Standard Operating Procedures
Utah State University
Institutional Biosafety Committee

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I. IBC Policies

A. Scope of the IBC

The existence of an Institutional Biosafety Committee (IBC) is required by the National Institutes of Health (NIH) for research involving recombinant and synthetic nucleic acids. In addition to recombinant DNA/nucleic acid, the Utah State University (USU) IBC reviews, approves and oversees project proposals involving biohazardous materials (including BSL-2/3 infectious agents), "Select Agents" (as stated in USU's Policy 583.11: *Safety and Health in Research*), and dual use of research of concern (DURC) (required under the 2015 US Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern).

The purpose of these Standard Operating Procedures (SOPs) is to provide guidance to USU personnel, including faculty, staff and members of the IBC as they carry out activities involving recombinant DNA/nucleic acid, biohazardous materials -including BSL-2/3 infectious agents and "Select Agents", and DURC at USU or under its jurisdiction.

These SOPs indicate how the latest versions of the "*NIH Guidelines for Research Involving Recombinant DNA Molecules*", *CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (5th edition)*, CDC and USDA Select Agents Regulations as well as other applicable federal, state, and local laws are to be implemented by USU employees. The *NIH Guidelines* are provided at the web site of the Office of Science Policy (OSP): https://osp.od.nih.gov/biotechnology/nih-guidelines/, and shall apply to all recombinant DNA research performed at USU, whether funded by NIH or not.

The IBC shall coordinate its activities with the Office of the Vice President for Research (VPR), the Office of Research Integrity and Compliance (RIC), the Office of Environmental Health and Safety (EH&S), the Sponsored Programs Office (SPO), Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), Chemical Hygiene Committee (CHC), Radiation Safety Committee (RSC), Risk Control Committee (RCC), and University Safety Committee, and other oversight committees of the university, to ensure that research carried out at the USU meets the high ethical standards of the institution.

B. IBC Authority

The IBC is a committee appointed by the Vice President for Research and authorized to independently review, approve and oversee research involving recombinant DNA/nucleic acid activities, biohazardous materials, select agents, and DURC activities. The IBC shall have the authority to assess the risks associated with undertaking covered research and, based on their findings, to approve or deny approval for such research.

Research involving human participants based on the 45 CFR 46, "*Common Rule*" shall require both IBC and IRB approval. If the IRB requires revisions to the approved IBC protocol, the Principal Investigators (PIs) shall immediately amend the protocol. No such research shall be initiated until all appropriate procedures and measures have been taken to ensure that human participants' rights and welfare are adequately protected.

The *NIH Guidelines* shall apply to all recombinant DNA research performed at USU unless such research falls within categories which are exempt from the Guidelines. Section I-C-1-a of the *NIH Guidelines* specifies that they are applicable to "research that is conducted at or sponsored by an institution that receives any support for recombinant DNA research from NIH…".

C. Ensuring compliance

In accordance with *NIH Guidelines* Section IV-B-2-b-(5), the IBC shall annually review research involving recombinant DNA/nucleic acid at USU to ensure compliance with *NIH Guidelines.* Furthermore, as per Section IV-B-3-c-(1), the Biological Safety Officer shall perform periodic inspections no less than once a year to ensure laboratory standards are rigorously followed.

Records of the IBC shall be retained by the Office of Environmental Health and Safety (EH&S) including but not limited to protocols, meeting agendas and minutes, and rosters of members. USU requires PIs to keep copies of research records. All records must be accessible for inspection and copying by authorized representatives for three years after expiration or termination of the study.

D. Conflict of Interest

In accordance with Section IV-B-2-a-(4) of the *NIH Guidelines*, members of the IBC shall not be involved in the review or approval of projects in which they hold a direct financial interest, except to provide information requested by the IBC. No member or consultant of the IBC may review or vote on a project with the following conflicts:

1. Institutional conflict of interest
2. Conflicts of commitment
3. Individual conflicts
    a) Financial
    b) Competing

E. Responsible Official and Noncompliance

In accordance with federal regulations 9 CFR Part 121 "*Possession, Use, and Transfer of Select Agents and Toxins*" and 42 CFR Part 73 "*Select Agents and Toxins*" an individual must be designated as the responsible official who ensures compliance. For USU, that individual is the Biological Safety Officer. Information concerning noncompliance with the *NIH Guidelines* and federal regulations on select agents and toxins may be brought forward by any person to the Biological Safety Officer, Responsible Official, the IBC Chair, and/or the IBC Vice Chair. All studies under the purview of the IBC must comply with *NIH Guidelines regarding Noncompliance*.

