

ARS □ ERS □ NASS □ NIFA

Policies and Procedures

Title: Institutional Biological Safety Committee

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This Directive states policy, responsibilities, committee membership, and committee procedures, including reporting requirements, for Institutional Biological Safety committees at ARS. This policy applies to all ARS research and testing projects that involve work with recombinant DNA and/or biohazards, including: (a) ARS locations, regardless of funding or physical resources, (b) all ARS research projects located at non-ARS locations using ARS personnel, facilities or funding.

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1. Purpose

The Agricultural Research Service (ARS), as the in-house research Agency for the Department of Agriculture (USDA), works with a variety of biological hazards, synthetic nucleic acid and/or recombinant Deoxyribonucleic Acid (rDNA) molecules in many of its research pursuits, including protecting crops and livestock from pests and disease or improving the quality and safety of agricultural products. One essential part of the Institutional Biosafety Committee (IBC) is the review of experimental procedures utilizing biological materials, biological toxins, non-exempt rDNA and synthetic nucleic acid molecules to ensure such research is conducted responsibly and safely.

ARS management has concluded that the creation of an IBC review system to evaluate the safety aspects of ARS research involving biohazardous material, toxins, rDNA and synthetic nucleic acid molecules further promotes a culture of responsibility within ARS which incorporates safety as an organizational value. Therefore, stated herein are policy, procedures, responsibilities, definitions, and guidelines for establishment and operation of ARS IBCs. ARS IBCs shall be responsible for the review and approval of the safety aspects of research projects involving biohazardous materials, biological toxins, non-exempt rDNA and synthetic nucleic acid technologies.

The provisions of this policy will be implemented at all ARS locations regardless of funding source, where biohazardous materials, biological toxins, non-exempt rDNA or synthetic nucleic acid molecules are utilized in the laboratory, greenhouse, or the field. Specific written operational procedures in accordance with this policy shall be implemented at each location where these materials may present a potential hazard to employees, public health, agriculture or the environment. Additionally, the policy shall be implemented as specified at all non-ARS locations being supported by ARS funding or where ARS personnel are engaging in research and testing that involves work with biohazardous materials, biological toxins, non-exempt rDNA, and synthetic nucleic acid molecules. These projects will be required to have an IBC review of the safety aspects and operational procedures used in their projects prior to initiation for compliance with ARS policy, the National Institutes of Health (NIH) *Guidelines for Research Involving Recombinant DNA or Synthetic Nucleic Acid Molecules* (NIH Guidelines), and all other regulations and guidelines as appropriate.

2. Background

The NIH Guidelines, established in 1976, have provided principles for the safe conduct of research employing recombinant technology. IBCs were established under the NIH Guidelines to provide local review and oversight of nearly all forms of research utilizing recombinant DNA or synthetic nucleic acids. Over time the role of IBCs at many research institutions has been expanded in scope to include the review of a variety of experimentation that involves other potential biohazards (e.g., infectious agents, oncogenes, zoonotic pathogens, and biological toxins) in addition to research involving the use of rDNA molecules.

ARS has developed an Agency wide Biosafety Program. The Biosafety Program is a framework

comprised of organizational structure, policies, practices, and guidance, instituted and supported by Agency management, that provides procedures and accountability for the safe and proper handling of biological agents, as well as the prevention of occupationally-acquired infections or release of harmful organisms into the environment.

The establishment of IBCs to conduct reviews of biosafety practices and approve research involving potential biohazards and rDNA molecules is the cornerstone of the Agency biosafety management program. It is Agency policy for an IBC to review, approve, and register research utilizing biohazards and rDNA molecules. This review and approval process protects research scientists by further documenting their possession, use and storage of biological agents such as pathogens or toxins. This is especially critical since the USA Patriot Act of 2001 amended Section 175 of the U.S. Criminal Code allows prosecution of individuals who knowingly possess any biological agent, toxin, or delivery system of a type or in a quantity not reasonably justified by prophylactic, preventative, bona fide research, or other peaceful purpose.

3. Policy

It is ARS policy to establish and maintain ARS IBCs at its locations and Areas (where appropriate), or utilize a Partner IBC (e.g., University IBC) in situations of co-location for the review, approval, and registration of ARS research projects involving biohazardous materials, biological toxins, non-exempt rDNA, and synthetic nucleic acid molecules as defined in the definition section of this policy. An ARS location IBC shall review all ARS projects utilizing biohazardous materials, biological toxins, non-exempt rDNA, and synthetic nucleic acid molecules as appropriate to ensure that: a) appropriate work practices, employee training, facilities, and equipment are in place to reduce or prevent the possibility of accidental exposure of ARS employees, other persons, animals, plants, and the environment to biohazardous materials, biological toxins, non-exempt rDNA, and synthetic nucleic acid molecules, b) ensure compliance with all applicable regulations and guidelines, c) standard operating procedures, resources, and training are in place to address any accidental release or employee exposure, and d) reporting, investigation, and corrective actions occur and are appropriately documented should there be an incident/accident with any biohazardous/biological materials. In following this policy, the IBC will provide a review and approval for the process and procedures utilized for nearly all forms of research utilizing biohazardous materials, biological toxins, non-exempt rDNA, and synthetic nucleic acid molecules conducted by ARS as well as ensure compliance per the provisions outlined in this policy.

In those cases in which ARS locations do not have the resources (either funding or staff as determined by location management and the Area Director (AD) or their designee) to operate a local IBC, an Area level or collaborative IBC with another ARS location or if co-located, a cooperator IBC such as the University, will be appropriately constituted to serve as the IBC of record for the projects requiring review. If the ARS location is utilizing a cooperator IBC, then an Agreement by authorized staff shall be established to define the cooperation and services provided and the protection of information. (Consult the location IBC Responsibilities and Definitions sections of this policy for additional details and explanations.)

