected for a site visit. Observations including best practices, areas where improvement is needed, and common compliance challenges will be discussed

4:45 - 5:00 PM

Questions and Open Discussion

An opportunity to ask questions and exchange information and ideas.

5:00 PM

Adjournment