Working in microbiological and biomedical laboratories poses special risks with the involvement of infectious agents, recombinant DNA, synthetic nucleic acid molecules, and laboratory animals. Laboratory-associated infections (LAIs) are a reality, but with the implementation and subsequent adoption of regulations/guidelines, LAIs have become infrequent. Strict adherence to standard microbiological practices and techniques outlined in the Biosafety in Microbiological and Biomedical Laboratories manual (BMBL) and the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) is paramount for biosafety and protection of laboratory personnel from LAIs. Understanding the principles of biosafety and adherence to the microbiological practices, containment, and facility safeguards contributes to a safer and healthier work environment for not only laboratory staff, but also adjacent personnel and the surrounding community.

The intent of this manual is to articulate the administrative actions the University of Oklahoma (OU) and OU Health Sciences Center (OUHSC) has/will take to ensure a safe, healthy and secure environment for all faculty, staff, students, and visitors.

1. **OU’s role is to establish a process for compliance with the following documents:**

   1.1. *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines),* current edition;
   1.2. *Biosafety in Microbiological and Biomedical Laboratories (BMBL),* current edition.
   1.3. *The Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Standard, 29 CFR 1910.1030*

2. **Definition**

2.1. **Biosafety**

   2.1.1. Biosafety or biological safety encompasses all aspects of containment to prevent any exposure to and accidental release of infectious biological material. This also includes the containment of plants and animals.

2.2. **NIH Definition of Recombinant and Synthetic Nucleic Acid Molecules are:**

   2.2.1. Molecules that:
   2.2.1.1. are constructed by joining nucleic acid molecules and
   2.2.1.2. that can replicate in a living cell, i.e., recombinant nucleic acids;
   2.2.2. Nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or
   2.2.3. Molecules that result from the replication of those molecules described in the first two points above.
2.3. **Biohazards:**

2.3.1. EPA defines biohazards as “any solid waste that is generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals.” Categories of potentially infectious biological materials including the following:

2.3.1.1. Cultures and stocks of infectious agents and associated biologicals
2.3.1.2. Human pathological waste
2.3.1.3. Human blood and blood products
2.3.1.4. Sharps that have been used on animals or humans
2.3.1.5. Contaminated animal waste from research
2.3.1.6. Contaminated solid waste (gloves, plates, tubes, pipettes, dishes, etc.)
2.3.1.7. Isolate waste products
2.3.1.8. Cultured human cells and potentially infectious agents these cells may contain.
2.3.1.9. Recombinant or synthetic nucleic acid molecules.

3. **Institutional Biosafety Committee**

3.1. **Mission of the Institutional Biosafety Committee**

3.1.1. The Mission of the OU and OUHSC Institutional Biosafety Committees (IBC) is to serve as the cornerstone of institutional oversight and facilitate research involving recombinant or synthetic nucleic acid molecules, microorganisms, viruses, and biological toxins to ensure personnel safety and compliance with all applicable guidelines, codes and regulations.

3.2. **Authority Granted to Institution Biosafety Committee**

3.2.1. NIH sponsorship of research involving the use of recombinant or synthetic nucleic acid molecules covered by the *NIH Guidelines* requires the oversight of such research by the institution to ensure compliance with the *NIH Guidelines*. As such, OU and OUHSC established and IBC under the direction of the Institutional Official (IO) carry out that function. Furthermore, the IBC has established and implemented the following policies and procedures to ensure compliance with the *NIH Guidelines*, other applicable laws, and University Policies. The IBC has authority to approve, require modification to secure approval, disapprove, suspend or terminate research actives as required to assure compliance.

3.3. **Membership and Procedure**

3.3.1. The IBC must be comprised of no fewer than five members so selected that they collectively have experience and expertise in recombinant or synthetic nucleic acid molecule technology and the capability to assess the safety of recombinant or synthetic nucleic acid molecules research and to
identify any potential risk to public health or the environment. At least two members shall not be affiliated with the institution (apart from their membership on the IBC) and who represent the interest of the surrounding community with respect to health and protection of the environment (e.g., officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns in the community). The IBC may include at least one individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments utilizing Appendix P, Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecules Research are evaluated.

3.3.2. The institution shall file annual report with NIH/OBA which includes:
3.3.2.1. A roster of all IBC members clearly indicating the Chair, contact person, Biological Safety Officer (BSO) (if applicable), plant expert (if applicable), animal expert (if applicable), human gene therapy expertise or ad hoc consultant (if applicable); and
3.3.2.2. Biographical sketches of all IBC members (including community members).

