Institutional Biosafety Committee Policy Manual

Research Integrity & Compliance

TABLE OF CONTENTS

1.1.4 Biosafety Level 4 (BSL-4) a

biological and physical containment levels for biohazardous materials or rDNA that are subject to its review and approval.

Section 4.0 Regulations and Guidelines

4.1 The IBC Policy is drafted in accordance with the following regulations and guidelines:

a. NIH Guidelines. The NIH Guidelines publication is available from the NIH OSP.
b. CDC/NIH BMBL, published by the CDC and NIH. The BMBL is considered the standard for biosafety.
c. Code of Federal Regulations (CFR) 42 CFR 73,
d. Agricultural Bioterrorism Protection Act of 2002, 7 CFR 331, and 9 CFR 121,
e. USA Patriot Act (October 2001),
f. Public Health Security and Bioterrorism Preparedness Response Act of 2002,
g. OSHA Bloodborne pathogen standards (1910.1030)

Section 5.0 Institutional Official

5.1 The Vice President for Research Innovation is the Institutional Official responsible for the Biosafety Program.

5.2 The Vice President for Research Innovation is responsible for the IBC.

5.3 The Vice President for Research Innovation is responsible for the appointment of IBC members.

5.4 The Vice President for Research Innovation shall appoint the chairperson, vice chairperson, members, and alternates of the IBC. Qualified members shall be nominated as required, based on the recommendation of the IBC, the IBC Chairperson, and/or the Director of RIC. Procedures for appointment of alternate members, terms of appointment, length of service, and duties are the same as for regular IBC members

5.5 The Vice President for Research Innovation is responsible for notifying the NIH OSP (Office of Science Policy) and/or CDC of incidents of s a[f-6 (t)-62 (d -0.00(h)-10 7MC
j -0.00 0 Td ( )Tj EMC [(po8 Tw [((6-30 Tc y4 Tc 0.04 (e)4 8 Tw [((6-30 Tc 4 (e)]TJ -0.013 Tc)3 (orf4 Tc 0.00d9.07 0

6.0.2 The USF RIC Biosafety Program provides professional and administrative support to the IBC

Section 6.1 Charge of the Committee

6.1.1 The IBC has been granted authority by the Vice President for Research Innovation on all matters pertaining to the safe use of biohazardous materials and/or rDNA in research at USF.

a. The IBC establishes guidelines, supports, and facilitates research and teaching and ensures compliance for USF faculty, staff, students, volunteers, and visitors conducting research and/or teaching programs involving biohazardous materials and/or rDNA which are potentially pathogenic to hu0 Tc 0 Tw 1c t.u0 Tc.ote a

c. A member from each affiliate (e.g., James A Haley Veterans Administration and H. Lee Moffitt Cancer Center)

6.2.3 The IBC shall include:

a. one individual with expertise in human gene transfer principles and safety issues when research involving human subjects.

b. one individual with expertise in animal containment principles when research involving animals and/or biohazardous materials and/or rDNA.

c. one individual with expertise in plant pathogen, and/or plant pest containment principles when research involving recombinant plants.

6.2.4 IBC members and alternates are appointed by the Vice President for Research Innovation.

6.2.5 IBC thamedu <</MCID 8 .nou</MCID 12 >>-shall i 12 >>neii.(ha)4 (l)-2 (n (s)-1h4 -6r)3 3
. i u i 6 < b l /

d. overseeing the conduct of inspections, to ensure adherence to federal, state, and University regulations and IBC policy for the use of biohazardous materials and/or rDNA at USF.
e. monitoring federal, state, and local regulatory trends and communicating such to the IBC and responsible institutional representatives.
f. conducting certain activities on behalf of the IBC in support of the program (e.g., review/inspect individual facilities, biosafety manuals) and confirm compliance with NIH and/or CDC guidelines and/or USF IBC policy, procedures, and requirements.
g. providing recommendations to the IBC on biosafety matters.
h. acting as a liaison with University and Institutional Review Boards (IRBs), Institutional Animal Care and Use Committees (IACUC), Infection Control Units, and the Environmental Health and Safety (EHS) office.
i. maintaining the official roster of IBC members
j. scheduling IBC meetings
k. ensuring that all meeting materials are available to members prior to the scheduled meeting
l. compiling and maintaining the minutes of IBC meetings in compliance with regulatory requirements.
m. maintaining all IBC documentation and records.
n. facilitating communication between investigators and the IBC.
o. tracking the progress of each protocol submitted to the IBC.
p. utilizing the electronic platform (BiosafetyNet) for tracking purposes.
q. serving as a resource for investigators on regulatory information, biosafety procedures, and practices, and providing guidance regarding submission procedures.
r. conducting laboratory inspections.
s. proposing, reviewing, and revising IBC documents.
t. drafting reports and correspondence on behalf of the IBC or IBC Chairperson.
u. reviewing IBC applications.

