USF
UNIVERSITY OF
SOUTH FLORIDA

Institutional Biosafety Committee Policy Manual

Research Integrity & Compliance

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Purpose

The University of South Florida (USF), Research Integrity & Compliance (RIC), Biosafety Program and the USF Institutional Biosafety Committee (IBC) is committed to incorporating health and safety practices governing all USF personnel working with biohazardous materials in research and/or teaching activities at USF. The USF Biosafety Program was established to reduce the risk of potential occupational exposure to biohazardous materials and/or Recombinant or Synthetic Nucleic Acid Molecules (rDNA) in a research and/or teaching environment.

It is the policy of the USF Biosafety Program that all research and/or teaching involving infectious agents, biological toxins, Select Agents/Toxins, and rDNA must be conducted in a safe manner. Biosafety containment practices protect the faculty, staff, students, volunteers, and visitors from exposure to infectious agents, biological toxins, Biological Select Agents/Toxins (BSAT), and rDNA and prevent the release of biological hazards into the environment. To ensure safe handling, USF requires compliance with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines, April 2019)*)*, Centers for Disease Control and Prevention (CDC) (*Biosafety in Microbiological and Biomedical Laboratories*, 6th Edition, 2020, US Department of Health and Human Services (HHS), Office of Science Policy, USF Biosafety Program Institutional Biosafety Manual, and other applicable federal, state, and local regulations.

SECTION 1.0 IBC Policy Regarding Use of Biohazardous Agents

Section 1.1 Overview

1.1.1 USF Biosafety committee approval is required for all research and/or teaching laboratory activities which involve the use or manipulation of biohazardous materials and/or rDNA which are:
- a. conducted by USF faculty, students, or staff.
- b. conducted by a USF affiliated institution supported faculty (i.e., H. Lee Moffitt Cancer Center, James A. Haley Veterans Hospital, and Bay Pines Veterans Hospital).
- c. conducted on USF premises, or in a building or location administered by or under the control of USF; and/or at an affiliated institution facility.
- d. supported by funds provided by or through USF and/or executed agreements.

1.1.2 The Principal Investigators (PI) at USF and its affiliated institutions is responsible for securing approval from the USF IBC if they plan to possess, store, manipulate, or transport biohazardous materials such as:
- a. infectious agent(s),
- b. Biological Select Agent(s)/Toxin(s),
- c. and/or rDNA

1.1.3 The PI is responsible for the procurement of, use, handling, storage, transportation, and disposal of biohazardous materials and/or rDNA in research and/or teaching in accordance with USF policy.

1.1.4 Biosafety Level 4 (BSL-4) agents may not be used or stored at USF facilities dictated by the lack of qualifying facilities at USF. See Appendix B-IV of the NIH *Guidelines* for a list of these agents.

1.1.5 All work with biohazardous materials and/or rDNA will be conducted in compliance with USF IBC policy, the publications CDC/NIH *BMBL* and the NIH *Guidelines*, and 42 CFR 73, 9 CFR 121, and 7 CFR 331 for Select Agents.

Section 1.2 Scope of IBC Policy

1.2.1 This applies to USF faculty, staff, students, volunteers, visiting scientists, or vendors who are involved in any research and/or teaching activities involving biohazardous materials and/or at USF and its affiliated institutions.

Section 2.0 Biohazardous Materials

Section 2.1 Types of Biohazardous Materials that Require IBC Review and Approval

2.1.1 USF IBC review and approval is required prior to using the following biohazardous agents:

a. Recombinant or synthetic nucleic acid molecule (Section III-A-F) as defined by the *NIH Guidelines*.
b. Any microorganism (e.g., bacteria, viruses, fungi, rickettsia, protozoa, or parasites), or infectious substance, which is capable of causing death, disease, or other biological malfunction in a human, an animal, or a plant;
c. Biological Select Agents and Toxins, High Consequence Livestock Pathogens, and Restricted Plant Pathogens as identified by 42 CFR 73, 9 CFR 121, and 7 CFR 331; See the list of HHS and USDA Select Agents and Toxins
d. Any clinical materials that may contain wild poliovirus;
e. Unknown biohazards that do not appear to fall into one of the above criteria (e.g., prions or cells lines known to be infected with viruses). These will be reviewed on a case-by-case basis by the IBC chairperson and the USF Institutional Biosafety Officer (BSO).

2.1.2 All use of biohazardous materials and/or rDNA must be reviewed and approved by the IBC via BiosafetyNet on the ARC platform.

Section 3.0 Assessment and Selection of Appropriate Safeguards

3.1 The PI is responsible for conducting a preliminary risk assessment to determine the appropriate level of risk and biological and physical containment level prior to possessing or using biohazardous material(s) and/or rDNA.

