THE ABC'S OF IBC'S

A brief overview of the NIH Guidelines

1. PURPOSE

The NIH Guidelines outline the safe practices and requirements for laboratory and clinical research that involves recombinant or synthetic nucleic acids (r/sNAs).

2. COMPLIANCE

All institutions or projects that receive funding from the NIH are required to comply with the NIH Guidelines. In addition, if an institution is the recipient of NIH funding, all research conducted there is required to comply, even if projects are not funded by the NIH directly.

3. NON-COMPLIANCE

Institutions that fail to comply with the NIH Guidelines risk losing NIH funding and suspension of part or all of research funding provided by the NIH until corrective actions have been taken.

4. INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

IBCs are established to review safety and provide oversight over research that involves the use of recombinant or synthetic nucleic acids. This review includes accessing the risks involved in working with the agent, the facilities, and the procedures, practices, and training of the personnel conducting the research.

5. OFFICE OF SCIENCE POLICY

The NIH OSP reviews and approves the IBC membership, reviews high-risk research, and provides advice. Accidental exposures and non- compliance to the NIH Guidelines are reported to the NIH OSP.

6. HUMAN GENE TRANSFER

Human Gene Transfer (HGT) encompasses the deliberate transfer of synthetic or recombinant genetic material into human research subjects. HGT funded by the NIH requires review by a local IBC.

7. RISK ASSESSMENT

An assessment is made of the risks involved in working with biological agents. This involves defining the risk group for the agent, reviewing how it will be manipulated and potential consequences of occupational exposures.

THE ABC'S OF IBC'S

A brief overview of the NIH Guidelines (continued)

8. REPORTING

IBCs are required to register with NIH and file an annual report. When non-compliance to NIH guidelines is identified it must be reported to the NIH OSP within 30 days. A function of the IBC is to assist with this reporting.

9. IBC MEMBERS

An IBC must have at least 5 members, but there is no maximum. Members must have the expertise to review the research conducted at the institution (e.g. Human Gene Transfer), including an IBC Chair, representatives from the intuition, and at least two members from the local area, unaffiliated with the institution.

10. IBC OVERSIGHT

The IBC assesses and oversees the biosafety of research that is subject to the NIH guidelines, including HGT in human participants. The majority of research falling into this category requires IBC approval before the initiation of the study.

11. BIOSAFETY LEVELS

Biosafety levels refer to physical containment requirements, laboratory/clinic practices, containment equipment, and PPE. The lowest level, BSL-1, includes the use of standard microbiological practices, and easy-to-clean facilities and generally, doesn't require special physical containment equipment. BSL-4, the highest level, requires special facilities referred to as maximum containment laboratories and specialized PPE.

12. EXEMPTION

Some research may be exempt from the NIH Guidelines. These are typically agents that have had little to no modification or manipulation, possess no toxic or potentially oncogenic properties, may occur naturally, and pose no hazard to human health.