3.3.3. No member of an IBC may be involved (except to provide information requested by the Committee) in the review or approval of a project in which he/she has been or expects to be engaged or has a direct financial interest.

3.3.4. The institution, that is ultimately responsible for the effectiveness of the IBC, may establish procedures that the IBC shall follow in its initial and continuing review and approval of applications, proposals, and activities.

3.3.5. When possible and consistent with protection of privacy and proprietary interests, the institution is encouraged to open its IBC meetings to the public.

3.3.6. Upon request, the institution shall make available to the public all IBC meeting minutes and any documents submitted to or received from funding agencies which the latter are required to make available to the public.

3.4. Function or Responsibilities

3.4.1. Reviewing recombinant or synthetic nucleic acid molecules research conducted at or sponsored by the institution for compliance with the NIH Guidelines and approving those research projects that are found to conform to the NIH Guidelines.

3.4.1.1. Independent assessment of the containment levels required by the NIH Guidelines for the proposed research.
3.4.1.2. Assessment of the facilities, procedures, practices, and training and expertise of the personnel involved in recombinant or synthetic nucleic acid molecules research.

3.4.1.3. Ensuring that all aspects of human gene transfer have been appropriately addressed by the Principal Investigator (PI).

3.4.1.4. Ensuring that no research participant is in a human gene transfer experiment until human gene transfer protocols selected for public RAC review and discussion, consideration of the issues raised and recommendations made as a result of this review and consideration of the PI response to the recommendations.

3.4.1.5. Ensuring that final IBC approval is granted only after the NIH protocol registration process has been completed.

3.4.1.6. Ensuring compliance with all surveillance, data reporting, and adverse event reporting requirements set forth in the NIH Guidelines.

3.4.2. Notifying the PI of the results of the IBC’s review and approval.

3.4.3. Lowering containment levels for certain experiments as specified in experiments in which DNA from RG2, RG3, RG4 or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems.

3.4.4. Setting containment levels as specified in experiments involving whole animals and experiments involving whole plants.

3.4.5. Periodically reviewing recombinant or synthetic nucleic acid molecules research conducted at the institution to ensure compliance with the NIH Guidelines.

3.4.6. Adopting emergency plans covering accidental spills and personnel contamination resulting from recombinant or synthetic nucleic acid molecules research.

3.4.7. Reporting any significant problems with or violations of the NIH Guidelines and any significant research-related accidents or illnesses to the appropriate IO and NIH Office of Science Policy (OSP) within 30 days, unless the IBC determines that a report has already been filed by the PI.

3.4.8. Submitting an annual report of IBC activities, proceedings and accomplishments to the appropriate IO, Vice President for Research at OUHSC and Provost Office at OU Norman campus, respectively.

3.4.9. The IBC may not authorize initiation of experiments which are not explicitly covered by the NIH Guidelines until NIH establishes the containment requirement.

3.4.10. Performing other functions as may be delegated to the IBC.
4. Institutional Official and University Responsibilities

4.1. The IBC at the OUHSC is under the direction of the Vice President for Research, while the IBC at OU is under direction of the Assistant Provost. The IO is responsible for:
4.1.1. Appointing IBC members
4.1.2. Evaluation of IBC members in coordination with the committee Chair
4.1.3. Naming of the IBC chairperson
4.1.4. Directs reporting of noncompliance

4.2. Committee Composition
4.2.1. The IO has the authority to appoint the Chair, members and alternate members of the IBC. Appointment must be made formally in writing. In accordance with the NIH Guidelines, the IBC is comprised of at least five members with:
4.2.2. At least one committee member expert in recombinant or synthetic nucleic acid molecules technology
4.2.3. At least one committee member expert in biological safety and physical containment
4.2.4. At least one committee member expert in select agent and biological toxin
4.2.5. At least one committee member expert in plant biology (if applicable)
4.2.6. At least one committee member expert in animal containment principles
4.2.7. At least two committee members shall not be affiliated with the University and who represent the interest of the surrounding community with respect to health and protection of the environment.
4.2.8. The BSO.

4.3. Specialized Expertise Requirements
4.3.1. In the event review of a specific protocol requires expertise outside of that possessed by the committee, the committee may retain a suitable consultant to advise and assist in the review. Each recruited consultant will attend meetings and contribute to protocol discussion, but shall not vote or count towards quorum. If the need arises, the consultant will be appointed to the committee by the IO and the roster of the committee amended and filed with NIH.