Section 6.8 Reporting to NIH — Recombinant or Synthetic Nucleic Acids

6.8.1 The BSO on behalf of the IBC, shall report to the NIH OSP:

a. any significant problems with or violations of, and any significant research related accidents or illnesses to the NIH OSP within 30 days; unless the IBC determines that a report has already been filed by the PI.
b. BSL-2 spills and accidents which result in ***overt exposures*** to organisms containing rDNA are immediately reported to IBC and NIH OSP
c. BSL-3 spills and accidents which result in overt or potential exposures to organisms containing rDNA are immediately reported to IBC and NIH OSP.

R

6.8.2 The BSO or designee, on behalf of the IBC, shall file an annual report with NIH OSP which includes:

a. a roster of all IBC members clearly indicating the Chairperson, contact person, BSO, plant expert (if applicable), animal expert, human gene therapy expert, or ad hoc consultant (if applicable).
b. biographical sketches of IBC members, including community members.

Section 6.9 Director of Research Integrity & Compliance (RIC)

6.9.1 Is designated as overall administrator for the USF IBC and is responsible for ensuring that it functions and operates within USF in compliance with all federal, state, and local laws and regulations and USF IBC policy and procedures that govern the safe use of biohazardous materials and rDNA in the conduct of research and

7.1.3 The PI must make an initial determination of the required levels of biological safety containment and the appropriate section of the NIH guidelines and the CDC/NIH BMBL, 6th edition.

7.1.4 The PI must

e. ensure equipment and lab spaces are thoroughly decontaminated prior to maintenance being conducted.
f. ensure that research materials are properly decontaminated before disposal.
g. report any potential exposures. For information, see the Exposures, Incidents and Near Misses web page.
h. comply with shipping requirements for biohazardous materials and/or rDNA.

Section 7.

8.2.4 Based on a risk assessment, for research involving human subjects, the USF IBC may consider a continuing review of six or twelve months.

8.2.5 Based on risk assessment and the NIH Guidelines, IBC oversight of human gene transfer protocols may conclude after the last participant is administered the final dose(s) of the product.

8.2.6 All amendments and continuing reviews that are submitted to the IRB related to the gene transfer study or in support of gene transfer protocol must be submitted to the IBC for review. This includes:

a. all Continuing Review Reports to the IRB.
b. all Change in Procedures/Investigator's brochure reported to the IRB
c. report(s) of significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses.

Section 8.3 Use

9.4.4 In handling human blood or blood products the IBC recommends that samples be handled with Standard

Section 11.0 IBC Review and Approval Process

11.1 The IBC reviews all use of biohazardous materials and/or rDNA activities involving biohazardous materials must be revie

11.9 The IBC protocol will be available to all members, and they have the opportunity to discuss issues with the protocol during the convened meeting.

11.10 The IBC may take one of the following actions:

a. Approval - Full approval for the protocols as described will be granted by the IBC if there are no outstanding biosafety issues. The PI may initiate the research only after receiving an approval letter.

b. Requires Modifications to Secure Approval - Additional information or clarifications are delineated by the IBC. The PI must respond by revising their protocol as requested by the IBC. The revised protocol is reviewed by the primary reviewer. The research may be approved by the primary reviewer or the chairperson.

c. Deferred - The IBC determines that a deferred study lacks sufficient information about the research procedures or safety practices, or a complete risk assessment of the protocol cannot be performed. After revision, the deferred protocol must be reviewed at a subsequent meeting.

d. Disapproval - The IBC has determined that the research proposal has substantive biosafety issues. Protocols that are disapproved require submi Pro[on aboo4 (t)su/2 (r)3 (e)4 fetfe [(A).Td 29 0 3

c. Change in Protocol Sponsor
d. Change in Lab Location
e. Change in Procedure
f. Change in Personnel
g. Changes that do not alter the overall risk of the study

12.3 The Amendments are reviewed and approved by the IBC chairperson, a designated IBC member or BSO through an expedited process. The reviewer has the discretion to request a full committee review.

12.4 When an amendment does not meet the criteria for Expedited Review (policy item 12.2) then the full IBC must review the proposed change(s) at a convened meeting. The IBC will determine whether the proposed amendment is substantive and request further information or a new IBC protocol.

Section 13.0 Biosafety Laboratory Inspections

13.5 Grades of Deficiencies:

Serious: An immediate threat to human health, and/or security of biological agents and/or toxins and those that indicate a need for systemic improvements.

In selected cases, an Immediate Action Report will be submitted within 7 days to PI and IBC Chair following the inspection. Required corrective action may include ceasing work or addressing departures within a shortened period of time. Other departures will be reported in the routine inspection report sent to the PI within 7 days.

Moderate: Have the potential to be a threat to human, plant, or animal health, animal,or plant products, and/or security of biological agents and/or toxins.