F. USU Investigators Responsibilities

All PIs shall become familiar with applicable *NIH Guidelines*, Center of Disease Control's *Biosafety and Microbiological and Biomedical Laboratories (BMBL)*, *DURC* and *Select Agent Regulations* and shall adhere to their intent, as well as to the specific elements contained in them. Further, it is the responsibility of the PI to obtain the necessary approvals before initiating research.

G. Conflict of Interest for Investigators and Research Team

In accordance with USU's Policy 307.2 "University employees shall not realize personal gain in any form which improperly influences the conduct of their University duties. They shall not knowingly use University property, funds, position, or power for personal or political gain, nor engage in any financial or personal activity which may disadvantage the University. They shall report in writing all reasonably foreseeable conflicts. Financial conflicts are to be reported via Kuali COI for review and approval. All other conflicts must be reported to the RIC Director for clarification on how to proceed.

H. Investigator Training

Utah State University is responsible for ensuring that the PI has appropriate training, *NIH Guidelines* Section IV-B-1-h. However, this responsibility may be delegated to the IBC or the BSO. PIs shall obtain training available through the IBC, EH&S and CITI, USU's Policy 583.11.

The PI is responsible for ensuring that laboratory staff are appropriately trained in laboratory safety and implementation of *NIH Guidelines*. They shall ascertain

that all laboratory personnel receive appropriate training to carry out their functions safely and in a scientifically appropriate manner.

I. Appeal of an IBC Decision

PIs have a right to appeal IBC decisions concerning their research projects. Such request for appeal of an IBC decision must be made in writing to the IBC Chair or IBC Vice Chair.

J. Investigator separation and data ownership

In accordance with USU's Research Policy 588.3 entitled *Ownership of Data,* "OMB Uniform Guidance, Section 200.315(a) provides guidance on ownership and use of Intangible Property, including Research Data. USU applies this guidance to all Research Data. Therefore, title to Research Data vests in Utah State University (USU) immediately upon its acquisition. USU must use Research Data for any originally-authorized purpose as outlined in any funding agreement sponsoring the Research and must not restrict access to the Research Data in contravention of Federal or other applicable regulations or contractual requirements."

Further, "...Original Research Data and preliminary data collected or acquired in the conduct of Research at USU must be retained at USU, except as set forth below when the PI leaves the university. When an investigator at USU leaves the University, the investigator may take copies of Research Data and other data associated with the Research when the individual's participation in the design, conduct or reporting of the associated project can be established, and with permission from an authorized university representative.

When a PI leaves USU the Department Head and/or Dean, shall determine who will take responsibility for Research Data as set forth in RGS Procedure 588-PR." (USU Research Policy #588.6 *Transfer of Research Data Associated with a Transferred Contract or Grant).*

II. IBC Administrator Responsibilities

As set forth by *NIH Guidelines* Section IV-B-2-a-(5) Utah State University may establish procedures that the IBC shall follow in its review and approval of protocols. USU has delegated the following responsibility to the IBC Administrator:

- Update IBC procedures.
- Oversee documentation of registration and approval process.
- Oversee documentation of information requests and non-compliance incidents.
- Retain documentation in an orderly and retrievable fashion.
- Delete documentation after retaining for 5 years.