4.4. Chair of Institutional Biosafety Committee
4.4.1. The Chair presides over the IBC meetings and acts a voting member. If necessary it will be the chair’s responsibility to designate a member of the committee to serve in his or her absence. In addition, the chair should act as a liaison between the research personnel and the IBC as well as provide primary review along with the BSO for registered protocols.
4.5. **Biosafety Officer**

4.5.1. The institution shall appoint a BSO for the following if it engages in largescale research or production activities involving viable organisms containing recombinant or synthetic nucleic acid molecules.

4.5.2. The institution shall appoint a BSO if it engages in recombinant or synthetic nucleic acid molecules research at BSL-3 or BSL-4. The BSO shall be a member of the IBC.

4.5.3. The BSO’s duties include, but are not be limited to:

4.5.3.1. Periodic inspections to ensure that laboratory standards are rigorously followed;

4.5.3.2. Reporting to the IBC and the institution any significant problems, violations of the NIH Guidelines, and any significant research-related accidents or illnesses of which the BSO becomes aware unless the BSO determines that a report has already been filed by the PI;

4.5.3.3. Developing emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents involving recombinant or synthetic nucleic acid molecules research;

4.5.3.4. Providing advice on laboratory security;

4.5.3.5. Providing technical advice to PI’s and the IBC on research safety procedures.

4.6. **Education of IBC Members**

4.6.1. New members of the IBC receive introductory training from the Chair and BSO to ensure they are familiar with the NIH Guidelines. Members of the committee are provided a copy of the NIH Guidelines, either in written or digital form, and must complete the campus Biosafety Training. In addition, further educational opportunities and updates are provided at IBC meetings including onsite training and webinars.

4.7. **Committee Meeting Schedule and Submission Deadline**

4.7.1. The frequency of IBC meetings is commensurate with the volume of protocols needing review, the nature and risks of the research, and the need for continuing oversight. The committee meets monthly as needed (last Thursday of every month) and follows the guidelines provided by the NIH Office of Biotechnology Activities (OBA) involving research with recombinant DNA. For more detailed information regarding submission deadline and meeting dates, please visit the IBC website at http://compliance.ouhsc.edu/ibc/Home.aspx.

4.8. **Quorum**

4.8.1. The conduct of official IBC business occurs at convened meetings that must include a quorum of members in order for the meeting to be held. The IBC defines a “quorum” as more than half the regular voting members. A protocol is approved only if a quorum is present, and if more than fifty
percent of the quorum votes in favor of protocol approval. For reasons, other than conflict of interest, abstentions from voting do not alter the quorum or change the number of votes required.

4.8.1.1. In the event the OUHSC Institutional Disaster Plan is implemented to indicate only Mission-Critical operations shall occur, the quorum of the IBC will be defined as six (6) total members to be chosen by the Chair and the BSO even if six (6) members are less than 50% of the currently approved NIH roster. For approval, four (4) votes are needed. In addition, if necessary meetings will be held using a virtual meeting space. As such, all rostered members of the IBC should provide an alternate email, other than the University supplied email, and a (cell) phone number to ensure communications and ability to join virtual meetings during “Mission-Critical” operations.

4.8.2. Any IBC member or ad hoc member who has a conflict of interest with regard to a research project that will be reviewed at the convened IBC meeting will recuse him/herself from the convened IBC meeting for the voting on that research project. The member in conflict will not be present during discussion of the project unless the committee requests the member to stay to clarify aspects of the protocol.

4.9. Materials Distributed to Committee Members for Review
4.9.1. Prior to the meeting, each member will have access to all disclosures and related documentation to be reviewed at the meeting via an email and/or https://Topaz.ouhsc.edu for OUHSC only. Minutes of the previous meetings will also be distributed via an email with the agenda of the current meeting.

4.10. Institutional Biosafety Committee Registration
4.10.1. The IBC is registered with the NIH’s OBA. The annual report, required by OBA, is filed annually on behalf of the IBC and the University of Oklahoma by the EHSO and includes an updated list of IBC members’ indicating the role of each member and biosketches for each member.

