

Appendix F - NIH Oversight of Research Involving Recombinant DNA

The NIH Guidelines for Research Involving Recombinant DNA Molecules

(https://osp.od.nih.gov/wpcontent/uploads/NIH_Guidelines.html) contain procedures for the containment of rDNA research. The

Guidelines apply to all institutions that receive NIH funding for rDNA. All Investigators at the institution

must comply with the Guidelines, even if their individual research is not funded by NIH.

Consequences

of noncompliance include suspension, limitation, or termination of NIH funds for rDNA research at the

institution, or a requirement for prior NIH approval of rDNA projects at the institution.

The original guidelines were issued in 1976 due to public concern for safety, environmental impact, and

ethical implications of rDNA research. The purpose of the guidelines is to specify safe handling practices

and containment levels for rDNA molecules, organisms and viruses containing rDNA molecules, and transgenic animals.

Responsibilities under the Guidelines:

- The Institution must: establish an Institutional Biosafety Committee to ensure compliance with the NIH Guidelines by investigators and report any significant problems, violations or significant research-related accidents or illnesses to NIH within 30 days.

- The Institutional Biosafety Committee must: review, approve and oversee rDNA research to ensure compliance with the Guidelines, determine necessity of health surveillance of personnel, ensure training for IBC members, staff, PIs, and laboratory staff,

- set biosafety containment levels as required by the Guidelines for some experiments under IIID-4-b

- Incident Reporting to NIH

The following incidents must be reported to NIH OBA within 30 days: any significant problems or violations of the NIH Guidelines, e.g. failure to adhere to the containment and biosafety practices in the

Guidelines, any significant research-related accidents and illnesses, e.g. spill or accident leading to personal injury or illness or a breach in containment, e.g. escape or improper disposition of a transgenic animal.

The following incidents require immediate reporting to NIH OBA: spills or accidents involving rDNA requiring BSL2 containment resulting in an overt exposure, e.g. needlestick; splash in eyes, nose,

mouth;
or accidental aerosolization/inhalation.

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