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Compliance is Mandatory

BIOSAFETY REVIEW BOARD OPERATIONS AND REQUIREMENTS

Responsible Office: Human Health and Performance Directorate

TABLE OF CONTENTS

P.1 PURPOSE 5
P.2 APPLICABILITY 5
P.3 AUTHORITY 5
P.4 APPLICABLE DOCUMENTS AND FORMS 6
P.5 MEASUREMENT/VERIFICATION 6
P.6 CANCELLATION 6
CHAPTER 1 RESPONSIBILITIES 7
1.1 GENERAL RESPONSIBILITIES OF THE BIOSAFETY REVIEW BOARD 7
1.2 INDIVIDUAL BIOSAFETY REVIEW BOARD RESPONSIBILITIES 7
CHAPTER 2. APPROACH TO BIOSAFETY RISK ASSESSMENTS 8
2.1 DEFINITION OF BIOSAFETY 8
2.2 CLASSIFICATION OF BIOHAZARDOUS MATERIALS 8
2.3 NASA IN FLIGHT BSLS 9
CHAPTER 3 BIOSAFETY REVIEW PROCESS PROCEDURES 11
3.1 BIOSAFETY REVIEW 11
3.2 PAYLOAD ASSESSMENT REQUIREMENTS 11
3.3 ELECTRONIC HAZARDOUS MATERIALS SUMMARY TABLE (EHMST) 11
3.4 SUBMISSION OF INFORMATION FOR PAYLOAD ASSESSMENT 12
3.5 PAYLOAD ASSESSMENT PROCESS 12
3.6 HANDLING OF PAYLOAD PROPRIETARY INFORMATION 12
3.7 PAYLOAD INFORMATION SUBMISSION REQUIREMENT. 13
3.8 RE-FLOWN AND PREVIOUSLY ASSESSED PAYLOADS REQUIREMENT 13
3.9 INCORPORATION OF BSL IN COMBINED HAZARD CLASSIFICATION 13
3.10 GROUND BASED EXPERIMENT ASSESSMENT REQUIREMENTS 14
3.11 REQUIRED INFORMATION FOR GROUND -BASED EXPERIMENT ASSESSMENT 14
3.12 SUBMISSION OF INFORMATION FOR GROUND BASED EXPERIMENT ASSESSMENT 15
3.13 GROUND BASED EXPERIMENT ASSESSMENT PROCESS 15
3.15 GROUND BASED EXPERIMENT INFORMATION SUBMISSION REQUIREMENT 15
3.16 RDNA/RNA EXPERIMENT ASSESSMENT REQUIREMENTS 15
3.17 REQUIRED INFORMATION FOR RDNA/RNA EXPERIMENT ASSESSMENT 16
3.18 SUBMISSION OF INFORMATION FOR RDNA/RNA EXPERIMENT ASSESSMENT 16
3.19 RDNA/RNA EXPERIMENT ASSESSMENT PROCESS 16
3.20 HANDLING OF RDNA/RNA EXPERIMENT PROPRIETARY INFORMATION 17

3.21 RDNA/RNA EXPERIMENT INFORMATION SUBMISSION REQUIREMENT 17
CHAPTER 4 BIOSAFETY INSPECTION OF JSC LABORATORIES UTILIZING BIOLOGICAL MATERIALS 18
4.1 JSC LABORATORIES UTILIZING BIOHAZARDOUS MATERIALS 18
4.2 PURPOSE OF THE BIOSAFETY INSPECTION 18
4.3 BIOSAFETY INSPECTION CHECKLIST 18
CHAPTER 5 INVENTORY OF BIOHAZARDOUS MATERIALS 19
5.1 ALL JSC LABORATORIES UTILIZING BIOHAZARDOUS BIOLOGICAL MATERIALS SHALL SUBMIT A BIOHAZARDOUS MATERIALS INVENTORY ANNUALLY. 19
5.2 SUBMISSION OF BIOHAZARDOUS MATERIALS INVENTORY 19
5.3 BIOHAZARDOUS MATERIALS INFORMATION 19
CHAPTER 6 BIOSAFETY TRAINING 20
6.1 COMPUTER-BASED BIOSAFETY TRAINING 20
6.2 EMPLOYEES SHALL BE REQUIRED TO TAKE A REFRESHER COURSE EVERY TWO YEARS. 20
CHAPTER 7 RECORDS 21
APPENDIX A TERMS AND DEFINITIONS 22
APPENDIX B GUIDELINES FOR USE OF EXPERIMENTAL ANIMALS - JOINT REQUIREMENTS AND RECOMMENDATIONS WITH THE AGENCY VETERINARIAN 25
APPENDIX C SPECIFIC PATHOGEN FREE (SPF) REQUIREMENTS FOR FLIGHT CERTIFICATION OF MICE – PER THE AGENCY VETERINARIAN 27