- Maintain "IBC Registration Database".
- Create protocol registration forms for project proposals involving recombinant DNA/nucleic acid, biohazardous materials - including BSL-2/3 infectious agents and "Select Agents", dual use research of concern (DURC), annual reviews, and safety reports (adverse event).
- Oversee training of IBC members on registration forms and approval process.
- Maintain documentation throughout the approval process in a designated platform (ServiceNow). Such documentation includes:
    - Registration Protocols.
    - Questions concerning the project proposal by the IBC.
    - Correspondence with the PI concerning IBC questions about the project proposal.
    - Resolution of questions about a project proposal.
    - Modifications to a proposal/protocol.
    - Risk Mitigation Plans (DURC).
    - IBC approval and annual review letters.
    - Safety Report (Adverse Event).
    - Reviewed and approved Standard Operating Procedures (SOPs).
- Provide annual reporting to NIH. In accordance with *NIH Guidelines Section IV-B-2-a-(3)* Utah State University shall file an annual report with NIH OSP which includes:
    - A roster of all Institutional Biosafety Committee members clearly indicating the Chair, contact person, Biological Safety Officer (if applicable), plant expert (if applicable), animal expert (if applicable), human gene therapy expertise or ad hoc consultant (if applicable).
    - Biographical sketches of all Institutional Biosafety Committee members (including community members).
- Organize, record, and paraphrase IBC meetings
    - Create an "Agenda" a week prior to IBC meetings.
    - Record IBC meetings.
    - Create hard copy of IBC meetings minutes.
    - Retain all meeting "Agendas" and "Minutes."
    - Make all Agendas and Minutes available to the public upon request.
- Correlate IBC and PI correspondence to NIH
    - Committee members shall upload on ServiceNow or make available to the IBC Administrator any correspondence concerning a research proposal from the approval process, designated review, and/or after committee approval that is conducted outside the designated platform.
- Retain all records submitted through a designated platform (ServiceNow) by PIs to the IBC

        - Original proposals and modifications.
        - Changes made to a research protocol following initial approval.
        - Written reports of any adverse event (Safety Report) *NIH Guidelines* Appendix M-I-C-4.
    - Review of submitted protocols for completeness
        - Check the submitted protocol for completeness, but not content.
        - If incomplete, return to PI for additional information.
        - Send to the IBC Chair.
    - PI Notification of IBC determination
        - Prepare a notification letter.
            - Approved
            - Returned for clarification/additional information
        - E-mail notification letter to the PI.
        - Upload determination to ServiceNow.

III. IBC Standard Operating Procedures

A. **Membership of the IBC**

Composition of the IBC will be based on the types of research to be performed at USU. The IBC will be composed of no fewer than five voting members from the USU community with the collective experience and expertise to assess the safety of research involving biohazardous material, including an expert in plant containment principles and an expert in animal containment principles. Further description of the specific areas of expertise and associated experiments can be found in the *NIH Guidelines* Section IV-B-2-a.

As required by the *NIH Guidelines*, because USU performs research at Biosafety Level 2 and 3 (BSL-2 and BSL-3), the IBC shall include USU's Biological Safety Officer.

At least two additional members, known as "community members", shall be appointed from the local community by the VPR and cannot be affiliated with the University apart from their membership on the IBC. Community members are not expected to act as primary reviewers for research proposals. (*NIH Guidelines* Section IV-B-2-a*).*

The IBC may use consulting experts to execute its responsibilities or acquire needed expertise for select tasks. Consultants are not IBC voting members unless nominated and appointed as previously described. Consultants are held to the same standards for conflict of interest and confidentiality as voting members of the IBC.

B. **Responsibilities of the IBC**

- Review all USU research projects that fall under the *NIH Guidelines*; BSL-2/3 infectious agents, Dual Use Research of Concern (DURC) and 'Select Agents'.

- Review IBC procedures annually.
- Review and approve IBC policies in accordance with federal regulations and guidelines and make recommendations to the Vice President on relevant biosafety matters.
- Assess containment levels, facilities, procedures, practices, training and expertise of personnel involved in proposed research in accordance with current biosafety standards.
- Review and approve SOPs.
- Review incidents as reported by the BSO. When appropriate assist with an incident investigation and report results to PIs, Deans, Department Heads, and Vice President.
- Review and approve reported significant problems or violations to the NIH Office of Science Policy (OSP) as per Section IV-B-2-b-(7) of the *NIH Guidelines*, ensuring that the report follows *NIH Guidelines* for Safety Reporting found in Appendix M-I-C-4.
- Reviews minutes and reports.
- Review and maintain approved annual reports to NIH OSP as per Section IV-B-2-b-(7).
- Report results of activities and investigations to the University Safety Committee.
- Notify the PI of the results of the IBC review and approval process.
- Annual reports to the NIH OSP, as required under Section IV-B-2-a-(3) of the *NIH Guidelines*. Such reports shall include:
  - A roster of all IBC members, indicating the chair, contact person, Biological Safety Officer, plant expert and animal expert, and
  - Biographical sketches of all IBC members, including community members.
- Report required problems, accidents, illnesses or violations of the *NIH Guidelines* to the NIH OSP and to appropriate institutional officials within 30 days. Section IV-B-2-b-(7),
- Public comments concerning actions taken by the IBC shall be submitted to the NIH OSP, along with any institutional response to such comments.
- The IBC shall act in an approval and advisory capacity for investigators who wish to submit Major Actions to the NIH for approval or to undertake research which is not covered under the *NIH Guidelines*.