3.2 The PI consults with the USF Biosafety Program regarding the risk group and biosafety containment level. The IBC determines the level of risk and appropriate

biological and physical containment levels for biohazardous materials and/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 BSO, 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 serious or continuing noncompliance with IBC policy or applicable federal regulations.

Section 6.0 Institutional Biosafety Committee (IBC)

6.0.1 An IBC is an appropriately constituted group that is designated to review the use of biohazardous materials and/or rDNA as described in an IBC protocol. The IBC is responsible for assessing biosafety containment and safety procedures in accordance with the NIH Guidelines and the CDC/NIH BMBL.

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 humans, animals, and/or plants and harmful to the environment.

6.1.2 The IBC establishes, monitors, and enforces policies, practices, and/or procedures for review of all projects involving the use of biohazardous materials and/or rDNA to assure compliance with federal, state, and local regulations and guidelines.

6.1.3 The IBC reviews and ensures approval is secured prior to the possession of and/or the use of the biohazardous materials and/or rDNA.

6.1.4 The IBC shall attempt to maintain diverse expertise to represent the community and a variety of research interests.

6.1.5 The IBC shall consult with ad hoc experts to advise the IBC, as necessary.

6.1.6 The IBC has the authority to suspend or terminate activities involving biohazardous materials and rDNA that jeopardizes the health and safety of any USF faculty, staff, students, volunteers, and visitors at USF, repeated safety violations, and/or continued noncompliance with IBC regulations and policy.

Section 6.2 IBC Membership

6.2.1 IBC members and their alternates will be selected to have collective expertise to fully evaluate the variety of biosafety risks associated with the research and/or teaching activity involving biohazardous materials and rDNA.

6.2.2 The IBC shall be composed of scientists/researchers from USF, its affiliated institutions, and representative(s) from the community.

a. The IBC must consist of at least five members; of which at least two members are not affiliated with USF but represent the interests of the surrounding community with respect to health and protection of the community and the environment.
b. The BSO serves as a voting member of the IBC.

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 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 members that have a conflict of interest must recuse themselves (except to provide information requested by the IBC) from participating in the review, discussion and vote on a protocol in which they have the conflict. At the beginning of each meeting, the IBC chairperson reads a statement regarding member conflict of interest.

6.2.6 A quorum is required to conduct routine IBC business. In order to establish a quorum, the number of committee members present must equal or be greater than 50% of the total committee membership. A motion will pass via a simple majority of members present; minority views will be recorded in the minutes.

6.2.7 IBC alternates are appointed to ensure that when a regular member is unavailable to ensure that quorum is met.

6.2.8 IBC members are expected to attend regular scheduled meetings or send their alternate. Members must notify the IBC administrative staff of planned absences prior to protocol review assignments.

6.2.9 Visitors and guests are allowed to attend IBC meetings but are not allowed to participate in the discussions unless acknowledged by the IBC Chairperson.

Section 6.3 Operational Procedures and Guidelines

6.3.1 The IBC shall adopt and adhere to the operating procedures and principles as described in the NIH *Guidelines for Research Involving Recombinant or Synthetic DNA Molecules* and the CDC/NIH ***BMBL***.

Section 6.4 Institutional Biosafety Committee (IBC) Responsibilities

6.4.1 The committee develops recommendations, operating policies, and procedures regarding the use of biohazardous materials and/or rDNA, as needed to supplement the federal, state, and local regulations and guidelines.

6.4.2 The IBC reviews the use of biohazardous materials and/or rDNA in research conducted at or sponsored by the USF or its affiliates for compliance with the applicable guidelines and regulations. The review will include:
a. assessing potential risks to health and the environment for the proposed research.
b. assessing the containment levels of the proposed research.
c. assessing the research facilities, procedures, practices, training, and expertise of personnel for safety;
d. evaluating and reclassifying the containment levels based on risk assessment;
e. discussing any biosafety concerns and resolving any biosafety issues brought before the IBC.
f. notifying the PI of the IBC determination.

Section 6.6 Chairperson/Vice Chairperson

6.6.1 The Vice President for Research & Innovation will appoint the Chairperson and Vice Chairperson. A qualified Chairperson and Vice Chairperson will be nominated as required, based on the recommendation of the BSO, the IBC Chairperson, and/or the Director of RIC. Procedures for appointment of the Chairperson and length of service are similar to regular IBC members.

6.6.2 The IBC Chairperson has the following duties:
a. conducting each meeting in an orderly manner.
b. conducting business so that each protocol is fairly and completely reviewed.
c. conducting business so that the committee reaches a decision on the disposition of each protocol.
d. authorizing correspondence on behalf of the IBC as appropriate.