As a condition of support, all non-ARS institutions receiving ARS funds or material support for research involving rDNA or synthetic nucleic acids shall adhere to the NIH Guidelines and other

applicable regulations and guidelines as appropriate.

All ARS Research Protocols that meet the requirements of this Policy must submit an IBC research protocol registration to the IBC Chairperson for committee review and approval. Prior to submission the lead scientist/principal investigator (PI) shall conduct a risk assessment for the research protocol and include procedures and hazard mitigation measures to be implemented as part of the research protocol registration or as an addendum to it. The IBC approves the safety aspects of the research protocol identified in their review of the risk assessment developed by the PI. The risk assessment shall evaluate the process or methodology, facilities, and staff training proposed for completing the research protocol. Once the research protocol registration and associated risk assessment are approved by the IBC, the research protocol registration is approved for 5 years but subject to annual reviews as a minimum or when a component of the research protocol modifies or changes the original risk assessment. If the PI plans or makes changes outside the scope of the original IBC approved submission, it is the responsibility of the PI to notify the IBC Chairperson. Changes that require IBC notification and possible re-submission of all or part of the research protocol include, change in technology, agents, protocols or processes, change of space, equipment or personnel, legal requirements etc. Reference Part 4 “Roles and Responsibilities,” Section 13 “location IBC” for further explanation and details.

The PI will complete the location specific IBC Protocol Review Form with all the information and supporting documentation required for the committee to review, approve or disapprove the research protocol registration and report any specific approval conditions to the PI. Supporting documentation may include but not be limited to: Institutional Animal Care and Use Committee procedure approvals, radiological permit or cooperator support, employee training, immunization records, laboratory biosafety procedures, laboratory assessment/inspection results, etc. Once received, the information will be provided to the committee members for review and discussion. At the conclusion of the review period, the PI if present, will be excused from the meeting and the Committee members will evaluate and determine if the methodology proposed for conducting the research protocol is acceptable. If the research protocol registration is disapproved as submitted, the IBC will identify the required modifications to the PI and establish a time for re-submission and review. Issues that cannot be resolved at the IBC level shall be referred through line management to the next level (Area IBC, Agency Biosafety Officer).

4. Roles and Responsibilities

1) The ARS Administrator will:

- a) Ensure systems and processes are in place to provide ARS employees with places and conditions of employment that are free from recognized hazards that may contribute to the occurrence of work-related injury, illness, death or property/environmental damage.
- b) Ensure adequate resources (staff, funding, training, equipment, tools, etc.) are dedicated to the development, management, operation and evaluation of a comprehensive ARS Biosafety Program at all levels of the Agency.

- c) Promote the development or procurement of systems (e.g., IBC tracking and approval system), tools, and services that support the operation and management of an effective and comprehensive Biosafety Program.
- d) Ensure ARS Research programs and facilities are operated and managed in a manner that promotes and supports a viable Biosafety program and conforms to ARS Biosafety, Health, and Environmental Management (BSHEM) values.
- e) Ensure Biosafety Programs are reviewed on a routine basis and that the criteria for the review are based on established guidelines or other recognized consensus standards or criteria in addition to specific Agency goals, objectives, and or criteria. The results of the review are documented to drive appropriate changes or adjustments to the relevant program.

2) ARS Associate Administrator for National Programs will:

- a) Ensure all Project Plans utilizing biohazardous materials, biological toxins, non-exempt rDNA, and synthetic nucleic acid molecules are properly planned, coded or marked for review and evaluation in accordance with this ARS IBC Policy.

3) ARS Associate Administrator for Research Operations will:

- a) Provide oversight, accountability for compliance and guidance to the AD and Deputy Administrator for Administrative and Financial Management to ensure resources are available for the operation, management and evaluation of a comprehensive Biosafety, Occupational Health and Worker's Compensation Program as appropriate and applicable within Administrative and Financial Management and the Business Service Centers.
- b) Ensure reporting systems are in place.

4) Deputy Administrator for Animal Production and Protection will:

- a) Provide management support, resources, accountability and oversight to the Agency Biosafety Program.
- b) Chair the Biosafety, Safety and Health Leadership Steering Committee for ARS.
- c) Provide oversight and support for compliance of IBC activities and support for the National Environmental Policy Act as required for scientific/research activities as appropriate.

5) Deputy Administrator, Office of National Programs (All) will:

- a) Provide support and oversight as appropriate for ARS research involving materials within the scope of this policy to promote compliance with the applicable regulatory standards, industry guidelines, best practices and policies of ARS.
- b) Promote and support the incorporation of ARS BSHEM policies into the planning phase of the project development.

6) ARS National Program Leaders will:

- a) Promote the responsible conduct of science of National Research Programs and promote/reinforce the need for project design to be in accordance with ARS BSHEM policies.

7) The Agency Biosafety Officer will:

- a) Administer the Agency Biological Safety Program and advise senior leadership on applicable regulations and standards, changes to regulations, status of the biosafety program within ARS, instances of non-compliance and accidents or incidents involving these agents.
- b) Advise on classification of agents relative to risk and recommend appropriate safety equipment, facilities and work practices.
- c) Perform announced and unannounced audits of ARS research locations, IBCs and/or individual research projects to ensure compliance with ARS policy and applicable regulations and guidelines.
- d) Coordinate and ensure annual reporting from all registered ARS IBCs to NIH Office of Biotechnology Activities (NIH OBA), review, approve, and forward all outgoing incident and violation reporting from ARS IBCs thru the Office of National Programs to the NIH OBA.
- e) Appoint Ad Hoc working groups or committees as required to review special or highly sensitive projects within ARS as appropriate.
- f) Facilitate the incorporation of biosafety and biocontainment principles and practices into ARS facilities and projects utilizing biohazards.
- g) Represent ARS on USDA Biosafety Committees or Working Groups and other appropriate interagency working groups as assigned.

