

Introduction

- The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* are rules that govern certain recombinant and genetic engineering experiment(s).
- In the [Clinical Trial world](#), this means the introduction of foreign or modified genetic material, or of products (i.e., cells, viruses, and microorganisms) created using genetic modification, into a human subject with an intent to express a foreign gene or modify expression of native genes.
- The [Institutional Biosafety Committee \(IBC\)](#) works to protect research staff and the environment.
 - The main focus is safety and the potential exposure and health risks these study agents pose to research staff, the community, and the environment.
- IBC oversight is required when:
 - Study agent contains recombinant material subject to Section III-C of the *NIH Guidelines*.
 - Federal funding has ever been used to support recombinant or synthetic nucleic acid research experiments or human clinical research studies.
 - This includes federal funding received by the Sponsor, CRO, or your institution.
 - This also includes research collaboration or contractual agreements.



The *NIH Guidelines* Define:

Institutional (Site) Responsibilities

- Establish policies for safe handling of the study agent(s) in use
- Study safety and training
- Adhere to *NIH Guidelines*
- Follow all IBC conditions for approval
- Notify IBC of any study modifications

Containment Strategies via Procedures, Practices and Facilities

Items That Constitute Gene Transfer

Principal Investigator Responsibilities

- Have the experience and training to safely oversee the study and staff as determined by the IBC
- Wait for IBC approval before initiating the study
- Report any problems, research-related accidents or illnesses, or *NIH Guidelines* violations to the IBC

IBC Responsibilities

- Approves procedures, practices, and facilities used in study
- Performs biological risk assessment
- Sabai will register IBC with NIH and handle all communication with NIH OSP