Section 6.7 Institutional Biosafety Program Support Team Staff

6.7.1 The USF RIC Biosafety Program personnel/staff (BSO, et al) will serve as support staff to the IBC.

6.7.2 IBC support staff supplements the function and operation of the IBC at the direction of and under the supervision of the BSO.

6.7.3 Responsibilities of the Institutional Biosafety Program Staff:
a. screening research protocols proposed by investigators for completeness and forwarding them to the IBC for review.
b. reporting to the IBC significant problems related to accidents and illnesses, operations, or other activities involved with proposed or approved protocols.
c. assisting laboratories in conforming to pertinent regulatory guidelines and IBC policy by providing training, facility inspection, and communication of program requirements.

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.

Reports to NIH OSP shall be sent to the Office of Science Policy, National Institutes of Health, preferably by e-mail to: NIHGuidelines@od.nih.gov

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/or rDNA in the conduct of research and/or teaching activities.

6.9.2 Delegates operational authority to USF BSO as appropriate.

6.9.3 Is responsible for immediate notification to the USF Vice President for Research Innovation regarding:
   a. any serious injury/exposure to biohazardous materials and/or rDNA;
   b. major biohazardous material spills;
   c. breach of Biosafety Level 3 agents;
   d. unanticipated problems;
   e. any theft of restricted agents;
   f. any biosecurity issues;
   g. serious or continuing non-compliance with IBC policy and requirements by research investigators; or
   h. suspension or termination of IBC approval.

SECTION 7.0 Responsibilities for Safe Use of Biohazardous Materials

Section 7.1 Principal Investigator

7.1.1 The Principal Investigator (PI) is defined as a:
   a. faculty member at USF conducting research/teaching activities.
   b. faculty member at its affiliated institutions conducting research/teaching activities.
   c. student at USF submitting an approved college course project with USF faculty listed on the project.
   d. private entity that has an approved agreement for services with USF biosafety.

The PI is responsible for the activities in their laboratory.

7.1.2 The PI must ensure that all use, storage, and/or possession of biohazardous materials and/or rDNA is reviewed, and IBC approval is secured prior to initiation.

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 describe the appropriate microbiological practices and laboratory techniques to be used for the research intended.

7.1.5 The PI must complete and submit their research protocol to the IBC for review and approval. IBC protocols are submitted through BiosafetyNet on the ARC platform.

7.1.6 Prior to initiation, the PI must submit all proposed modifications to a previously approved IBC study for IBC review and approval.

7.1.7 Prior to initiating research the PI shall:

a. provide all laboratory staff and involved facilities staff with the protocol that describes the potential biohazards and the precautions to be taken.
c. train all research personnel in protocol specific procedures.
d. ensure that the protocol is followed as described in their approved protocol.

7.1.8 During the Conduct of the Research the PI shall:

a. supervise the safety performance of the laboratory staff to ensure that the required safety practices are employed.
b. report any significant problems to the IBC.
c. notify the BSO/Biosafety Manager (813) 974-5091 (during normal working hours) or the University Police using 911 (after hours) of any incident which may result in the release of biohazardous material and/or the exposure of laboratory personnel or members of the public to biohazardous materials.
d. restrict access to the laboratory when experiments are in progress to those who are trained to safely handle biohazardous materials.
e. notify the IBC of any noncompliance of the applicable regulatory requirements (federal, state, and local) and IBC policy.
f. assume responsibility for full compliance with the policy, practices, and procedures set forth in this policy manual and as described in the approved IBC protocol.

7.1.9 As part of the general responsibilities, the PI shall:

a. complete the required Biosafety training.
b. develop and implement laboratory-specific biosafety procedures and containment practices (for BSL-2 and higher).
c. ensure that all laboratory personnel understand and comply with the laboratory specific biosafety procedures.
d. ensure that all laboratory personnel who have the potential to be exposed to any biohazardous materials are informed of the potential risk and the safety procedures required to minimize that risk.

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 our Exposures, Incidents and Near Misses web page.
h. comply with shipping requirements for biohazardous materials and/or rDNA.

Section 7.2 Laboratory Worker

7.2.1 Any person working with biohazardous materials and/or rDNA or who works in a laboratory where these materials are used/stored is defined as a laboratory worker.

7.2.2 It is the laboratory staff's responsibility to:
a. complete the required Biosafety training.
b. follow laboratory specific biosafety practices and procedures.
c. inform the PI of any personal health requirements that may require implementation of safety precautions.
d. report to the PI or the lab supervisor all incidents involving biohazardous materials. (e.g., spills, exposures, etc.).