Change Record Log

Revision	Date	Originator	Description of Changes
Baseline	06/2017	SK /Jane McCourt/ 281-244-9799	Initial Release
A	06/2023	SK /Jane McCourt/ 281-244-9799	Updated to include new eHMST tool for ISS description of BSLs and responsibilities of the BRB

PREFACE

P.1 PURPOSE

a. This directive addresses the safe handling, transportation, and containment of infectious microorganisms and hazardous biological materials.

b. This directive defines the requirements for submission of information used by the Johnson Space Center's (JSC) Biosafety Review Board (BRB) to identify and assess biohazardous materials utilized in spaceflight or ground-based experiments.

c. This directive defines the requirements for tracking biohazardous materials that are stored at JSC facilities and the inspection of JSC facilities utilizing biohazardous materials.

P.2 APPLICABILITY

a. This directive is applicable to all ground-based activities involving the use or storage of biohazardous materials at JSC facilities (excluding the White Sands Test Facility, Ellington Field, and the Sonny Carter Training Facility). This directive is also applicable to NASA and commercial spacecraft, habitats, and cargo vehicles that use or store biohazardous materials.

b. These requirements include, but are not limited to, BRB assessments of science experiments, government furnished equipment (GFE), spacecraft life support systems, life science experiments, and medical studies.

c. Requirements also apply to vectors such as animals, plants, and non-biological materials such as soil that may harbor biohazardous materials.

d. The requirements in this directive do not apply to astronaut food, personal preference items, or inflight vehicle systems where a BRB memo has previously provided guidance.

e. The requirements in this directive do not apply to potential or incidental ground-based exposure to biological hazards because of a complication to one's normal industrial work (such as plumber or custodian) or clinical medical functions.

f. The language in this directive applies to other contactors, recipients of grants, or cooperative agreements, or parties to other agreements, only to the extent specified or referenced in the appropriate contract grant or agreement.

g. In this directive, all mandatory actions (i.e., requirements) are denoted by statements containing the term "shall." The terms: "may" or "can" denote discretionary privilege or permission, "should" denotes a good practice, and is recommended, but not required, "will" denotes expected outcome, and "are/is" denotes descriptive material.

h. In this directive, all document citations are assumed to be the latest version unless otherwise noted.

P.3 AUTHORITY

NPR 1800.1D "NASA Occupational Health Program Procedures"

P.4 APPLICABLE DOCUMENTS AND FORMS

Biosafety in Microbiological and Biomedical Laboratories 6th Edition

JSC 27472

FRM-BRB-001- Data submission form for Ground Based Payloads

P.5 MEASUREMENT/VERIFICATION

a. To determine compliance for the submission of required information, the BRB monitors and requests missing information from researchers or payload developers (PDs).

b. To monitor biohazardous biological materials, used or stored onsite at JSC, the BRB conducts an annual review of the biohazardous biological materials inventory.

c. To ensure JSC laboratories storing/utilizing/disposing biohazardous materials are in conformance with the biosafety guidelines as outlined in the latest edition of Biosafety in Microbiological and Biomedical Laboratories an annual biosafety inspection is conducted.

d. Completion of Biosafety training is monitored by reviewing training records.

