



# NIH Recombinant DNA Compliance

44-MINUTE ONLINE COURSE | LEVEL 1

## OVERVIEW

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**NIH Recombinant DNA Compliance** highlights the history and current legislative initiatives for NIH compliance, how these may affect your institution and the operation of the Institutional Biosafety Committee (IBC), expectations of Principal Investigators, awareness of the IBC and its responsibilities, exempt vs. non-exempt experiments, as well as, what to expect during an NIH site visit/audit or facility inspection, and common compliance challenges. It also provides a detailed look at the purpose, composition, responsibilities, and management of IBCs. Requirements set forth by the NIH and other relevant institutions will be covered.

### Five Takeaways:

1. Define recombinant DNA.
2. Explain why the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) were established and how have the NIH Guidelines changed over the past 40 years.
3. Lists the scope of the NIH guidelines and who is subject to these guidelines.
4. Lists the types of protocols the IBC is required and not required to review.
5. Describe what the NIH will audit during a site visit.

## AGENDA

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- **What Is Recombinant DNA?** This section defines recombinant DNA, describes how recombinant DNA is made to make genetically engineered cells, and explains how genetically engineered cells are used.
- **History of the NIH Guidelines for Research Involving Recombinant DNA Molecules** explains why the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) were established and how the NIH Guidelines have changed over the past 40 years.
- **Basics of Institutional Biosafety Committees (IBC)** lists the scope of the NIH guidelines and who is subject to these guidelines. Next, this section describes the expectations of the Principal Investigator (PI) and the Institutional Biosafety Committee (IBC) in terms of the NIH Guidelines.

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- **Sections of the NIH Guidelines** lists the what the different appendices cover within the NIH Guidelines.
- **IBC Review of Infectious Agents Protocols** lists the types of protocols the IBC is required and not required to review.
- **Site Visits by NIH** explains what the NIH will audit during a site visit and lists the components of a robust biosafety program.