5. Administrative Support for the Institutional Biosafety Committee

5.1. Responsibilities of the Environmental Health and Safety Office (EHSO) and the Office of Biological Safety (OBA)
5.1.1. EHSO is responsible for maintaining OU’s registration with the NIH OBA reporting to OBA at least annually; updating the committee roster and biosketches; and facilitating the institution’s responsibilities for administrative, oversight, review and reporting functions. The EHSO has further responsibility for maintaining the official records for the IBC,
including correspondence with the OBA, meeting minutes, disclosure records, and committee rosters and biosketches.

5.2. Meeting Minutes
5.2.1. Access to Minutes and Other Official Records of the IBC in accordance with the NIH Guidelines upon request, the institution shall make available to the public all Institutional Biosafety Committee meeting minutes and any documents submitted to or received from funding agencies which the latter are required to make available to the public. If public comments are made on IBC actions, the institution shall forward both the public comments and the IBC’s response to the NIH OSP, preferably by e-mail to: NIHGuidelines@od.nih.gov; additional contact information is also available here and on the OSP website (www.od.osp.gov).

5.3. Records Retention
5.3.1. Records of the IBC shall be retained by the EHSO including IBC disclosures, meeting minutes, and rosters of IBC members for a period of three years. For disclosures, the three years begins after expiration or termination.

5.3.2. PIs are responsible for keeping copies of research records, such as IBC protocols for a period of three years after closure of the project. All records must be accessible for inspection.

6. IBC Disclosure Review Process

6.1. Types of Review
6.1.1. Chair Review
Biosafety level 1 or exempt recombinant or synthetic nucleic acid molecules protocols will be reviewed by the IBC chair. The chair will notify the PI the approval of the protocol and no additional is action required. As long as the research activity does not significantly change, no additional action is required by the IBC or the PI.

6.1.2. Designated review
The designated review process is an expedited committee review process where the IBC chair appoints a subcommittee member to review the disclosure or amendment along with the BSO. The IBC chair will conduct the review and has the authority to approve, request modification, or recommend full committee review.
6.1.3. Full Committee Review
Protocols which involve non-exempt recombinant DNA activity, or biosafety level 2 and higher biocontainment levels will be reviewed during regular IBC meetings.

6.1.3.1. Possible outcomes include:
6.1.3.1.1. Approval: Submission satisfactorily addresses all issues and the submission is fully approved. No modification is necessary on the part of the PI.
6.1.3.1.2. Approval with Required Modifications: Minor issues remained such as training, etc. that must be addressed by the PI prior to approval.
6.1.3.1.3. Tabled: If the protocol requires major clarification or significant issues remain that require full IBC review upon the PI’s response to the requested revisions.
6.1.3.1.4. Withhold Approval: The protocol submission has not adequately addressed all of the requirements of the IBC questions as applicable. The IBC committee may withhold approval.

6.2. Delinquent PI Responses to IBC Review Letters

6.2.1. Failure to respond to submission review emails and/or notices within 3 months will result in a final notice letter from the IBC Chair. If the PI fails to respond to the final notice in 5 business days, this will result in withdrawal of the original submission. The PI needs to contact the IBC Chair if the PI is unable to respond to the reviews on a timely basis.

6.3. Review of Disclosures

6.3.1. Principal Investigator must complete and submit a disclosure form to the IBC for review. The disclosure will be assigned a disclosure number for reference by TOPAZ. The type of review the disclosure receives will be determined by its classification as outlined in Table-1 below.

6.3.2. Renewal
6.3.2.1. At the expiration date of each IBC protocol, a new disclosure must have been submitted to the IBC or the disclosure will be considered closed. All protocols are subject to renewal every three years via TOPAZ. Principal Investigators will be notified through an email 90, 60, and 30-days prior of the IBC protocol expiration date. It is the PI’s responsibility to ensure a protocol is current.
Table 1.

<table>
<thead>
<tr>
<th>Category</th>
<th>Review Type</th>
<th>Approval Period</th>
</tr>
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<tr>
<td>BSL-1 Disclosures Exempt from NIH Guidelines</td>
<td>Chair Review</td>
<td>3 Years</td>
</tr>
<tr>
<td>BSL-2 Disclosure Exempt from NIH Guidelines</td>
<td>Designated Committee Review (DCR) or Full Committee Review (FCR)</td>
<td>3 Years</td>
</tr>
<tr>
<td>Disclosure Not Exempt from NIH Guidelines</td>
<td>Full Committee Review (FCR)</td>
<td>3 Years</td>
</tr>
<tr>
<td>III-C Disclosures for Human Gene Transfer</td>
<td>Full Committee Review (FCR)</td>
<td>Duration of Project*</td>
</tr>
<tr>
<td>All Other Disclosures</td>
<td>Full Committee Review (FCR)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

*See section 6.4.2.