P.6 CANCELLATION

JSC 63828, Biosafety Review Board Operations and Requirements Document

Original Signed By:

_____

Michelle Frieling
Director, Human Health & Performance

Distribution:
JDMS

CHAPTER 1 RESPONSIBILITIES

1.1 General Responsibilities of the Biosafety Review Board

1.1.1 The BRB oversees ground based or spaceflight activities involving biohazardous materials.

1.1.2 The BRB's primary objective is to protect personnel, the general public, the facility, and the environment from biohazards.

1.1.3 The BRB provides biosafety and operational-level guidance to all personnel at JSC such as civil servants, contractors, visiting scientists, interns, and students.

1.1.4 The BRB monitors the inventory of onsite biohazardous biological materials, reviewing research protocols of ground-based experiments involving biohazards at JSC, and providing assistance in the shipping and receiving of biohazardous materials.

1.1.5 The BRB reviews spaceflight studies, including animal experiments (Appendix B), and vehicle systems involving biohazards and providing a biosafety assessment to the appropriate spaceflight program safety panel (e.g., International Space Station (ISS) Safety Review Panel (ISRP)).

1.1.6 The BRB meets quarterly to discuss board activities and the board also conducts an annual review of all JSC laboratories involving biohazards to ensure facilities and training of personnel are appropriate for conducting investigations utilizing biohazardous materials.

1.1.7 A link to the Center Directives Management System (CDMS) website where this directive resides shall be posted on the Biomedical Research and Environmental Division website.

1.2 Individual Biosafety Review Board Responsibilities

1.2.1 The Director of Human Health and Performance (HH&P) shall name the BRB Chairperson

1.2.2.1 The BRB chairperson shall select the Executive Officer and other board members of the BRB.

1.2.2.2 The BRB chairperson shall oversee and approve changes to this document and the functions of the BRB.

1.2.2.3 The BRB chairperson may appoint designated members to provide biological risk assessments.

1.2.3 The Executive Officer of the BRB shall provide technical expertise related to biological safety assessments, support BRB meetings, and coordinate annual reviews of JSC facilities.

1.2.4 BRB members shall provide technical support and review of current BRB activities.

A NASA memorandum, for the purpose of identifying the JSC BRB membership roster, and the mission of the BRB, shall be made available to and issued by the HH&P Directorate and distributed to stakeholders and the members of the BRB annually.

CHAPTER 2. APPROACH TO BIOSAFETY RISK ASSESSMENTS

2.1 Definition of Biosafety

Biosafety is the discipline addressing the safe handling, transportation, and containment of infectious microorganisms and hazardous biological materials. The principles of biosafety are containment and risk assessment. The fundamentals of containment include the microbiological practices, operational controls, safety equipment, and facility safeguards that protect laboratory workers, the environment, and the public from exposure to infectious microorganisms. Risk assessment is the process that enables the appropriate selection of microbiological practices, safety equipment, and facility safeguards that can prevent infections. The primary risk criteria used to define biosafety levels (BSLs) are infectivity, severity of disease, transmissibility, and the nature of the work being conducted. A general description of approaches to NASA's microbial risk assessments that guide BSL assessments can be found in *Microbial Risk Assessment Guideline: Pathogenic Organisms with Focus on Food and Water* (https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/Microbial_Risk_Assessment_Guideline_2012-001.pdf)."

Primary routes of exposure include inhalation, ingestion, cutaneous and percutaneous injury, mucous membrane, and ocular exposure

2.2 Classification of Biohazardous Materials

Biological materials are classified as either non-hazardous or biohazardous. Biohazardous materials may include bacteria, fungi, protozoa, viruses, cell cultures, recombinant Deoxyribonucleic acid (rDNA), recombinant Ribonucleic acid (rRNA), prions, microbial toxins, allergens, and others.

Vectors such as plants, animals, and some inanimate objects (e.g., soil) may harbor biohazardous agents and must be evaluated.

Biohazardous agents may be infectious and result in disease or contamination of water and food supplies or the crew environment.

2.2.1 NASA Ground-based BSLs

The NASA ground based BSL are identical to those of the Centers for Disease Control and Prevention (CDC), and the National Institutes of Health (NIH). Biohazardous materials are classified by BSL as defined in Biosafety in Microbiological and Biomedical Laboratories (latest edition). This publication was developed and distributed by the U.S. Department of Health and Human Services, the CDC, and NIH.

