PRINCIPAL INVESTIGATOR RESPONSIBILITIES

NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACIDS

https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm

Section IV-B-7. Principal Investigator (PI)

On behalf of the institution, the Principal Investigator is responsible for full compliance with the NIH Guidelines in the conduct of recombinant or synthetic nucleic acid molecule research.

Section IV-B-7-a.: General Responsibilities	As part of this general responsibility, the Principal Investigator shall:
Section IV-B-7-a-(1).	Initiate or modify no recombinant or synthetic nucleic acid molecule research which requires Institutional Biosafety Committee approval prior to initiation (see Sections III-A, III-B, III-C, III-D, and IIIE, Experiments Covered by the NIH Guidelines) until that research or the proposed modification thereof has been approved by the Institutional Biosafety Committee and has met all other requirements of the NIH Guidelines;
Section IV-B-7-a-(2).	Determine whether experiments are covered by Section III- E, *Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation*, and ensure that the appropriate procedures are followed;
Section IV-B-7-a-(3).	Report any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses to the Biological Safety Officer (where applicable), Greenhouse/Animal Facility Director (where applicable), Institutional Biosafety Committee, NIH OSP, and other appropriate authorities (if applicable) within 30 days. Reports to NIH OSP shall be sent to the Office of Science Policy, National Institutes of Health, preferably by e-mail to: NIHGuidelines@od.nih.gov; additional contact information is also available here and on the OSP website (www.osp.od.nih.gov).
Section IV-B-7-a-(4).	Report any new information bearing on the *NIH Guidelines* to the Institutional Biosafety Committee and to NIH OSP (reports shall be sent to the NIH Office of Science Policy – see contact information in Section IV-B-7-a-(3))
Section IV-B-7-a-(5).	Be adequately trained in good microbiological techniques;
Section IV-B-7-a-(6).	Adhere to Institutional Biosafety Committee approved emergency plans for handling accidental spills and personnel contamination; and
Section IV-B-7-a-(7).	Comply with shipping requirements for recombinant or synthetic nucleic acid molecules (see Appendix H, *Shipment*, and the *Laboratory Safety Monograph* for technical recommendations).

Section IV-B-7-b.: Information to Be Submitted by the Principal Investigator to NIH OSP	The Principal Investigator shall:
Section IV-B-7-b-(1).	Submit information to NIH OSP for certification of new host- vector systems;
Section IV-B-7-b-(2).	Petition NIH OSP, with notice to the Institutional Biosafety Committee, for proposed exemptions to the *NIH Guidelines*;
Section IV-B-7-b-(3).	Petition NIH OSP, with concurrence of the Institutional Biosafety Committee, for approval to conduct experiments specified in Sections III-A-1, *Major Actions Under the NIH Guidelines*, and III-B, *Experiments that Require NIH OSP and Institutional Biosafety Committee Approval Before Initiation*;
Section IV-B-7-b-(4).	Petition NIH OSP for determination of containment for experiments requiring case-by-case review; and
Section IV-B-7-b-(5).	Petition NIH OSP for determination of containment for experiments not covered by the *NIH Guidelines*.

Section IV-B-7-c.: Submissions by the Principal Investigator to the Institutional Biosafety Committee	The Principal Investigator shall:
Section IV-B-7-c-(1).	Make an initial determination of the required levels of physical and biological containment in accordance with the *NIH Guidelines*;
Section IV-B-7-c-(2).	Select appropriate microbiological practices and laboratory techniques to be used for the research;
Section IV-B-7-c-(3).	Submit the initial research protocol and any subsequent changes (e.g., changes in the source of DNA or host-vector system), if covered under Sections III-A, III-B, III-C, III-D, or III-E (*Experiments Covered by the NIH Guidelines*), to the Institutional Biosafety Committee for review and approval or disapproval; and
Section IV-B-7-c-(4).	Remain in communication with the Institutional Biosafety Committee throughout the conduct of the project.

Section IV-B-7-d.: Responsibilities of the Principal Investigator Prior to Initiating Research	The Principal Investigator shall:
Section IV-B-7-d-(1).	Make available to all laboratory staff the protocols that describe the potential biohazards and the precautions to be taken;
Section IV-B-7-d-(2).	Instruct and train laboratory staff in: (i) the practices and techniques required to ensure safety, and (ii) the procedures for dealing with accidents; and
Section IV-B-7-d-(3).	Inform the laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection).

Section IV-B-7-e.: Responsibilities of the Principal Investigator During the Conduct of Research	The Principal Investigator shall:
Section IV-B-7-e-(1).	Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed;
Section IV-B-7-e-(2).	Investigate and report any significant problems pertaining to the operation and implementation of containment practices and procedures in writing to the Biological Safety Officer (where applicable), Greenhouse/Animal Facility Director (where applicable), Institutional Biosafety Committee, NIH OSP, and other appropriate authorities (if applicable) (reports to NIH OSP shall be sent to the Office of Science Policy, National Institutes of Health, preferably by e-mail to: NIHGuidelines@od.nih.gov; additional contact information is also available here and on the OSP website (www.osp.od.nih.gov).
Section IV-B-7-e-(3).	Correct work errors and conditions that may result in the release of recombinant or synthetic nucleic acid molecule materials; and
Section IV-B-7-e-(4).	Ensure the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., purity and genotypic and phenotypic characteristics).