6.4 Amendment of Disclosures

6.4.1. Principal Investigator must complete and submit a protocol amendment form to the IBC for review of any modifications to approved research. The amendment will be assigned a disclosure number for reference by TOPAZ. The type of review the disclosure receives will be determined by its classification as outlined in Table-1.

6.4.2. Human gene transfer disclosures, those filed under NIH category III-C, are approved for the duration of the project. As such, it is vitally important that all modifications to the approved research are disclosed to the IBC for review and approval.

7. Experiments covered by the NIH Guidelines

7.1. Many experiments involving recombinant or synthetic nucleic acid molecules require registration and approval by the IBC before work may be initiated.

7.1.1. Experiments that require IBC approval before initiation include those that involve:

7.1.1.1. Risk Group 2, 3, 4, or Restricted Agents as host-vector systems
7.1.1.2. cloning DNA from Risk Group 2, 3, 4, or Restricted Agents into nonpathogenic prokaryotic or lower eukaryotic host-vector systems
7.1.1.3. the use of infectious DNA or RNA viruses, or defective DNA or RNA viruses in the presence of helper virus in tissue culture
7.1.1.4. whole plants or animals
7.1.1.5. more than 10 liters of cultures

7.1.2. Experiment that must be registered at the time of initiation include those that involve:
7.1.2.1. the formation of recombinant DNA molecules containing no more than 2/3 of the genome of any eukaryotic virus propagated in tissue culture
7.1.2.2. recombinant DNA modified whole plants, and/or recombinant DNA modified organisms associate with whole plants, except those that fall under section III-A, III-B, III-C or III-D of the Guidelines
7.1.2.3. The generation of transgenic rodents that require BSL-1 containment

7.1.3. Experiments exempt from the NIH Guidelines
7.1.3.1. Experiments exempt from the *NIH Guidelines*, although requiring registration with the IBC, may be initiated immediately. The BSO will review the registration and confirm that the work is classified correctly according to the *NIH Guidelines*. Exempt experiments are those that:
7.1.3.1.1. use of synthetic nucleic acid molecules that can neither replicate nor generate nucleic acids capable of replicating in any living cell; are not designed to integrate into DNA, and do not produce a toxin that is lethal for vertebrates at an LD50 of <100 ng/kg body weight
7.1.3.1.2. use recombinant DNA molecules that are not in organisms or viruses
7.1.3.1.3. consist entirely of DNA segments from a single nonchromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent
7.1.3.1.4. consist entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well-established physiological means
7.1.3.1.5. consist entirely of DNA from an eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species)
7.1.3.1.6. consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent
7.1.3.1.7. do not present a significant risk to health or the environment as determined by the NIH Director, with the advice of the Recombinant DNA Advisory Committee (RAC), and
following appropriate notice and opportunity for public comment
7.1.3.1.8. contain less than one-half of any eukaryotic viral genome propagated in cell culture
7.1.3.1.9. use *E. coli* K12, *Saccharomyces cerevisiae*, or *Bacillus subtilis* host-vector systems, unless genes from Risk Group 3 or 4 pathogens are cloned into these hosts.

8. Principal Investigator (PI) General Responsibilities

8.1. Prior to the commencement of any project involving any use of such material, the PI must perform the following steps:
8.1.1. Review the applicable guidelines and regulations and become familiar with the biological safety procedures and requirements. These guidelines and regulations include:
8.1.1.1. The National Institutes of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules;
8.1.1.2. The Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH) publication entitled Biosafety in Microbiological and Biomedical Labs (BMBL) 5th edition; [https://www.cdc.gov/biosafety/publications/bmbl5/](https://www.cdc.gov/biosafety/publications/bmbl5/)
8.1.1.3. 32 CFR Part 626 Biological Defense Safety Program and 32 CFR Part 627 Biological Defense Safety Program, Technical Safety Requirements (DA Pamphlet 385-69); and
8.1.1.5. The CDC/United States Department to Agriculture (USDA) Select Agent program.
8.1.2. Perform a risk assessment of the agents and procedures to determine potential safety and environmental hazards.
8.1.3. Develop laboratory specific Standard Operating Procedures (SOPs) based on the risk assessment, guidelines, and regulations.
8.1.4. For all non-exempt recombinant DNA research; microorganism/virus work or work with human blood, tissue, xenograft or cell lines, complete and submit the appropriate IBC registration form(s):
8.1.4.1. Registration of Research with Recombinant or Synthetic Nucleic Acid Molecules Form
8.1.4.2. Infectious Agent Registration at [http://apps.ouhsc.edu/IBCinventory/newbiologicalovt/](http://apps.ouhsc.edu/IBCinventory/newbiologicalovt/)
8.1.5. Do not initiate or modify any recombinant or synthetic nucleic acid molecules research which requires IBC approval prior to initiation until
that research or the proposed modification thereof has been approved by the IBC and has met all other requirements of the NIH Guidelines;