Biohazardous materials are classified as BSL-1 through BSL-4 risks. BSL classifications can be accessed through the CDC Web Site http://www.cdc.gov/biosafety/publications/bmbl5/index.htm, and this directive at http://www.nasa.gov/feature/biosafety-review-board-brb.

The guidelines are widely used by academia, government, and industry in the U.S. and internationally.

2.2.2 The four BSLs, categorized by CDC/NIH are described below:

a. BSL-1: Well-characterized agents not known to consistently cause diseases in healthy adults, and of minimal potential hazard to laboratory personnel and the environment.

Example: Bacillus subtilis.

b. BSL-2: Agents that pose moderate potential hazard to personnel and the environment (absence of aerosols). It includes various bacteria and viruses that cause only mild disease to humans.

Examples: Influenza, Legionella

c. BSL-3*: Indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route (applicable to clinical, diagnostic, teaching, research, or production facilities).

Examples: West Nile Virus, Mycobacterium tuberculosis

d. BSL-4*: Dangerous and exotic agents that pose a high individual risk of aerosol- transmitted laboratory infections and life-threatening disease that is frequently fatal, for which there are no vaccines or treatments, or a related agent with unknown risk of transmission.

Example: Ebola Virus

*National Aeronautics and Space Administration (NASA) does not have facilities on the ground or in spacecraft capable of providing BSL 3 or 4 protection. Thus, only BSL-1 and BSL-2 agents are allowed.

2.3 NASA in Flight BSLs

The BRB has modified the BSLs categorized by the CDC/NIH for in-flight biohazardous materials and conditions. Due to the unique environment and conditions associated with spaceflight, BSL-2 agents are divided into two classes, BSL-2M (Moderate Risk) and BSL-2H (High Risk) agents. Due to microgravity conditions, aerosols of microorganisms can be more of a risk factor in microgravity than under Earth gravity (1- g). Larger particles and droplets can be suspended as aerosols for much longer than experienced at 1-g. The NASA in-flight BSLs listed in Table 1 are applicable to all payloads containing biohazardous materials.

Table 1 includes information pertaining to NASA Hazard Levels, NASA ISRP, or appropriate safety panel Containment Levels, and that BSL-3 and -4 agents are currently not allowed on crewed spacecraft because of lack of proper containment and severe health risks.

Table 1 NASA in Flight Biosafety Levels

Allowed on NASA and commercial spacecraft, habitats, and cargo vehicles			
ISRP Risk Groups	BSL	Description	*Levels of Containment/Control
Marginal	1	Biological agents and conditions not known to consistently cause disease in healthy adults	1
Critical	2 (moderate)	Biological agents and conditions associated with human diseases. Primary routes of exposure include inhalation, ingestion, cutaneous and percutaneous injury, mucous membrane, and ocular exposure.	2
Catastrophic	2 (high)	Biological agents and conditions with specific factors that increase the risk of human disease or limit its mitigation. Risk factors include but are not limited to pathogens with elevated virulence, antibiotic resistance or conditions, and likelihood of aerosolized microorganisms. Primary routes of exposure include inhalation, ingestion, cutaneous and percutaneous injury, mucous membrane, and ocular exposure.	3
*****BSL-3 and BSL-4 are NOT Allowed on any NASA and commercial space craft, habitats, or cargo vehicles**			
Catastrophic	3	Biological agents and conditions with potential for airborne transmission. May cause life-threatening diseases.	N/A
	4	Biological agents and conditions with high potential for life-threatening diseases. High potential for aerosol transmission of agent with no prophylactic or specific therapy.	N/A

*Level of containment/control is determined by the ISRP or appropriate safety panel.

CHAPTER 3 BIOSAFETY REVIEW PROCESS PROCEDURES

3.1 Biosafety Review

All payloads containing biological materials and all ground-based experiments utilizing biological materials shall be subject to a biological risk assessment.

Each biohazardous agent/material shall be assigned a NASA BSL based on the risk assessment.

Many proteins, genetic material, etc. are considered Not Applicable (N/A) for biosafety risk grouping, but not all. Therefore, all of the biological materials to be considered for review shall be submitted for Biosafety review and should not assumed to be N/A.