Section 7.3 Authorized Maintenance and Janitorial Personnel

7.3.1 USF Physical Plant personnel that are required to enter laboratory facilities where biohazardous materials are being used, stored, and/or disposed of (e.g., BSL-2 labs) should be informed of the potential risks associated with biohazardous materials.

If there are concerns regarding biosafety issues, these should be discussed with their supervisor, the PI, or the BSO.

7.3.2 Maintenance personnel do not have unrestricted access to Biological Safety Level 3 (BSL-3) laboratories. Any maintenance personnel who enter a BSL-3 facility must be supervised at all times.

No work with biohazardous materials and/or rDNA is allowed during a visit by maintenance personnel. BSL-3 personal protection equipment (PPE) is provided to the maintenance personnel.

7.3.3 USF Biosafety Office provides biological training annually for Physical Plant personnel.

Section 8.0 Activities Involving Recombinant DNA (rDNA) Material

8.0.1 All research involving rDNA at USF must comply with the NIH Guidelines, (published by the NIH).

8.0.2 Recombinant and Synthetic DNA as defined by the NIH *Guidelines* as:

a. molecules that
   i. are constructed by joining nucleic acid molecules and
   ii. that can replicate in a living cell, i.e., recombinant nucleic acids;
b. nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or
c. molecules that result from the replication of those described in (i) or (ii) above.”

Section 8.1 rDNA Experiments

8.1.1 Research and/or teaching involving the use of rDNA as defined by the NIH *Guidelines* must be reviewed and approved by the IBC by submitting a protocol in BiosafetyNet prior to handling agent.

8.1.2 All changes to an approved rDNA protocol must be submitted in BiosafetyNet.

No changes can be implemented in a previously approved rDNA protocol until they have been approved by the IBC.

8.1.3 rDNA protocols require full committee review, and a new protocol must be submitted at the expiration of the protocol.

8.1.3.1.1 Sections III-A to III-D (NIH *Guidelines*) are approved for a three-year period.

8.1.3.1.2 Section III-E and Section III-F (NIH *Guidelines*) are approved for a five-year period.

Section 8.2 Recombinant DNA Studies Involving Human Research Participants

8.2.1 PIs performing human gene transfer (HGT) work must adhere to the responsibilities that are detailed in the most current version of the NIH *Guidelines*.

8.2.2 The HGT protocol must be submitted via BiosafetyNet for review and approval by the IBC.

8.2.3 Experiments involving the deliberate transfer of rDNA, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into human research participants, these shall not be initiated (see definition of initiation in Section I-E-4) until IBC and IRB approval has been obtained.

8.2.3 For human gene transfer protocols, the rDNA study is assigned to two IBC members for review.

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 of Recombinant Viral Vectors with Animals

8.3.1 Investigators planning to administer rDNA to animals should visit the USF Comparative Medicine Website for additional guidance on animals.

8.3.2 Work involving laboratory animals requires USF IACUC approval and IBC approval before initiation of the animal work described in the protocol. To obtain approval to work with animals visit the USF IACUC website.

8.3.3 Animals that are infected with adenovirus or adeno-associated viral vectors, must utilize an Animal BSL-2 (ABSL-2) containment area. ABSL-2 housing is required.

a. Animals exposed to replication incompetent adenovirus or adeno-associated viral vector(s) must be housed under ABSL-2 containment practices for first the 72 hours following infection of the animal.
b. Precautions must be taken to minimize aerosol creation (e.g., emptying animal waste material, washing down cages, cleaning the room with water hoses).

8.3.4 Animals that are infected with lentiviral/retroviral vectors must utilize an Animal BSL-2 (ABSL-2) containment area. ABSL-2 housing is required.

a. Animals exposed to replication incompetent lentiviral/retroviral vector(s) as a part of the research protocol, must be housed under ABSL-2 containment practices for:
   i. the life of the study for direct administration of other viral vectors (e.g., Lentivirus, retrovirus) that are co-administered with human cells to the animals.
   ii. seven days for direct administration of other viral vectors (e.g., Lentivirus, retrovirus) that are not co-administered with human cells to the animals.
b. Precautions must be taken to minimize aerosol creation (e.g., emptying animal waste material, washing down cages, cleaning the room with water hoses).

Section 8.4 Using rDNA to Create Genetically Engineered/Transgenic Animals

8.4.1 Investigators who create genetically engineered animals (either by pronuclear microinjection of DNA, or by blastocyst microinjection of embryonic stem cells that have been electroporated with DNA, or by other methods of genetic engineering involving recombinant DNA) must submit an IBC protocol prior to initiation of the experiment.

8.4.2 Experiments involving the purchase of, or the transfer of, transgenic rodents that require Biosafety Level 1(BSL-1) containment practices are exempt from the NIH *Guidelines* and IBC registration.