C. **Education of IBC Members**

- USU shall ensure appropriate training for the IBC Chair, IBC Vice Chair, BSO and other containment experts (when applicable).
- The IBC Chair and IBC Vice Chair are responsible for ensuring that IBC members are appropriately trained.
- The BSO is responsible for ensuring that the PIs have sufficient training.
- The PI is responsible for ensuring that laboratory staff are appropriately trained.

D. **IBC Meetings and Reporting**

i. Agenda

For each scheduled meeting, an "Agenda" shall be provided by the IBC Administrator at least one week prior to the meeting.

ii. Meetings

Meetings of the IBC shall be held on a regular basis at times and in places as determined by the Chair of the IBC. In general, meetings will be scheduled monthly, but may be cancelled if no new business has been identified for the meeting's agenda. The meeting cannot be conducted until quorum (half plus one) has been established.

All IBC meetings shall be open to the public, during discussions of confidential or proprietary information the Chair shall have the right and responsibility to convene closed sessions whenever appropriate, and as allowed under the *NIH Guidelines* and state and federal statutes.

A record of each scheduled meeting "Minutes" shall be taken in audio format and transcribed in a hard copy, then deleted after approval by the IBC. At a minimum the "Minutes" shall include:

1. Date
2. Meeting convening time
3. Location
4. Attendance
5. Why the meeting was opened or closed
6. Major points of discussion
7. Rationale behind decisions
8. Major motions
9. Motion passage or failure
10. Major points of order
11. Meeting adjournment time

Following *NIH Guidelines* Section IV-B-2-a-(7), USU shall, upon request, make available to the public all IBC meeting minutes and other documents submitted to or received from federal funding agencies when those agencies are required to make such documents available.

E. IBC Review Procedures

- The PI completes protocol registration form (ServiceNow).
- The IBC Administrator reviews the protocol for completeness, then sends completed form to the IBC Chair (full committee review) or IBC Vice Chair (designated review) to review the proposed protocol.
- If the IBC Chair or IBC Vice Chair has questions, then comments will be submitted to the PI through ServiceNow.

- The PI answers the IBC Chair's or IBC Vice Chair's questions through ServiceNow.
- Once the IBC Chair or IBC Vice Chair is satisfied with the protocol content, the Chair will designate the proposed protocol as
    - Exempt
        - Research proposals which are exempt from the *NIH Guidelines* do not require registration with the IBC. However, they may still be required to follow other federal and state biosafety standards. If a change is made to an exempt protocol which may render it no longer exempt from *NIH Guidelines*, it must be submitted and approved by the IBC prior to the PI implementing the changes.
    - Designated Review
        - Research proposals exempt from NIH Guidelines, may receive a designated review where the IBC Vice Chair will designate at least one qualified member of the IBC to review the proposal. The Designated Review will suggest to the IBC Vice Chair that the research proposal be approved, require modifications, or request full committee review.
        - All IBC members will be given access to the proposal and may request the proposal go before full committee.
        - Documentation for exempt determinations shall be maintained in IBC records.
    - Full review
        - A convened IBC review of a research proposal shall be required of all recombinant DNA/nucleic acid registrations, unless exempt from *NIH Guidelines* or as specified under "Exempt Determination". In the review of each research proposal, the IBC shall assess containment levels, facilities, procedures, practices, training and expertise of personnel involved in proposed research in accordance with current biosafety standards.
        - Updated research proposals originally approved with conditions during full committee review will be returned to an IBC member designated by the IBC Chair for final approval, require clarifications and modifications, or request full committee review. All IBC members will have access to the updated proposal. Any committee member may request that the updated proposal go before full committee.
- The proposed protocol will be to forwarded all committee members through ServiceNow.
- The IBC Administrator adds the form to the agenda for the next scheduled IBC meeting.
- The IBC Administrator informs the PI the of meeting date, time, and location, inviting them to attend and address any committee questions.
- IBC members may review and comment on forms found in ServiceNow prior to any convened meeting.