If not corrected, such departures will impact the safety of humans and/or security of biological agents and/or toxins and increase the risk of more serious departures. A routine inspection report will be sent to the PI within 7 days of the inspection.

biological agents and/or toxins but are not consistent with safe and secure standards of practice. -2 (he2 (on.)18.77 0 Td)4 (ys)-1 (c)4 (t)-2 (e)4 (11 >>BDC 12 0 0

S e c t i o n - 2

Section 14.2 Registration with the USF IBC for Use of Select Agents

14.2.1 A PI planning to work with any Select Agent/Toxin material must also submit a

Section 15.3 Office of Sponsored Research

15.3.1 The Biosafety Office makes available to the Office of Sponsored Research approval letters of all studies approved by the IBC.

Section 16.0 Biosafety Education and Training

Section 16.1 Persons Required to Complete Training

16.1.1 Training and education in microbiological techniques is required for anyone working with biohazardous materials and/or rDNA at BSL-2 or who works in a laboratory where these materials are used and/or stored.

a. The PI is responsible for ensuring personnel are properly trained in the laboratory regarding microbiological techniques.
b. The Biosafety Program provides the required education in biosafety principles and practices for all personnel directly involved in the conduct of research with biohazardous materials and/or rDNA or who works in a laboratory where these materials are used and/or stored.

Section 16.2 Training Requirements

16.2.1 There are three types of Biosafety training requirements:

a. Core Course – The Biosafety Principles and Practices course. All persons involved in the conduct of research with biohazardous materials and/or rDNA must complete the core course requirements before they directly handle the biological material
b. Continuing Education – Triennial completion of an IBC approved continuing education course by all personnel involved in all IBC approved studies.
c. Special Topics C-11 (2 (orET BTi)Span (e)4 (d.65Td ( )Tj)-gj EMo)-4 (p)-8 (i)-6 12ild in ogicalrlecialpleourd(.004i [(c)4 (om)2 (nvoy-(pl)-2 (pe)2 (orET /Artifact B (or)-0-4 rg equi T* [y, (N)-8 -6 (s)- 226Smpd [(lia)-6 n

18.3 The IBC reports the findings of its deliberations to the PI and the Vice President of Research.

18.4 If the IBC suspends an activity involving biological materials and/or rDNA, the PI will be informed in writing of the suspension, its conditions, and the expectations which need to be met before activities resume.

18.4 The IBC may vote to suspend or terminate approval of the protocol that has been associated with noncompliance regarding applicable regulatory requirements and/or IBC policy.

Section 20.0 Policy Review

20.1 This policy will be reviewed annually.

APPENDIX I - HHS & USDA Regulated Select Agents and Toxins

HHS Select Agents and Toxins

1. Abrin [6]
2. Bacillus cereus Biovar anthracis [1]
3. Botulinum neurotoxins [1][6]
4. Botulinum neurotoxin producing species of Clostridium [1]
5. Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$) [6]
6. Coxiella burnetii
7. Crimean-Congo haemorrhagic fever virus
8. Diacetoxyscirpenol [6]
9. Eastern Equine Encephalitis virus [4][5]
10. Ebola virus [1]
11. Francisella tularensis [1]
12. Lassa fever virus
13. Lujo virus
14. Marburg virus [1]
15. Mpox virus [4][9]
16. Reconstructed replication competent forms of the 1918 pandemic influenza virus

32. Kyasanur Forest disease virus[5]
33. Omsk hemorrhagic fever virus[5]
34. Variola major virus (Smallpox virus)[1]
35. Variola minor virus (Alastrim)[1]
36. Yersinia pestis[1]

Overlap Select Agents and Toxins

37. Bacillus anthracis[1]
38. Bacillus anthracis Pasteur strain
39. Brucella abortus
40. Brucella melitensis
41. Brucella suis
42. Burkholderia mallei[1]
43. Burkholderia pseudomallei[1]
44. Hendra virus
45. Nipah virus
46. Rift Valley fever virus
47. Venezuelan equine encephalitis virus[4][5][8]

USDA Veterinary Services (VS) Select Agents and Toxins

48. African horse sickness virus
49. African swine fever virus
50. Avian influenza virus[4]
51. Classical swine fever virus[5]
52. Foot-and-mouth disease virus[1][5]
53. Goat pox virus
54. Lumpy skin disease virus
55. Mycoplasma capricolum[4]
56. Mycoplasma mycoides[4]
57. Newcastle disease virus[3][4]
58. Peste des petits ruminants virus
59. Rinderpest virus[1]
60. Sheep pox virus
61. Swine vesicular disease virus[5]

USDA <</MCI16 (n)-4 (e v)-4 (es(d)2 e0 12 2T B12 2T B12 2T B12 BDC 0es(d)2 e0 12 2T

[1] Denotes Tier 1 Agent
[2] C = Cysteine residues are all present as disulfides, with the 1st and 3rd Cysteine, and the 2nd and 4th Cysteine forming specific disulfide bridges; The consensus sequence includes known toxins a-MI and a-GI (shown above) as well as a-GIA, Ac1.1a, and Cnd-A,