Boston University Institutional Biosafety Committee
Inactivated Biological Samples

I. Purpose

The purpose of this policy is to set forth the procedures by which inactivated biological samples derived from BSL-3 and BSL-4 select agents, received from outside entities, can be handled at the lower biosafety containment level designated for the inactivated material at Boston University (BU).

II. Covered Parties

This policy applies to all individuals engaged in research at or under the auspices of BU and covers all inactivated biological samples that meet all of the following criteria:

- Inactivated material derived from a select agent, regulated nucleic acid (that can produce infectious forms of any select agent virus) or select toxin that requires BSL-3 or BSL-4 containment.
- Inactivation through an in-house validated procedure that has been confirmed through a viability testing protocol that renders the select agent, regulated nucleic acid nonviable or a select toxin non-toxic; and
- The inactivated material is being transferred to BU from an outside entity.

This policy does not apply to:

- Select agents and toxins excluded by the Federal Select Agent Program (FSAP) as an attenuated strain of a select agent or a select toxin modified to be less potent or toxic.
- Decontamination or a destruction procedure for waste disposal.
- Exempt clinical or diagnostic laboratories that possess, use or transfer a select agent or toxin that is contained in a specimen presented for diagnosis or verification.

III. Policy

The transfer of inactivated biological samples derived from BSL3 and BSL4 select agents or toxins from outside entities to BU, must be reviewed and approved by the Institutional Biosafety Committee (IBC) and the Responsible Official (RO) prior to being received and used at BU.

IV. Procedures

The Principal Investigator (PI) must have an IBC approved protocol in place with the Inactivated Biological Samples Use Section completed before a transfer of inactivated material be initiated.

The IBC and RO must review and approve all requests to transfer inactivated biological samples derived from BSL-3 and BSL-4 select agents before the shipment of the inactivated material can be received and before work with the inactivated material could begin. The RO must be notified of all incoming shipments.

Before the initiation of any shipment, BU must perform a compliance verification to ensure that materials being received have all necessary approvals in place. To facilitate this process, many shipments require a signed Material Transfer Agreement (MTA), which details the agents and biosafety level of the laboratory that will receive the material. Generally, incoming MTAs are initiated by the transferring/shipping outside entity. Once received, The PI must complete the online MTA form: Incoming, and attach a copy of the outside entity's MTA. The Office of Contracts and Agreements will work with NEIDL EHS, and the IBC Office, to verify all appropriate approvals are in place. Note that even where an actual MTA is not required by the outside entity providing the inactivated material, the PI nonetheless must complete an online Material Transfer Agreement form.

BU will accept inactivated materials when the source entity employs in-house validated inactivation methods as defined by the Federal Select Agent 2018 Guidance on the Inactivation of Select Agents and Toxins for Future Use. These methods may include:

- Irradiation: Biological agents may be inactivated by exposure to ionizing radiation (generally gamma radiation) at high radiation doses (typically 5 Mega-rads or above).
- Heat: Biological samples may be inactivated by exposing the samples to a thermal process for a period of time approved by the institution.
- Chemical: Inactivation of BSL-3 or BSL-4 agents by chemical means must include the use of chemicals at concentrations known to be effective for deactivation.
- Fixation: BSL-3 or BSL-4 samples that have been fixed at the source.
- Combination: a combination of two or more of the above.

Documentation

A copy of a Certificate of Inactivation signed by the PI (or in the absence of that PI, the individual designated by that PI and approved by the entity RO to sign the certificate in his or her absence) must accompany the inactivated material to denote that the PI or designee responsible for the specific agent has reviewed the inactivation procedure used and the validation or verification data. The Certificate of Inactivation must include:

- the date of inactivation or viable select agent removal.
- the validated inactivation or viable select agent removal method used: and
- the name of the PI.

The receiving PI at BU is responsible for keeping a copy of the Certificate of inactivation and shipment documents for as long as the inactivated material exists. If the material is transferred from BU to an outside entity or to another lab withing BU, a copy of the Inactivation Certificate must accompany the transferred inactivated material.

V. Responsible Parties

Principal Investigators are responsible for: preparing and submitting online applications for MTA; making modifications in applications in order secure IBC approval; ensuring adherence to approved protocols; ensuring that all personnel have completed required training; and reporting any adverse events to the IBC.

The IBC and RO are responsible for ensuring biological materials received by or under the auspices of BU are handled in a safe manner. This includes establishing criteria that ensure that any pathogenic materials that are received as "inactivated" as defined by the FSAP.

The RO is responsible for assuring that inactivation methods utilized by the outside entity continue to be appropriate and effective.

VI. Definitions

Entity: Any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.

Inactivation: A procedure to render a select agent or regulated nucleic acids as non-viable or a select toxin non-toxic while retaining characteristic(s) of interest for future use.

Non-infectious nucleic acid: Nucleic acids no longer capable of producing infectious forms of a select agent virus (e.g. regulated positive sense RNA virus genomes like FMDV or EEE).

Non-viable select agent: A select agent no longer capable of growing, replicating, infecting, or causing disease.

Non-toxic select toxin: A toxin no longer capable of exerting a toxic effect.

Principal investigator: The one individual who is designated by the entity to direct a project or program and who is responsible to the entity for the scientific and technical direction of that project or program.

Responsible Official: The individual designated by an entity with the authority and control to ensure compliance with the regulations in this part.

Validated inactivation procedure: A procedure, whose efficacy is confirmed by data generated from a viability testing protocol, to render a select agent non-viable but allows the select agent to retain characteristics of interest for future use; or to render any nucleic acids that can produce infectious forms of any select agent virus non-infectious for future use.

Verification: The demonstration of obtaining established performance (e.g., accuracy, precision, and the analytical sensitivity and specificity) specifications for any procedure used for diagnosis.

Viability testing protocol: A protocol to confirm the validated inactivation procedure by demonstrating the material is free of all viable select agent.

VII. References

Select Agents Regulations (SAR)

- 7 C.F.R. Part 331
- 9 C.F.R. Part 121
- 42 C.F.R. Part 73

Guidance on the Inactivation or Removal of Select Agents and Toxins for Future Use

(Federal Select Agent Program)

Federal Select Agent Program Policy Statement (FSAP): Application of the requirement for a "validated inactivation procedure" as used in the select agent regulations

FSAP Regulatory Interpretation regarding surrogate strains which can be used to validate inactivation procedures

FSAP Regulatory Interpretation regarding signature by "Principal Investigator" on Inactivation Certificates

VIII. Related Documents

None

IX. History

Original Date Approved: 12/14/2011
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