Section 8.5 Using recombinant or synthetic nucleic acid molecules to Create Genetically Engineered /Transgenic Plants

8.5.1 Experiments to genetically engineered plants by rDNA methods require IBC review and approval.

8.5.2 To prevent the release of transgenic plant materials into the environment, the NIH *Guidelines* provides containment recommendations that must be implemented.

Section 8.6 Research Studies and Protocols Involving Oligonucleotides

8.6.1 All human oligonucleotide therapy protocols will be examined on a case-by-case basis by the IBC chairperson and/or BSO to determine whether they pose any biosafety issues.

Section 9.0 Activities Involving Infectious Agents

Section 9.1 Infectious Agents

9.1.1 **Definition**: Infectious/Biological Agent refers to any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsia, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or other living organism.

9.1.2 All research and teaching involving the use of infectious agents must be submitted via BiosafetyNet for review and approval by the IBC.

9.1.3 Infectious material protocols are approved for a three-year period. A new protocol must be submitted to and approved by the full committee every three (3) years.

9.1.4 The use of agents requiring BSL-3 containment will be restricted to laboratories designated as BSL-3 containment laboratories. Protocols requesting the use of BSL-3 containment facility and practices will be reviewed by the IBC.

Section 9.2 Cell Lines

9.2.1 Cell lines known to contain/express an infectious/pathogenic agent are classified at the same level as that recommended for the agent and these must obtain IBC review and approval.

9.2.2 Cell lines which are non-human in origin (excluding non-human primate NHP cell lines) and are well characterized are classified as Risk Group 1 and can be used under Biosafety Level 1 containment practices.

9.2.3 All cell lines exposed to or transformed by a primate oncogenic virus, and all viruses containing cell lines are classified as Risk Group 2 and can be used under Biosafety Level 2 containment practices.

Section 9.3 Use of Potentially Infectious Pathogens with Animals

9.3.1 Animal Biosafety Level (ABSL) Criteria. ABSL criteria must be adhered to as specified in the CDC/NIH BMBL (6th edition) when using infectious agents in animals. This work must be submitted to the IBC for review and approval.

9.3.2 Housing of animals infected with BSL-2/BSL-3 must be housed at ABSL-2/ABSL-3 for the life of the study.

Section 9.4 Transplantation of Human Blood or Blood Products into Research Animals

9.4.1 The IBC in conjunction with the Division of Comparative Medicine has implemented specific practices to be followed to reduce the risk of exposure of research faculty and staff, animal care personnel, and animals to potentially infected human tissues and/or clinical samples.

9.4.2 Samples Characterized for Pathogens Prior To Transplantation

a. If the testing results are positive for any pathogen and will be transplanted into animals, these animals must be housed in accordance with ABSL-2 practices.
b. If the testing results are positive for any pathogen, this requires an IBC protocol to be reviewed and approved.

9.4.3 Samples Not Screened for Pathogens Prior To Transplantation

a. The usage of any unscreened sample(s) of human blood or blood products in animals will require the animals to be housed under ABSL-2 containment.

9.4.4 In handling human blood or blood products the IBC recommends that samples be handled with Standard Precautions (OSHA Bloodborne Pathogen Standard). At a minimum, which should include the use of gloves, lab coats, and protective eyewear.

9.4.5 During transport of human blood or blood products, specimens must be placed inside a watertight primary container, which is then placed into a watertight, leak proof and durable secondary container for transportation, with absorbent material placed between the two containers to absorb contents of the container in case of a spill.

Section 9.5 Transplantation of Xenografts into Research Animals

9.5.1 The IBC in conjunction with the Division of Comparative Medicine has implemented specific practices to be followed to reduce the risk of exposure of research faculty and staff, animal care personnel, and animals to potentially infected human tissues and/or clinical samples.

9.5.2 Animals administered uncharacterized primary human tumor resections, tissue explants, blood, or other patient-derived xenografts are housed in ABSL-2 containment. This must be done in accordance to Comparative Medicine SOP #408

9.5.3 In handling any and all xenografts the IBC recommends that samples be handled with Standard Precautions (OSHA Blood Borne Pathogen Standard). At a minimum that should include the use of gloves, lab coats and protective eyewear.

9.5.4 During transport of xenografts, specimens must be placed inside a watertight primary container, which is then placed into a watertight, leak proof and durable secondary container for transportation, with absorbent material placed between the two containers to absorb contents of the container in case of a spill.

Section 10.0 Work with Select Agent Toxins

10.1 **Definition**: Select agents and toxins are biological agents and toxins that have the potential to pose a severe threat to public health and safety.

10.2 Protocols for the use of select agent toxins are required for all Select Agent Toxins in any amount. The protocols must be reviewed and approved by the IBC. See the permissible amounts of toxins on the CDC web site (http://www.selectagents.gov/PermissibleToxinAmounts.html).