3.2 Payload Assessment Requirements

All payloads manifested for flight on the ISS, other US habitable space vehicles participating in a joint mission involving the ISS, or U.S. operated spacecraft such as the Commercial Orbital Transportation System (COTS) cargo vehicle shall undergo a thorough safety assessment. The ISRP or other appropriate safety review panel conducts this assessment.

The BRB shall review all biological materials, identify biohazardous materials, provide a biosafety assessment as part of the overall safety evaluation, and report findings to the appropriate safety panel.

3.3 Electronic Hazardous Materials Summary Table (eHMST)

Data shall be submitted via the eHMST tool at https://mycmc-apps-ext.jsc.nasa.gov/eHMST/(If you do not have access to this tool, please submit a NAMS request for access to JSC – CMC External Tools).

The following information shall be provided to the BRB through the e-HMST tool to obtain an in-flight payload biohazardous material(s) assessment and biosafety rating.

a. General information

(1) Hardware point of contact(s) and e-mail address.

(2) Hardware owner

(3) HMST need date

b. Hardware information

(1) The name and number of the experiment or hardware.

(2) Orbit investigation name and ID

(3) The name and acronym of payload (if different than the name of the experiment).

(4) Brief summary of the experiment or conditions of use including process conditions.

(5) ISS hazard system (HIS) record number

c. Biological Materials Information

(1) The identification and origin of the biological material(s) to be assessed.

(2) Indicate if the biological materials are known human pathogens or contain pathogens.

(3) The BSL of the biological material, if known.

(4) The maximum concentration of each biological sample and the maximum number of samples.

(5) The American Type Culture Collection (ATCC) number(s) for the biological material(s), if known.

(6) Indicate if cell cultures of human origin are free of Hepatitis A, B, C, Human T- lymphotropic virus (HTLV) 1 and 2, and Human Immunodeficiency Virus (HIV) 1 and 2.

(7) Indicate if biological material is genetically engineered or contains recombinant or synthetic nucleic acid.

(8) Provide detailed information regarding nature of recombinant DNA /RNA

3.4 Submission of information for Payload Assessment

The required information for payload assessment shall be submitted online by creating an e-HMST submittal through the on-line e-HMST tool

Data shall be verified for accuracy before submitting.

Inaccurate or incomplete information may result in the delay of the assessment process.

3.5 Payload Assessment Process

Upon receipt of the e-HMST record by the biosafety SME, the biological materials shall be reviewed by the BRB SME or a subcommittee composed of BRB members to determine if biohazardous materials are present in the payload. The BRB shall assess the available biosafety information with the specifics of the payload on-orbit operations.

Mitigating factors that might affect the BSL level assessment may include the amount of biohazardous agent, liquid or solid growth medium used, infectivity dose, medical or spacecraft integrity consequences, proposed containment configuration, and others.

If sufficient information is not made available to the BRB, the NASA in-flight BSL may be elevated to ensure safe conditions for the crew. The containment of the biohazardous materials is determined by the ISRP. The levels of containment correlate with the NASA BRB BSL assigned to the biohazardous agents.

When two or more biohazardous agents are present in the same payload, the levels of containment required will be driven by the most hazardous (highest BSL) agent included. Under most conditions, BSL-1 agents will require 1 level of containment; BSL- 2 (Moderate Risk) agents will require 2 levels of containment; and BSL-2 (High Risk) agents will require 3 levels of containment in the payload design. All final determinations of levels of containment are made by the ISRP.

3.6 Handling of Payload Proprietary Information

Proprietary formulations are included with the understanding that the information shall be protected from non-essential disclosure.

At the time when information is submitted into the eHMST tool, the submitter shall designate, which information, if any, should be treated as proprietary. Through the tool, you will request to unlock fields for proprietary data entry. Do not enter Proprietary data into fields which are not marked "Proprietary"

If proprietary data is provided, all HW POCs /Principal Investigators named in the record and Subject Matter Experts performing assessments will be able to view proprietary data. Proprietary data is not included in any reports created by the eHMST tool.