8) Area Directors will:

- a) Ensure that allocated resources are appropriately managed and provide the resources and management support to establish, maintain, and support an IBC in all locations in their Area, as necessary.
- b) Ensure that all research projects involving: biohazardous materials, biological toxins, non-exempt rDNA, and synthetic nucleic acid molecules (as defined in this policy), at either an ARS location (regardless of source of funds) or at another location using ARS resources is reviewed by an IBC.
- c) Ensure that ARS policies, applicable regulations, and guidelines are enforced.
- d) Ensure compliance with the National Environmental Policy Act as required for scientific/research activities as appropriate.
- e) Where appropriate and necessary appoint the Area level IBC Chairperson and committee members based on the nature of the project or issue according to NIH Guidelines. The Area Biological Safety Officer (BSO), location BSOs, and the BSCSHM are not permitted to hold the position of Chair within an IBC since they shall have a direct role in supporting the IBC.

- f) Appoint or designate, in writing, an individual to serve as the Area focal point for biosafety and/or biorisk management activities.
- g) Hold the Area IBC Chair accountable for the operation of the Area IBC in accordance with Agency policy and other guidelines as appropriate.
- h) Ensure that noncompliance with ARS Policy and NIH Guidelines are appropriately reported, documented and corrected/resolved in a timely manner.
- i) Ensure adequate resources are in place to support appropriate occupational health/medical surveillance programs.
- j) Include a certification in the Issues of Concern Statement section of Project Plans acknowledging the above AD responsibilities for relevant project plans: e.g. Biological materials, biological toxins, non-exempt rDNA and synthetic nucleic acid molecules.

9) Center Director/Laboratory Director/Location Coordinator will:

- a) Develop, implement and provide oversight for a location BSHEM program that conforms with and supports the Agency Policies and Area guidance for BSHEM.
- b) Hire, appoint or designate a BSO or Collateral Duty Biosafety Officer to support the location biosafety program.
- c) When biohazardous materials, biological toxins, non-exempt rDNA, and synthetic nucleic acid molecules are used, appoint or designate, in writing an individual who will serve as the location IBC Chairperson.
- d) Provide resources for operation, training, and provide/approve the charter of the committee and ensure that the committee operates within the scope of the ARS IBC Policy.
- e) Hold the IBC Chair accountable for the operation of the IBC in accordance with Agency policy and other guidelines as appropriate.
- f) Provide a process and ensure that all research protocols and experiments using biohazardous materials, biological toxins, non-exempt rDNA, and synthetic nucleic acid molecules receive IBC review per the ARS IBC Policy.
- g) Ensure employees report any work related accidents, illnesses, injuries, near misses or releases of biological materials and that the reported incidents are investigated and corrective actions or improvements are taken as appropriate, communicated and documented.
- h) Ensure that the location and individual work areas have appropriate emergency response procedures in place, documented and reviewed on an annual basis or after an emergency has occurred.

10) Location/Area IBC Chair will:

- a) Work/consult with the AD, Center Director (CD)/Laboratory Director/Research Leader (RL) as appropriate to appoint committee members and *ad hoc* committee members for all projects the IBC may review. Draft an IBC appointment letter for management approval and signature to selected committee members.
- b) Ensure that IBC activities comply with regulatory requirements. Develop and submit reports and updates to AD/CD/LD/RL, ARS ABO, and NIH Office of Biotechnologies (OBA) as appropriate.
- c) Make recommendations to AD/CD/LD/RL or others as appropriate on any aspect of biohazardous materials, biological toxins, non-exempt rDNA, and synthetic nucleic acid molecules research protocols either on their own initiative, or upon request of the IBC members.
- d) Ensure that the committee operates in accordance with this policy, the NIH Guidelines and other relevant regulations and guidelines.
- e) Initiate the timely review of research protocols to ensure they are scheduled, reviewed and completed so as not to delay the research submittals.
- f) Initiate IBC meetings as often as required for timely review of research protocol registration submissions by researchers and other business. Meetings must be held biannually at a minimum; however, more frequent meetings are encouraged to ensure that research protocols are reviewed and approved on a timely basis (i.e., monthly or quarterly).
- g) Promptly lead or delegate the investigation of allegations of non-compliance regarding ARS IBC policy and/or NIH Guidelines. Review and report results of investigations to the appropriate management officials as outlined in the ARS Policy “Incidents and Accidents Reporting Involving Biological Agents and Toxins” or REE Manual 160, Safety, Health, and Environmental Management Program policies and, if warranted, documentation to support corrective action to the appropriate Agency managers.
- h) Upon Public inquiry requesting information associated with a research protocol reviewed by the IBC, forward the request to the ARS Information staff for review and instructions on responding to the request.

11) Area/Location IBC Secretary will:

- a) Record minutes at IBC meetings.
- b) Prepare the reports developed by the IBC chairperson.
- c) Maintain file of IBC members and any secondary files agreed upon by the ARS location's management.
- d) Send out IBC meeting notices, draft minutes, and meeting agendas to IBC members in a timely manner.
- e) Maintain a registry of all active, approved registrations.