10.3 Requirements for use must be followed as specified in the CDC/NIH BMBL, Appendix I, as the minimum containment required for this work. Containment requirements are subject to modification by the IBC.

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 reviewed and approved by the IBC prior to initiation or continuation of the protocol.

11.2 IBC meetings are held on the third Tuesday of every month. The IBC meeting schedule is available at https://www.usf.edu/research-innovation/research-integrity-compliance/committees-meeting-schedules.aspx#bio. The IBC conducts full board initial review of all protocols at a convened meeting.

11.3 A protocol must be submitted by the submission deadline. Protocols received after this date will automatically be put on the next month's agenda for review.

11.4 Protocols for biohazardous materials and/or rDNA that are limited to storage are reviewed by a designated member through an expedited process. The designated member has the discretion to request a full committee review. Prior to agent manipulation or use in research, an IBC protocol must be reviewed and approved by the IBC.

11.5 A quorum of the IBC members (or their designated alternates) must be present to conduct a convened meeting. For research to be approved, it must receive the approval of a majority of the members present at the meeting.

11.6 The IBC reviews are conducted in accordance with applicable federal, state and local requirements (e.g., NIH *Guidelines* and the CDC/NIH *BMBL 6th edition*).

11.7 The IBC uses a primary reviewer system for the initial review of new protocols (except Human Gene Transfer studies) at a convened meeting. The primary reviewer for initial reviews is responsible for:

a. conducting an in-depth review of the application and all supporting materials;
b. presenting a review of the research at the convened meeting;
c. proposing a motion of action (i.e., Approval, Requires Modifications to Secure Approval, Deferred, or Disapprove).

The IBC uses a primary and secondary reviewer system in the initial review of research involving Human Gene transfer studies.

11.8 IBC staff selects a primary reviewer based on the member's expertise. The primary reviewer cannot be listed as personnel on the IBC protocol to prevent a *Conflict of Interest*. The IBC may rely on *ad hoc* consultant(s) to review the study in the absence of IBC expertise in a particular area. Consultants will have access to all documents submitted to the IBC relevant to the protocol under review. The consultant may participate in the deliberations and make recommendations but may not vote.

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 and 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 submission of a new protocol with requested changes for review by the full IBC.

11.11 After committee review, the decision of the committee is communicated to the PI by email notification from BiosafetyNet.

11.12 **Investigator Assurance for All Approvals**: The PI, by submitting their protocol agrees to adhere to the practices and procedures as described in the protocol as it was reviewed and approved by the IBC.

11.13 Under an expedited review procedure, the IBC Chairperson and/or the BSO may review and approve on behalf of the IBC.

11.14 To continue a protocol after the expiration, a renewal of this protocol must be submitted for review and approval by the IBC prior to the expiration of the previous protocol.

Section 12.0 Amendments to an IBC Approved Protocol

12.1 All proposed amendments to an approved research protocol involving biohazardous materials and/or rDNA must be submitted to the IBC for review and approval prior to the implementation of the proposed modifications.

12.2 The IBC utilizes an Expedited Review process for the following amendments to a previously approved protocol.

a. Change in Biological Agent (must remain within the same family of agents previously approved-must not change overall BSL)
b. Change in Protocol Title

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

13.1 Laboratory Inspections are required to ensure and document that the laboratory meets the BMBL criteria for the Biosafety level.
a. If required by the granting/funding agency.
b. To establish an account to purchase items (e.g., cell lines) from a vendor and secure the BSO's signature.

13.2 Laboratory inspections for biosafety containment practices, facilities, and equipment must be conducted as part of the IBC's review and approval process for protocols requiring BSL-2 or higher. Protocols that may require a biosafety inspection are as follows:
a. All new IBC protocols unless an inspection of the lab space has occurred within a year.
b. IBC protocols with an amendment to a protocol for the addition of lab spaces.
c. Annually for IBC protocols involving infectious agents.
d. Post incident events.

13.3 All biosafety laboratory inspections will be performed in accordance with requirements published by the CDC/NIH in the BMBL for the required biosafety containment level for the biohazardous materials utilized.

13.4 Lab Inspections are not required for the following applications:
a. Human Gene Transfer studies that occur in a clinical setting. (The Biosafety office will not inspect these facilities as they defer to the inspections performed by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) as acceptable standard precautions inspections in lieu of BSL-2 at the current time for these clinical areas.)
b. rDNA protocols approved at BSL-1.

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.

Low: Unlikely to pose an immediate threat to human health and/or security of biological agents and/or toxins but are not consistent with safe and secure standards of practice.