- During convened a IBC meeting, committee members review registrations (new and updated protocols via annual reviews) as listed on the "Meeting Agenda".
- During the review of their protocol, the PI may sit in to address questions by committee members.
- Any new comments and/or questions are added to the form on ServiceNow as well as their resolutions.
- After review of their form is complete, the PI may leave.
- Committee members then deliberate and vote on the research proposal. Committee members may vote to 1) Approve, 2) Approve with conditional changes, or 3) Deny approval.
- If approved, the IBC Administrator emails an "Approval Letter" to the PI and all committee members. The Administrator uploads the "Approval Letter" to ServiceNow for record purposes.
- The "Approval Letter" shall contain:
    - Researcher Name
    - IBC convened meeting date
    - Research activity name
    - Notice of research activity approval
    - Notice of biosafety level to be used
    - Reminder that if any changes are made to the protocol, the Chair must be notified.
- If approved with conditional changes, the IBC Chair designates at least one qualified committee member to review the proposal once the changes are made. The IBC Chair then sends the form back to the PI to further clarify questions. Any changes made to the proposal must be made available to all committee members. If any committee member feels the proposal should go before full committee again, then its review must be deferred until the next convened IBC meeting.
- Once the IBC Chair and Designated Reviewer are satisfied with the protocol content, then the protocol is approved and the Administrator sends an approval letter to the PI. The Administrator uploads the "Approval Letter" to ServiceNow for record purposes.

F. <u>Annual Review</u>

- The IBC Administrator sends out an email reminder in July to all PIs with active registrations to complete an Annual Review form via ServiceNow. If an Annual Review is not received after one month the IBC Administrator will send out a second email reminder, followed by a third email reminder two weeks later if necessary.
- The PI completes the Annual Review form for an approved research protocol.
- The IBC Administrator reviews the form for completion.
- The IBC Chair checks form for content.
    - No changes to the approved research protocol.

- If there are minor changes to the approved research protocol, the IBC Chair may designate at least one qualified member of the IBC and him/herself to review the proposed changes for approval, clarifications and modifications, or request full committee review. All IBC members will have access to the proposed changes.
    - A typographical error.
    - Updating contact information.
    - Updating Project Personnel (if all required training has been complete).
- If a significant change is made to the protocol then it shall automatically go to full committee review. The protocol shall then go through the convened IBC review process. Once approved, the IBC Administrator sends an "Approval Letter" to the PI.
- Significant changes to the approved research protocol will automatically go to full committee review.
    - Change in PI.
    - Change to original research design or methodology.
    - Change to the project risk assessment.
    - Change to the project hazard mitigation.
    - Change in approval from other institutional committees.
- The IBC Chair, or any IBC member, may submit questions on approved research protocols submitted for annual review.

- Once changes are approved by the Designated Reviewer or the full committee, the IBC Administrator sends a "Approval Letter" to the PI.

G. <u>Inactive Protocols</u>

- The PI completes the Annual Review form for an approved research protocol. In Section 2, the PI marks that the research project is no longer active.
- The IBC Administrator reviews the form for completion.
- The IBC Administrator verifies with the PI that the research project is no longer active.
- The IBC Administrator notes in the "IBC Registration Database" that the protocol is closed.
- The IBC Administrator moves the protocol folder from "IBC Active Registrations" to "IBC Closed Registrations" (in BOX).
- The protocol folder is marked for deletion in 5 years.