12) Area IBC will:

- a) Be responsible to review and ensure consistency of compliance with relevant Agency policy and the NIH Guidelines by subordinate location IBCs as appropriate or assigned.
- b) Be charged with the review and registration of research protocols utilizing biohazardous materials, biological toxins, non-exempt rDNA, and synthetic nucleic acid molecules, as defined in this policy for locations lacking the expertise for the review and do not have the resources to support an individual location IBC.
- c) Provide an open forum for pro-active discussion of Area biosafety concerns and assists location IBCs, the BSO, and BSCSHM in the resolution of any contentious or ambiguous biosafety issues or disputes brought before the committee. The Area IBC shall refer biosafety issues that cannot be resolved at the Area level to the ARS ABO for resolution.
- d) Ensure that appropriate containment levels are utilized in accordance with recognized guidelines, such as those listed within the authorities section of this document.
- e) Ensure that appropriate emergency plans covering accidental spills or releases and personnel exposures to biohazardous materials are in place.
- f) Will perform the same responsibilities and duties as a Local IBC, as outlined below, in addition to its Area wide responsibilities described above, if it reviews protocols of ARS locations that do not have the staff or resources to support a location IBC.
 - If the Area IBC is considered remote (>50-75 miles) to the ARS site location, the Area IBC will appoint two non-affiliated members to the IBC to represent the interests of the community around each local ARS site that Area IBC is serving.
 - The Area IBC will be comprised of members who are familiar with the local facilities at each of the ARS sites the Area IBC is serving.
 - The Area IBC members will have the authority to oversee compliance with the IBC's approval conditions when serving as the location IBC of record.
 - If the Area IBC is performing the review, the facility assessment may be conducted by the location BSO or safety staff (full time or Collateral Duty) or BSCSHM or qualified staff acting on behalf of the IBC.
 - Report as appropriate any reviewed projects that conduct research on any of the 15 agents identified as potentially Dual Use Research of Concern (DURC) as defined in the 2014 United States Government Policy for Institutional Oversight of Life Sciences DURC to appropriate Area and National Program staff reviewing potential DURC research.

13) Location IBC will:

- a) Review and approve all biohazardous materials, biological toxins, non-exempt rDNA, and synthetic nucleic acid molecules activities conducted at its ARS location, regardless of source of funds, and ensure compliance with the NIH Guidelines as specified in Section III, Experiments Covered by the NIH Guidelines. This review shall include: (a) independent assessment of the containment levels required by biosafety standards and the risk assessment for the proposed research and (b) pre-approval assessment of the facilities, procedures, practices, and training and expertise of personnel involved in research

utilizing the covered materials. The facility assessment may be conducted by the location BSO or safety staff (full time or collateral duty) or BSCSHM or other qualified staff (IBC member) acting on behalf of the IBC.

- b) In instances where the ARS IBC support is provided by a Cooperator/University IBC the ARS location should request membership on the committee and depending on the level of support explore having this stipulation within the agreement in place as noted in the Agreement definition of this policy. The ARS location should register the University IBC as the IBC of record with NIH OBA for the ARS location.
- c) Review and approve all submitted registrations for research protocols involving biohazards, as defined by this policy.
- d) Work with the PI/Lead Researcher, BSO, location safety staff, and/or BSCSHM during its review, to assess the appropriateness of the proposed laboratory facility, the procedures and practices, the availability of medical countermeasures or medical surveillance, and the training and expertise of the personnel involved in research. The committee may suggest or require changes in procedures, personal protective equipment, engineering controls, or physical containment specifications.
- e) Work with the investigators and their personnel in conjunction with the BSO, location safety staff, and BSCSHM to adopt emergency plans covering spills or contamination from all containment laboratories.
- f) Notify the PI who submitted the registration of the results of the IBC's review and approval/disapproval and/or any conditions of approval.
- g) Monitor experiments using the project registration document and annual updates to ensure that once an experimental procedure within the project has been approved, no substantial change is made unless a formal request (amended registration document) with appropriate justification is submitted to the IBC and approved. A major change would include a change in laboratory space, addition of new pathogens (i.e., different genus and species from what was previously approved) or toxin, scope of work change such as going from bench scale to large scale processes, addition of vector systems, or major change in transgene insert. Minor changes such as the addition or deletion of staff to the registration can be made through a written notification to the IBC chair or secretary.
- h) Maintain files onsite documenting membership, annual reports, IBC meeting minutes, and information related to the review of research project registrations for at a minimum of 5 years. The submission of these documents through the chain of command to the ARS ABO should be performed as outlined in the reports section of this document.
- i) Conduct reviews of projects with an approved registration as required such as when complaints of nonconformance to the approved protocols are received by the IBC, or upon receipt of a request from the PI for approval to make a major change/modification. All major changes must be approved by the IBC prior to proceeding with the work. File maintenance and transmission of results of review are as stipulated in the paragraph above and reports section of this ARS policy.
- j) Promptly investigate all complaints concerning nonconformance with the stipulations of an approved activity, or failure to comply with provisions of the NIH Guidelines and ARS policies concerning use of rDNA or biohazards. If warranted, after investigation of

complaint(s), recommend as appropriate to the AD, CD, LD, or RL, a course of corrective action appropriate for the infraction. Corrective actions may include removal of an employee from the IBC approved research protocol registration, rescission of IBC approval for the research project, or other actions deemed necessary by the Supervisor.

- k) Communicate all noncompliance issues and adverse events as outlined in appropriate ARS Policy and the NIH OBA (if registered).
- l) In addition to its research protocol registration review function, provide an open forum to discuss biological safety concerns and assist in the resolution of any biological safety issues brought before the committee. The location IBC shall refer biosafety issues that cannot be resolved at the location level to the Area IBC.
- m) Upon public inquiry requesting the proceedings (i.e., minutes) of ARS IBC meetings, forward the request, requestor information, and the requested IBC proceedings through the Area IBC, AD, and the ARS ABO to the Agency Information Office for review.
- n) Report as appropriate any reviewed projects identified as conducting research on any of the 15 agents identified in the DURC as defined in the 2014 United States Government Policy for Institutional Oversight of Life Sciences DURC to appropriate Area and National Program staff.

14) Business Service Center - Safety, Health and Environmental Manager Will:

- a) In the absence of an Area BSO, coordinate and provide technical oversight for implementation of the Area Biosafety programs at serviced locations.
- b) Verify the location programs are consistent with the applicable Federal, State, and local regulations, policies and guidelines.
- c) Serve on the Area IBC as requested to review new or modified project plan proposals.