If not corrected, such departures degrade the culture of safety and security. Repetition of departures may be considered more serious and lead to enforcement actions. A routine inspection report will be sent to the PI within 7 days of the inspection.

Section 14.0 Select Agents and Toxins

Section 14.1 Background

14.1.1 The CDC/HHS and the United States Department of Agriculture (USDA) have identified certain biological agents.
a. The CDC/HHS list of biological agents and toxins has the potential to pose a severe threat to public health and safety.
b. The USDA list of biological agents has the potential to pose a severe threat to animal and plant health and safety, or animal or plant products.
c. CDC and APHIS share responsibility for some agents because they potentially threaten both humans and animals (overlap agents).

14.1.2 A select agent may not be possessed or used in the United States (US), received from outside the US, or transferred within the US by any individual(s), academic institution, or other legal entity unless the Select Agent or Toxin is registered with CDC/HHS and/or the USDA. USF requires PIs to register BSAT with the IBC and the CDC/HHS and/or the USDA.

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 protocol in BiosafetyNet to the USF IBC for review and approval.

Section 14.3 CDC/USDA Requirements for Use of Select Agents

14.3.1 Registration is valid only for the specific BSAT, the particular activities and locations involved, and the specific individuals approved to handle or use the regulated materials listed on the application.

14.3.2 The PI must consult with the USF Biosafety Office to develop and implement agent-specific plans for biosafety, site-specific plans for security (e.g., inventory control, access control, cyber security), and emergency response.

14.3.3 As part of the federal registration process the Responsible Official (RO) Alternate Responsible Official (ARO), PI, and staff will undergo a security risk assessment that includes a background check and fingerprinting.

14.3.4 Only those individuals who have documented a legitimate need to handle or use BSAT and who have appropriate training and skills to handle such agents will be granted access to the agents.

14.3.5 There are specific requirements for record keeping, notification of transfer, theft, loss, and/or destruction.

14.3.6 The RO or AROs must conduct regular inspections of the laboratory where select agents/toxins are used or stored.

Section 15.0. Coordination with other Compliance Committees/Divisions

Section 15.1 Animal Use

15.1.1 Review by the IBC is independent of review by the IACUC. However, there is representation on both committees that communicate and coordinate regarding biosafety issues in animal studies.

15.1.2 Initiation of the animal component of the study is contingent upon securing IACUC approval.

Section 15.2 Human Subjects Research

15.2.1 Review by the IBC is independent of review by the IRB. However, there is representation on both committees that communicate and coordinate regarding biosafety issues in Human Gene transfer trials.

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** – Required for persons involved in certain types of work (e.g., BSL-3 training, shipping infectious substances, and diagnostic specimens).

Section 17.0 Non-Compliance

17.1 Information regarding non-compliance and/or deficiencies with the NIH *Guidelines*, *CDC/NIH BMBL 6th edition*, and IBC policy may be brought to the attention of the USF IBC and/or the USF Biosafety Office by any individual.

17.2 Information concerning non-compliance and deficiencies with the NIH *Guidelines*, *CDC/NIH BMBL 6th edition*, and IBC policy protects the identity of the complainant, investigator, study, or facility.

17.3 Reports regarding biosafety concerns, deficiency, and non-compliance with the NIH *Guidelines*, *CDC/NIH BMBL 6th edition*, and IBC policy are immediately forwarded to the IBC chairperson. The BSO, in consultation with the IBC chairperson and Director of RIC shall have the authority to temporarily suspend

the protocol. The IBC will meet within three (3) business days and make a recommendation on how to address the situation before work will be allowed to resume.

17.4 In cases of non-compliance that is discovered during a safety inspection, but is a low risk to individuals, the BSO will notify the PI to correct the deficiencies. In instances where the noncompliance is not corrected, a two-step process will be followed:

Step 1: The BSO will notify the PI in writing describing the deficiencies and personnel involved and a corrective action will be provided. The PI is required to notify the IBC of the status of the corrective action. The laboratory will be scheduled for a follow-up inspection by the BSO.

Step 2: If the PI does not comply, the status of the situation will be brought to the IBC.

17.5 All reports of alleged biosafety concern(s), deficiency, or non-compliance are forwarded to the IBC for investigation and corrective action. The PI is informed of the allegation in writing by the IBC Chairperson and may be invited to meet with the IBC to respond to questions regarding the alleged deficiency.

17.6 The IBC on behalf of the institution shall report to the NIH OSP:

a. any significant violations 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. for BSL-2, any spills and accidents which result in **overt exposures** to organisms containing rDNA are **immediately reported** to the IBC and NIH OSP.
c. for BSL-3, any spills and accidents which result in **overt or potential exposures** to organisms containing rDNA are **immediately reported** to the BSO, IBC, and NIH OSP.