8.1.6. Determine whether experiments are covered by Section III-E, Experiment that Require IBC Notice Simultaneous with Initiation, and ensure that the appropriate procedures are allowed;

8.1.7. Report any significant problems, violations of the NIH Guidelines, or any significant research related accidents and illnesses to the BSO, IBC and other appropriated authorities within 30 days;

8.1.8. Report any new information bearing on the NIH Guidelines to the IBC and to NIH/OBA by email to: NIHGuidelines@od.nih.gov.

8.1.9. Be adequately trained in good microbiological techniques;

8.1.10. Adhere to IBC approved emergency plans for handling accidental spills and personnel contamination; and

8.1.11. Comply with shipping requirements for recombinant or synthetic nucleic acid molecules.

8.2. Overview of PI Responsibilities for Submissions

8.2.1. Make an initial determination of the required levels of physical and biological containment in accordance with the NIH guidelines

8.2.2. Select appropriate microbiological practices and laboratory techniques to be used for research;

8.2.3. 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/disapproval;

8.2.4. Remain in communication with the IBC throughout the length of the research project,

8.2.5. To submit IBC protocols for the University of Oklahoma, Norman campus, please visit our website at:

8.2.6. To submit IBC protocols for OUHSC and Tulsa campuses, please visit our website at: http://compliance.ouhsc.edu/ibc/Home/Forms/OUHSC.aspx.

8.3. Responsibilities of the PI Prior to Initiating Research

8.3.1. Protocols should be available to all laboratory personnel that describe the potential biohazards and the precautions to be taken.

8.3.2. Instruct and train laboratory staff in:

8.3.2.1. the practices and techniques required to ensure safety

8.3.2.2. the procedures for dealing with accidents
8.3.3 Inform laboratory personnel of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection).

8.4. Responsibilities of the PI During the Length of the Research Project

8.4.1. Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed.
8.4.2. Investigate and report any significant problems pertaining to the operation and implementation of containment practices, procedures, violations of the NIH Guidelines, or any significant research-related accidents and illnesses in writing to the BSO (where applicable), Animal Facility Director (where applicable), IBC, NIH OBA, and other appropriate authorities (if applicable) (reports to NIH OBA shall be sent to the NIH OSP, preferably by e-mail to: NIHGuidelines@od.nih.gov.
8.4.3. Correct work errors and conditions that may result in the release of recombinant or synthetic nucleic acid molecule materials.
8.4.4. Ensure the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., purity and genotypic and phenotypic characteristics).
8.4.5. Comply with reporting requirements for human gene transfer experiments conducted in compliance with the NIH Guidelines (see Appendix M-I-C, Reporting Requirements).
8.4.6. Determine the need for IBC review before modifying recombinant or synthetic nucleic acid molecules research already approved by the IBC. If help is required in determining this need, the PI may contact the IBC or the Biological Safety Officer.
8.4.7. Submit any subsequent changes (e.g., changes in the source of DNA or host-vector system) to the IBC for review and approval or disapproval.
8.4.8. Submit a new IBC protocol for review and approval at least every 3 years while the research is being conducted.

9. Requirement for Completion of Biosafety Training

9.1 The Biosafety Committee requires that all laboratory personnel working with biosafety level 1, 2 or 3 biohazards complete General Biosafety training prior IBC protocol approval.

10. References

10.1 BMBL https://www.cdc.gov/biosafety/publications/bmbl5/
10.2 NIH https://osp.od.nih.gov/biotechnology.nih-guidelines/
10.3 NIH Guidelines 2016
10.4 OUIBC Website http://compliance.ouhsc.edu/ibc/Home.aspx
10.5 OU EHSO Website: http://compliance.ouhsc.edu/ehso/Home.aspx