15) Research Leader will:

- a) Hold subordinate staff accountable for implementation and compliance with the Agency, Area, and location policies for BSHEM. Additionally ensure mechanisms are in place to hold all location employees accountable for their BSHEM responsibilities and establish methods for monitoring performance of those responsibilities.
- b) Ensure appropriate laboratory specific Standard Operating Procedures (SOP) for possessing, handling and working with biological materials are developed, and in place for all research projects in the Management Unit. This includes, emergency procedures/incident response, decontamination procedures, laboratory equipment or operation specific SOP, employee proficiency documentation, procedures for review, documenting, correcting and reporting of accidents/injuries, illnesses, near misses, releases/spills investigations by qualified staff, etc.
- c) Ensure adequate funding is available in the management unit to support the IBC program, training and operations.
- d) Ensure all Management Unit projects utilizing biohazardous materials, biological toxins, non-exempt rDNA, and synthetic nucleic acid molecules that involve ARS employees,

funding or facilities receive the appropriate reviews (IBC) prior to commencing the project.

- e) In consultation with the IBC chair select and approve employees to serve on the location IBC program/committee and support annual assessments of the facilities and written programs to ensure compliance with Agency, location, regulations and guidelines for biological programs.

16) Principal Investigator or Lead Scientist will:

- a) Ensure full compliance with ARS policies and the NIH Guidelines in the conduct of research using biohazardous materials, biological toxins, non-exempt rDNA, and synthetic nucleic acid molecules.
- b) Conduct initial risk assessment to be submitted to the IBC as part of the research protocol registration.
- c) Be directly responsible for all aspects of safety specific to their registered research protocol.
- d) Obtain and maintain the applicable Animal and Plant Health Inspection Service and/or Centers for Disease Control and Prevention (CDC) permits for work with pathogens or APHIS permits for conduct of field tests using recombinant plants or microorganisms.
- e) Ensure that the reviewing IBC and IBC chair are identified in the ARS project plan in the appropriate section of the issues page.
- f) Not commence or modify a research protocol involving biohazardous materials, biological toxins, non-exempt rDNA, and synthetic nucleic acid molecules that requires an IBC approval as defined in this policy (e.g. rDNA experiments covered by the NIH Guidelines) until that research or the proposed modification thereof has been reviewed and approved by the IBC and has met all other requirements of the NIH Guidelines and other applicable guidelines/regulations.
- g) PIs or lead scientists shall follow all applicable laws, regulations, policies, procedures, and guidelines governing the acquisition, storage, use, and disposal of biohazardous materials, biological toxins, non-exempt rDNA, and synthetic nucleic acid molecules materials in research.
 - I. Prior to engaging in research activities involving biohazardous materials, biological toxins, non-exempt rDNA, and synthetic nucleic acid molecules, ensure all staff listed on the registration document are appropriately trained on the applicable regulations, standard operating procedures, emergency procedures, and security and safety procedures as required by ARS IBC policy and applicable regulations and guidelines (9 CFR 121, NIH Guidelines, 29 CFR 1910.1030, etc.); ensure that necessary training is appropriately documented.
 - II. Ensure employees have demonstrated proficiency in performing laboratory operations according to the laboratory's standard operational procedures.
 - III. Supervise the safety performance of laboratory staff to ensure that the appropriate safety practices and good microbiological techniques are employed. Correct work errors that may put the employee or others into unsafe situations or

that result in the release of biohazardous materials, biological toxins, non-exempt rDNA, and synthetic nucleic acid molecules to the environment.

- IV. Receive and participate in adequate in-service training concerning biosafety and laboratory safety procedures.
- V. Abide by and carry out the decisions of the ARS IBCs.
- VI. Report all concerns, complaints, and adverse events regarding the acquisition, use, storage, release or disposal of biohazardous materials, biological toxins, non-exempt rDNA, and synthetic nucleic acid molecules following the “ARS Incidents and Accidents Reporting Involving Biological Agents and Toxins” Policy.
- VII. Ensure compliance with all surveillance, data reporting, and adverse event reporting requirements set forth in the NIH Guidelines and the ARS policy.

IBC Roles and Responsibilities:

Committee Membership

The IBC must have at least five members who collectively have the necessary experience and/or expertise to capably assess the risk of proposed research to public health, agriculture, or the environment. Individuals with knowledge or expertise in such fields as rDNA/synthetic nucleic acid technology, toxins, microbiology, animal research, biosafety, occupational health, veterinary medicine, public health, plant disease, plant pest containment, and regulatory compliance are representative of the types of individuals that serve on an IBC as a regular or *ad hoc* member when expertise in a particular field is required. At least two members shall not be affiliated with the institution (apart from their membership on the IBC). The two unaffiliated members’ role is to 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, veterinary, occupational health, or environmental concerns in the community). IBC members shall not participate in the review or approval process for a submitted protocol registration in which they have a role or there may be an actual or perceived appearance of a conflict of interest, unless prior approval is obtained from Area or Agency managers. IBCs serving locations with Biosafety Level (BSL) BSL-3 facilities shall have the BSO(s) of those facilities as full voting members of the committee.