H. <u>Confidentiality</u>

All business of the IBC shall be subject to disclosure according to USU policy, the *NIH Guidelines* and the *Freedom of Information Act*. Research reviews and other business of the IBC shall be conducted in compliance with these policies, guidelines and laws in such a matter as to preserve the academic freedom and confidentiality of the processes, participants and stakeholders to the extent possible.

I. Reporting

Reports of the activities of the IBC shall be made annually to the NIH OSP, as required under Section IV-B-2-a-(3) of the *NIH Guidelines*. Such reports shall include:

i. A roster of all IBC members, indicating the Chair, contact person, Biological Safety Officer, plant expert and animal expert, and
ii. Biographical sketches of all IBC members, including community members.

In addition to the annual report, as per Section IV-B-2-b-(7), the IBC shall report problems with or violations of the *NIH Guidelines* to the NIH OSP. Research-related accidents or illnesses shall also be reported to appropriate institutional officials and to the NIH OSP within 30 days.

If public comments are received concerning actions taken by the IBC, such comments shall be submitted by USU to the NIH OSP, along with any institutional response to such comments.

J. Non-compliance

In the event of a possible incidence of non-compliance involving recombinant DNA/nucleic acid, an initial review will be conducted by the BSO and/or IBC Chair. The information shall be reviewed by the IBC for appropriate action. The IBC shall forward a complete report of the incident – with any further action recommendations – to the VPR prior to submission to the NIH Office of Science Policy.

Noncompliance may result in:

i. Suspension, limitation, or termination of financial assistance for the noncompliant NIH-funded research project and of NIH funds for other recombinant or synthetic nucleic acid molecule research at the institution.
ii. Requirement for prior NIH approval of any or all recombinant or synthetic nucleic acid molecule projects at the institution.

K. Appeal of an IBC Decision

The PI may appeal the decision of the IBC. Once a request for appeal has been received, the IBC Chair will place the appeal on the agenda for the next IBC meeting. If a time constraint exists for the PI in terms of funding, the IBC Chair may choose to schedule a separate meeting. The IBC Chair invites the PI to attend the meeting to defend the appeal. The PI will be notified of the IBC's decision in writing. If the PI is still not satisfied with the IBC's decision, he or she may appeal to the Institutional Official (IO) – who is the Vice President of Research – and thereby initiate further IBC consideration if the IO so requests. However, the IO cannot approve research that has not been approved by the IBC.

IV. Investigator Responsibilities

The PI shall be responsible for initiating registration of any recombinant DNA/nucleic acid, biohazardous material – including BSL-2/3 infectious agents and "Select Agents", and dual use research of concern research proposal using the corresponding registration form found on the Environmental Health and Safety website via ServiceNow. The PI shall also have responsibility for coordinating with the IBC to petition the OBA for certifications of new host vector systems, approvals for exemption, major actions, and other matters as outlined in Section IV-B-7-b. A registration shall include:

- Describing the proposed research activity
- Initial determination of the required level of physical and biological containment
- Listing high-risk activities
- Listing pertinent project personnel along with their training, experience, and expertise
- Uploading any applicable SOP's.
- A risk assessment of the research ('Select Agents' and DURC)
- Completing a Risk Mitigation Plan (DURC)
- Completing DURC training (DURC)
- Acknowledgement of USU and federal policies, and an understanding of responsibility for compliance

The PI shall be responsible for responding to IBC requests for clarifications and modifications in a timely manner. If no reply is received in 30 days from a PI, then the IBC may vote to disapprove the proposal due to lack of response. The PI can attend the convened IBC meeting during the review of their research proposal in order to directly answer questions. The PI shall not initiate the proposed research until an "Approval Letter" is received.

Each year, the PI must complete an "Annual Review Form" for an approved protocol. The PI shall state whether the project is active or inactive, and mention any research related conflicts of interest, any adverse events associated with the research, as well as revise the protocol if any minor and/or significant changes need to be made. If the protocol is identified as inactive/closed, the PI no longer needs to complete request for review.

The PI shall disclose any conflict of interest via Kuali COI Disclosure when submitting the proposal and if any arise during the research.