Reports shall be sent to the NIH OSP by e-mail to: NIHGuidelines@od.nih.gov.

Section 18.0 Suspension or Termination of IBC Approval

18.1 The IBC may suspend an approved activity if it determines:

a. failure to willfully comply with federal/state regulations and/or IBC policy;
b. any activities adversely affecting the health and safety of any individual using biological materials and or rDNA;
c. the activity does not match the description originally approved by the IBC.

18.2 The IBC reviews reports of alleged deficiencies at its next monthly meeting, or the IBC Chairperson can call an emergency meeting to discuss the issue in advance of a regular meeting if deemed necessary.

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 containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
17. Ricin [6]
18. *Rickettsia prowazekii*
19. SARS-associated coronavirus (SARS-CoV) [5]
20. SARS-CoV/SARS-CoV-2 chimeric viruses resulting from any deliberate manipulation of SARS-CoV-2 to incorporate nucleic acids coding for SARS-CoV virulence factors
21. Saxitoxin [6]

South American Haemorrhagic Fever viruses:

22. Chapare
23. Guanarito
24. Junin
25. Machupo
26. Sabia

27. Staphylococcal enterotoxins (subtypes A,B,C,D,E) [6]
28. T-2 toxin [6]
29. Tetrodotoxin [6]

Tick-borne encephalitis complex (flavi) viruses:

30. Far Eastern subtype [5]
31. Siberian subtype [5]

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 Plant Protection And Quarantine (PPQ) Select Agents and Toxins

62. *Coniothyrium glycines* (formerly *Phoma glycinicola* and *Pyrenochaeta glycines*)
63. *Peronosclerospora philippinensis (Peronosclerospora sacchari)*
64. *Ralstonia solanacearum* [7]
65. *Rathayibacter toxicus*
66. *Sclerophthora rayssiae* [7]
67. *Synchytrium endobioticum*
68. *Xanthomonas oryzae*

[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, a-CnIA, a-CnIB; X1 = any amino acid(s) or Des-X; X2 = Asparagine or Histidine; P = Proline; A = Alanine; G = Glycine; X3 = Arginine or Lysine; X4 = Asparagine, Histidine, Lysine, Arginine, Tyrosine, Phenylalanine or Tryptophan; X5 = Tyrosine, Phenylalanine, or Tryptophan; X6 = Serine, Threonine, Glutamate, Aspartate, Glutamine, or Asparagine; X7 = Any amino acid(s) or Des X and; "Des X" = "an amino acid does not have to be present at this position." For example, if a peptide sequence were XCCHPA then the related peptide CCHPA would be designated as Des-X.
[3] A virulent Newcastle disease virus (avian paramyxovirus serotype 1) has an intracerebral pathogenicity index in day-old chicks (Gallus gallus) of 0.7 or greater or has an amino acid sequence at the fusion (F) protein cleavage site that is consistent with virulent strains of Newcastle disease virus. A failure to detect a cleavage site that is consistent with virulent strains does not confirm the absence of a virulent virus.
[4] Select agents that meet any of the following criteria are excluded from the requirements of this part: Any low pathogenic strains of avian influenza virus, South American genotype of eastern equine encephalitis virus, west African clade of Mpox viruses, any strain of Newcastle disease virus which does not meet the criteria for virulent Newcastle disease virus, all subspecies Mycoplasma capricolum except subspecies capripneumoniae (contagious caprine pleuropneumonia), all subspecies Mycoplasma mycoides except subspecies mycoides small colony (Mmm SC) (contagious bovine pleuropneumonia), and any subtypes of Venezuelan equine encephalitis virus except for Subtypes IAB or IC, provided that the individual or entity can verify that the agent is within the exclusion category.
[5] For determining the regulatory status of nucleic acids that are capable of producing infectious forms of select agent viruses, please reference guidance here.
[6] For determining the regulatory status of Recombinant and/or Synthetic nucleic acids that encode for the toxic form(s) of any select toxins if the nucleic acids (i) can be expressed in vivo or in vitro, or (ii) are in a vector or recombinant host genome and can be expressed in vivo or in vitro; please reference guidance here.
[7] Select agents or toxins that meet any of the following criteria are excluded from the requirements of this part: Any subspecies of *Ralstonia solanacearum* except race 3, biovar 2 and all subspecies of *Sclerophthora rayssiae* except var. *zeae,* provided that the individual or entity can identify that the agent is within the exclusion category.
[8] Modified Venezuelan Equine Encephalitis Virus TC-83(A3G) strain is a select agent.
[9] Note that this is a change in nomenclature, which is aligned with the World Health Organization decision, and does not represent a change in the listed agent.