IBC Meetings

- a) IBC meetings are held at least biannually.
- b) At least one meeting shall be held by a quorum of IBC members to review the results of the annual facility inspections. Recommendations made by the IBC shall be transmitted to appropriate line management for action.
- c) Research protocol registration review meetings must be held with a frequency that ensures timely transmission of review results to the PI/Lead Researcher. ARS allows registration document review by a subcommittee of the IBC as long as all members of the IBC receive a complete list of all protocol registrations to be reviewed and any member of the IBC can request review of the protocol registration by the full IBC. Any minority votes for disapproval of a protocol registration at a subcommittee review must be recorded and forwarded to the full committee for review.
- d) The IBC Secretary shall maintain meeting minutes that provide sufficient detail to serve as a record of major points of discussion and the committee's rationale for particular decisions, as well as document that the IBC has fulfilled its review and oversight responsibilities as outlined in this policy and under section IV-B-2-b of the NIH Guidelines. Written records of IBC meetings must be maintained a minimum of 5 years. Additional guidance on meeting minutes can be found on the NIH OBA web site http://oba.od.nih.gov/rdna_ibc/ibc.html and in such references as *Robert's Rules of Order*. Meeting minutes shall include the following as a minimum:
 - a. date and place of the meeting
 - b. time the meeting was called to order
 - c. individuals in attendance
 - d. committee members not in attendance
 - e. whether minutes of the prior meeting were approved
 - f. all major motions and major points of order
 - g. whether motions were approved or disapproved
 - h. any departure or arrival of a committee member
 - i. the time of meeting adjournment

Annual IBC Reports including those Co-Located or Receiving Support from another Institution:

IBC Chair or Representative to a Co-Located cooperator IBC Committee

On or before January 31 of each year, original and two copies of the annual report should be prepared, covering the previous calendar year ending December 31. The completed annual report shall include:

- a) Roster of all IBC members, clearly indicating the chair, secretary, BSO (if applicable), plant expert (if applicable), animal expert (if applicable), human gene therapy expert, or *ad hoc* consultant (if applicable).
- b) Biographical sketches of all IBC members (including community members).

The following should be part of the Annual report distributed to ARS Offices and available should NIH request them as an addendum to the Annual Report:

- c) Listing of ARS protocol registrations that have been reviewed within the reporting calendar year (indicate protocols reviewed and identify which receive any level of funding from NIH).
- d) Compilation of annual meeting minutes.
- e) Any documentation or reports regarding adverse events (spills, exposures, accidents, or environmental releases) reviewed or investigated by the IBC to include recommendations or requirements made by the committee to correct or otherwise resolve the issue.

The original is submitted to the NIH OBA (for facilities registered with NIH) following current guidelines and is distributed as follows: one hard copy filed onsite, one electronic copy to the Area IBC Point of Contact and a copy to the ARS ABO or designee. File copies must be retained for a minimum of 5 years.

Area/Local ARS IBC

For facilities registered with NIH, documents received should be prepared, reviewed for accuracy and compliance with ARS policy and NIH Guidelines then sent directly to the NIH OBA with electronic copies sent to the Area IBC Point of Contact and the ARS ABO at the following address:

ARS Biosafety Officer
Attn: ARS IBC Coordinator
5601 Sunnyside Avenue, Bldg. 4, Mailstop 5148
Beltsville, Maryland 20705.

One copy must be retained on file and discarded after 5 years.

Principal Investigator/Lead Scientist

Prior to initiating any research protocols involving biohazardous materials, biological toxins, non-exempt rDNA, and synthetic nucleic acid molecules, the PI should complete a protocol registration document, notify the IBC secretary in writing of any minor amendments (as defined within the glossary), and request IBC review and approval for major amendments to an existing registration prior to proceeding.

The original and two copies of the documents should be sent to the local IBC. (Send to Area IBC for review if location does not have an IBC).

One copy must be retained on file and discarded after 5 years.

Incident Reporting to NIH OBA

Detailed information on incident and NIH Guideline violation reporting may be found in the NIH OBA FAQs, entitled “Incident Reports to the NIH Office of Biotechnology Activities (OBA)” (http://oba.od.nih.gov/rdna_ibc/ibc_faq.html).

[Section IV-B-2-b-\(7\)](#) of the NIH Guidelines states that IBCs should report” any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and

illnesses" to NIH OBA within 30 days. Appendix G of the NIH Guidelines specifies certain types of accidents that must be reported on a more expedited basis. According to [Appendix G-II-B-2-k](#), spills or accidents in BL2 (see footnote in BSL definition, page 19), laboratories experiencing accidents that result in an overt exposure to organisms containing recombinant DNA molecules must be immediately (within 24 hours) reported to the NIH OBA (as well as the location and Area IBC). According to [Appendix G-II-C-2-q](#) and [Appendix G-II-D-2-k](#), spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure to organisms containing recombinant DNA molecules must be immediately reported to NIH OBA (as well as the IBC, and location BSO).

All incidents reportable to the NIH OBA must follow the template identified in the Incident Reporting to NIH and will go through the ARS ABO. Additional ARS specific reporting requirements are found in ARS Manual 160.0M, Chapter 20 accessible at <http://www.afm.ars.usda.gov/ppweb/PDF/160-0M.pdf> and the [ARS P&P \(document in draft form at time of issuance\) entitled ARS Incidents and Accidents Reporting Involving Biological Agents and Toxins \(Biohazards\)](#).

5. Authorities

The current edition of the *NIH Guidelines for Research Involving Recombinant DNA Molecules* may be viewed at http://oba.od.nih.gov/rdna/nih_guidelines_oba.html or obtained in print by contacting the NIH Office of Biotechnology Activities at 301- 496 9838.

The USDA APHIS User's Guide for Introducing Genetically Engineered Plants and Microorganisms, a Technical Bulletin from the APHIS Biotechnology Regulatory Service, may be viewed at <http://www.aphis.usda.gov/biotechnology/index.shtml> or obtained in print by contacting 301-734-7612 or 301-734-8669 (FAX).

The most current edition of the NIH/CDC Publication, *Biosafety in the Microbiological and Biomedical Laboratories*, may be viewed at [CDC - Biosafety in Microbiological and Biomedical Laboratories \(BMBL\) 5th Edition](#).

The current edition of "Biohazard Containment Design, Chapter 9," in the Manual 242.1M-ARS, "ARS Facility Design Standards," may be viewed at <http://www.afm.ars.usda.gov/ppweb/PDF/242-01M.pdf>.

The current edition of "International transfer and laboratory containment of animal pathogens," in the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* is available through the World Organization of Animal Health Web site at http://web.oie.int/eng/normes/mcode/en_chapitre_1.5.8.pdf.