The PI shall have responsibility for providing written protocols to all laboratory personnel (students, lab personnel, and staff within their workplace and/or laboratories) describing potential biohazards and precautions to be taken prior to initiating research, and for providing appropriate training and supervision to maintain a safe work environment. Such training shall include:

- Microbiological techniques

- Basic laboratory safety
- Biosafety level training
- Specific safety training relating to their areas of research
    - Make available to all laboratory staff the protocols that describe the potential biohazards and the precautions to be taken.
    - Instruct and train laboratory staff in: 1) the practices and techniques required to ensure safety, and 2) the procedures for dealing with accidents.
    - Inform the laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested.
- Other training as deemed appropriate and as provided by the EH&S Office.

As set forth in the *NIH Guidelines* Section IV-B-7-a-(3) and Appendix M-I-C 4, the PI shall be responsible for reporting significant problems, violations of *NIH Guidelines*, or significant research-related accidents or illnesses to the IBC, NIH OSP, and other appropriate authorities. PIs shall report adverse events in a timely manner either via the IBC Safety Report (Adverse Event) Form or to the NIH OSP by email, fax, or phone. The Safety Report must be reviewed by the IBC and VPR before submission to NIH OSP.

PIs shall provide a written report (via ServiceNow) of any adverse event, called a Safety Report. Any fatal or life-threatening event must be reported to NIH OSP no later than within 7 calendar days. Any serious adverse event must be reported to NIH OSP no later than within 15 calendar days.

All reports shall include:

- The date of the event
- Principal Investigator
- Designation of the report as an initial report or a follow-up report,
    - identification of all safety reports previously filed for the clinical protocol concerning a similar adverse event
    - analysis of the significance of the adverse event in light of previous similar reports.
        - Clinical site
        - NIH Protocol number
        - FDA's Investigational New Drug (IND) Application number
        - Vector type
        - Vector subtype
        - Gene delivery method
        - Route of administration
        - Dosing Schedule
        - Description of event
        - Relevant clinical observations
        - Relevant clinical history
        - Relevant conducted or planned tests

- Date of any treatment of event
- Suspected cause of event

As stated in USU's Policy #583.11 the PI shall coordinate with the University's Environmental Health and Safety Office (EH&S) to be certain that all persons involved in Research and support in their areas receive appropriate training in proper handling techniques and emergency procedures. Moreover, the PI shall regularly review EHS-documented safety training of workplace and/or laboratory members to confirm it is complete and up to date.

IV. **Conflict of Interest Notification**

The RIC shall notify the IBC chair whenever an individual conflict of interest is disclosed by an investigator working on recombinant DNA, biohazardous materials, or dual use research of concern projects. Conflicts of interest held by an investigator shall be reported to the IBC so that members of the committee are aware of the conflict during the research proposal review process. Should the IBC or any member of the IBC become aware of a conflict of interest held by an investigator using recombinant DNA, biohazardous materials, Select Agent, or dual use research of concern the RIC shall be notified of the conflict prior to approval of registrations materials to be used in the study. USU does not consider conflicts of interest to be negative unless they are not properly managed or are allowed to introduce bias into the decision-making process of the investigator.

IV. Glossary

Agent summary statements are included for agents that meet one or more of the following three criteria:

1. the agent is a proven hazard to laboratory personnel working with infectious materials;
2. the agent has a high potential for causing LAIs even though no documented cases exist; and
3. the agent causes grave disease or presents a significant public health hazard.

Biologically hazardous agents requiring BSL-2/3 containment - "a biological agent or condition that constitutes a hazard to humans or the environment".

Direct Financial Interest - A financial interest that is owned directly by an individual or entity or is under the control of an individual or entity. A financial interest that is beneficially owned through an intermediary is also considered a direct financial interest when the beneficiary either controls the intermediary or has the authority to supervise or participate in the intermediary's investment decisions. A financial interest is beneficially owned when an individual or entity is not the recorded owner of the interest but has a right to some or all of the underlying benefits of ownership.

Dual Use Research of Concern - "DURC is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, material, or national security". (NIH Office of Science Policy)

Recombinant DNA - Recombinant DNA molecules are defined as either: "(i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above." (*NIH Guidelines*, Section 1-B.)

Select Agent – "biological agents and toxins that have been determined to have the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal or plant products." (CDC, para.1) The following link will take you to the current list of select agents Select Agents and Toxins List