USPHS 42 CFR - Part 71 Foreign Quarantine. Part 71.54 Etiologic agents, hosts, and vectors.
USDA APHIS CFR 9 Chapter 1 Part 122.2 “Organisms and Vectors” reference section 1 entitled permit requirement may be viewed at http://www.aphis.usda.gov/import_export/index.shtml.
USDA APHIS CFR 7 Part 330 “Federal Plant Pest Regulations; General: Plant Pest;” Subpart Sec. 330.201 may be viewed at <http://www.aphis.usda.gov/ppq/permits/>.

DM 9610-001, USDA Security Policies and Procedures for Biosafety Level-3 Facilities, dated August 2002.

DM 9610-002, USDA Security Policies and Procedures for Laboratories and Technical Facilities (Excluding Biosafety Level-3 Facilities), dated April 2003

DR 4400-007, USDA Biological Safety Program, dated May 2006.
United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern, September 24, 2014 may be viewed at <http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf>

6. Definitions

Activity. Each unique, related series of procedures or research projects utilizing recombinant DNA or biohazardous material addressed in a single registration form.

Ad hoc Committee Members. Invited members that possess unique knowledge or expertise in a particular field not represented in the standing committee. These outside experts participate as needed or requested by the IBC during the review of a research project(s).

Agreement A formal document signed by an Authorized Departmental Officer on behalf of ARS and an authorized institutional official of one or more organizations outside of ARS. For the purpose of this Policy & Procedure (P&P), the agreement must be approved by the AD and address restrictions on transfer of information to a third party, intellectual property rights, and non-commercialization. Examples of such agreements are a Cooperative Research and Development Agreement (CRADA,) Memorandum of Agreement (MOA), Memorandum of Understanding (MOU), contract, or grant. If the provisions listed above are specified within the formal agreement and the non-ARS IBC has met the approval of the ARS location’s AD, then the ARS project may be reviewed and approved by a non-ARS IBC. ARS location representation on the non-ARS IBC committee should be considered as part of the agreement.

Biohazard(ous). “Biohazard” is the contraction of the words “biological” and “hazard.” A biohazard is defined as an infectious agent or hazardous biological agent or part thereof regardless of origin (naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance) that presents a real or potential risk to humans, animals, or plants, either directly through infection, or indirectly through the disruption of the environment.

Biohazards include certain types of recombinant DNA, synthetic nucleic acids; organisms and viruses infectious to humans, animals, or plants (e.g., parasites, viruses, bacteria, fungi, prions, rickettsia); and biologically active agents including CFR defined Select Agents (e.g., toxins, allergens, venoms) that may cause disease in living organisms or cause significant impact to the environment, community, commerce, or trade agreements.

Biosafety Level (BSL). A combination of work practices and physical containment requirements (facility and safety equipment) designed to reduce the risk of the microorganism's ability to cause injury through disease to an individual and community based on the severity of the disease, mode and ease of transmission, and reversibility through available agents and treatment. The degree of protection recommended is proportional to the risk associated with an agent and the proposed research operations. There are four Biosafety Levels (BSL) and four corresponding Animal Biosafety Levels described in the CDC/NIH publication entitled "Biosafety in Microbiological and Biomedical Laboratories (BMBL)." [CDC - Biosafety in Microbiological and Biomedical Laboratories \(BMBL\) 5th Edition](http://www.cdc.gov/biosafety/publications/bmbl5/BMBL5_appendixD.pdf) The NIH Guidelines in Appendix G (http://oba.od.nih.gov/rdna/nih_guidelines_new.htm#_Toc331174107) also describe four levels of biosafety and containment practices biosafety levels (BL)¹ that correspond to the potential risk of experimentation and require different levels of review for recombinant DNA research, based on the nature and risks of the activity.

For agriculture there is an additional concern with environmental protection, and an enhanced BSL-3 or ABSL-3 laboratory known as BSL-3 Agriculture has been defined by ARS within 242.1M-ARS "ARS Facility Design Standards, Section 9.4.4, Biosafety Level 3 Agriculture (BSL-3Ag)." It is also defined in the BMBL 5th edition within Appendix D (http://www.cdc.gov/biosafety/publications/bmbl5/BMBL5_appendixD.pdf) A risk assessment for agricultural research must take into account the possibility of the biological agent of interest being accidentally released and infecting other animals or plants within the facility or the surrounding environment and the potential economic or trade consequences of such a release, in addition to human health risks. BSL-3Ag is typically utilized for work in those situations in which the facility barriers now serve as the primary barrier (i.e., foreign animal disease work with large livestock species). Factors to be considered in the placement of a specific agent in a risk group or assignment of a biosafety level for work with a particular agent may include virulence, pathogenicity, communicability, environmental stability, host range, quantity and concentration of the agent, studies to be conducted, endemicity, availability of prophylaxis, or post-exposure treatment.

BSL-1. Facility and practices appropriate for work with well-characterized, low risk agents not known to cause disease in healthy humans, plants, or animals. No specialized practices other than good microbiological technique are utilized. These laboratories are typical of undergraduate or secondary education teaching laboratories.

BSL-2. Facility, safety equipment, and practices appropriate for agents of moderate potential hazard to people, animals, or agriculture; these agents are generally endemic, cause illness

¹ BL designation is used in the NIH Guidelines, while BSL is used in the CDC/NIH BMBL 5th edition. The NIH BL describe four levels of biosafety and containment practices that correspond to the potential risk of experimentation and require different levels of review for recombinant DNA research, based on the nature and risks of the activity. The NIH Guideline BL differs slightly from the BMBL BSL in some instances.

of varying degree, and are typically treatable or preventable. Most research and diagnostic laboratories that work with foodborne pathogens, human bloodborne pathogens, or human derived tissues are designed to perform work at this level.

BSL-3. Facilities, safety equipment, and practices applicable to clinical, diagnostic, research, or production facilities in which work is done with indigenous or exotic agents with a potential for aerosol transmission, and that may cause serious and potentially lethal infections or grave economic consequences if released. Laboratory facilities and practices include inward directional airflow, separation from non-laboratory areas, special laboratory protective clothing, and decontamination of laboratory waste. *Mycobacterium tuberculosis*, *Coxiella burnetii*, and St. Louis encephalitis virus are representative of biological agents assigned to this biosafety level.

BSL-3-Agriculture (BSL-3-Ag). ARS has defined an enhanced BSL-3 facility, safety equipment, and practices particular to agriculture research (i.e., infectious disease work with loose housed agricultural species) where the facility barriers, usually considered secondary barriers, now act as primary barriers. BSL-3-Ag facilities utilize the containment features of the standard BSL-3 facility (as defined in the BMBL) as a starting point, with a number of enhancements typically incorporated into BSL-4 that are specifically designed to protect the environment. Enhancements for BSL-3-Ag include HEPA filtration of supply and exhaust air, sewage decontamination, exit personnel showers, and facility integrity testing. This type of laboratory is appropriate for non-endemic pathogens, causing serious livestock or poultry disease that are readily transmitted though the aerosol route. Foot and Mouth Disease (FMD) and Classical Swine Fever (CSF) are examples of agricultural agents assigned to this biosafety level.

BSL-4. Facility, safety equipment, and practices appropriate for research on dangerous and exotic agents that pose high individual risk of life threatening disease, which may be transmitted via the aerosol route and for which there is no available vaccine or treatment. While there is no BSL-4 requirement for solely agricultural agents, recently two viruses have been discovered that are highly lethal for agricultural species and for humans (Nipah and Hendra viruses), and these can only be manipulated at laboratories having BSL-4 capability. Less than 20 viruses are currently designated at this level.

Cooperator. Any non-ARS personnel using recombinant DNA or biological hazards at an ARS location.

Genomic DNA. The full complement of DNA contained in the genome of a cell or organism. Genomic DNA of plants and bacteria that have acquired a transposable element, even if the latter was donated from a recombinant vector no longer present, are not subject to the NIH Guidelines unless the transposon itself contains recombinant DNA.

Principal Investigator (PI). A Principal Investigator is the scientist responsible for the conduct of an individual research protocol utilizing recombinant DNA technology and/or biohazardous material(s). These individuals may include ARS Category 1 or Category 2 scientist or other lead researcher positions within ARS. The PI is responsible for ensuring that laboratory staff/animal staff are aware of the hazards associated with the research project and the precautions to be taken; instructs and trains laboratory staff in the practices and techniques required for safety and the procedures for dealing with accidents, and supervises the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed.

Recombinant DNA (rDNA). Recombinant DNA is defined in the *NIH Guidelines* as: (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell or (ii) molecules that result from the replication of those described in (i) above.

Amended Registration Change

Major Change – change that modifies the level of risk or biosafety/biocontainment level of a project. Examples of such modifications include changes in the location, intent, or scope of the registered protocol/activity, addition of new agents or toxins, and significant modification of procedure or protective equipment. Such changes will require an amendment to be submitted for IBC review and approval prior to commencement.

Minor Change – change that is typically administrative in nature and does not alter the initial risk assessment. Examples of such changes include the addition or deletion of staff, change in contact information, addition of isolates or strains of an organism on an approved protocol registration (change is minor only if the level of risk is not changed), and minor procedural changes. Notification of minor changes may be accomplished by sending a memo to the IBC Secretary. The memo should reference the IBC protocol registration being amended and provide sufficient information to allow the IBC Secretary/Chair to concur that the change is, indeed, minor.

Registration Document. A risk assessment tool/form completed and submitted by the PI for IBC review and approval. Registration of all research protocols involving biohazards and/or recombinant DNA must be submitted through an IBC for review. Research protocols involving these items must contain a detailed description of how research with this material will be conducted; potential danger(s) posed by the agent(s); and a summary of safeguards, training, and procedures that will be employed to protect the laboratory personnel, other persons, animals, plants, and the environment.

Synthetic Nucleic Acid Molecules A region of a DNA molecule, such as a gene or a promoter that is produced synthetically. Synthetic DNA segments that are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or a pharmacologically active agent) are considered as equivalent to their natural DNA counterpart. If the synthetic DNA segment is not expressed *in vivo* as a biologically active polynucleotide or polypeptide product, it is exempt from the NIH Guidelines.

Toxins. Biological Toxin or Biotoxin – A broad range of substances, predominantly of natural origin but increasingly accessible by modern synthetic methods, that may cause death or severe incapacitation at relatively low exposure levels. Biological toxins include metabolites of living organisms, degradation products of dead organisms, and materials rendered toxic by the metabolic activity of microorganisms. Examples of toxins include staphylococcus enterotoxins, saxitoxin, cholera toxin, botulinum toxin, ricin, abrin, and mycotoxins.

7. Glossary

ABO – Agency Biosafety Officer

AD - Area Director

ARS – Agricultural Research Service

BSHEM – Biosafety, Safety, Health, and Environmental Management

BSL – Biosafety Level

BSO - Biological Safety Officer

BSCSHM - Business Service Center Safety and Health Management

CD - Center Director

CDC - Centers for Disease Control and Prevention

DURC – Dual Use Research of Concern

IBC - Institutional Biosafety Committee

LD – Laboratory Director

NIH - National Institutes of Health

NIH Guidelines - *NIH Guidelines for Research Involving Recombinant DNA Molecules*

NIH OBA – National Institutes of Health, Office of Biotechnology Activities

PI - Principal Investigator

rDNA – recombinant Deoxyribonucleic Acid

RL – Research Leader

SOP – Standard Operating Procedures

Approved by:

Steven R. Shafer
Associate Administrator

Date