3.7 Payload Information Submission Requirement.

BRB strives to complete all assessments in a timely manner but requests a minimum of 15 business days. If requested information required to complete the assessment is not received or is delayed, the biosafety rating may be delayed accordingly. This duration is independent of time required for other assessments that may be needed (Toxicology, Materials, or ECLSS assessments). The timeline should be taken into consideration when preparing for the review of hazardous materials for the HMST. Failure to submit supporting HMST records appropriate for the particular phased safety review may result in design impacts and/or delay of completion of the phased safety review.

Once the BRB has assessed the biological materials and determined the BSL, the record shall be returned to Toxicology for the next phase of eHMST generation.

Early submission (before the payload safety review has begun) enables the BRB to make an early biological assessment, which may help the hardware designer to ensure that planned containment and other built-in safeguards are adequate before final design or the construction of the hardware.

3.8 Re-flown and Previously Assessed Payloads Requirement

The e-HMST information shall be submitted for each payload containing biological materials whether the materials are being flown for the first time or have previously been flown and assessed.

3.9 Incorporation of BSL in Combined Hazard Classification

Once a payload has been assessed a BSL is assigned, and incorporation into the hazardous materials summary tables (HMSTs). These tables summarize the toxicity, biosafety, and flammability hazard levels. A combined hazard response level that incorporates all three potential hazards into a single labeling and spill response classification is calculated according to the table below (excerpt from flight rule B20-16).

	HRL (COLOR OF LABEL) [1]				
	0 (GREEN)	1 (BLUE)	2 (YELLOW)	3 (ORANGE)	4 (RED)
TOXICITY	0	1	2	3	4
BIO-SAFETY	1	2M	2H		
FLAMMABILITY [2]	0, 1	2, 3, 4 [3, 4]			

NOTES:

[1] NON-REACTIVE PARTICLES DO NOT PRESENT A TOXICOLOGICAL HAZARD AND ARE NOT INCLUDED IN THE HRL. HOWEVER, THEY MAY PRESENT A PHYSICAL HAZARD (DAMAGE THE EYES OR SUFFOCATION RISK). AN HRL 1 RESPONSE SHOULD BE TAKEN TO PROTECT CREW FROM PHYSICAL HAZARDS, INCLUDING BROKEN/ CRACKED GLASS.

[2] THE FLAMMABILITY HAZARD LEVEL OF A LIQUID IS DETERMINED BY A COMBINATION OF THE FLASH POINT AND VOLUME OF THAT LIQUID AND IS BASED UPON THE ASSUMPTION THAT THE ENTIRE VOLUME OF LIQUID IS SPILLED. FOR GASES, THE FLAMMABILITY HAZARD LEVEL IS DETERMINED ON A CASE BY CASE BASIS.

[3] SUBSTANCES THAT HAVE A FLAMMABILITY HAZARD LEVEL OF 3 OR 4 ARE GIVEN A FLAMMABILITY LABEL [FLAME] ALONG WITH A HAZARD LABEL BASED ON THE WORST-CASE HAZARD.

[4] WHILE THE FLAMMABILITY HAZARD LEVEL (FHL) OF A SUBSTANCE DOES NOT DRIVE A NEED FOR PPE, FHL 2-4 REQUIRE AT LEAST 2 LEVELS OF CONTAINMENT FOR CLEAN-UP, AND ARE THEREFORE DESIGNATED HRL 1.

3.10 Ground Based Experiment Assessment Requirements

All ground-based experiments utilizing biological material(s) shall be assessed by the BRB. The BRB shall designate a NASA ground based BSL to each identified biohazardous material and list the requirements for safe handling of the agent

The assessments shall enable the principal investigator to ensure that the appropriate facility and personal protective equipment are utilized, and that proper handling techniques are used when working with the identified biohazardous material(s).

All blood-borne pathogens-related exposure evaluation requests shall be directed to the JSC Occupational Health Branch.

3.11 Required Information for Ground -Based Experiment Assessment

In order to obtain a ground based biological material(s) assessment and approval, the following information shall be provided to the BRB using the ground-based data submittal form. The form is located at https://www.nasa.gov/feature/biosafety-review- board-brb

a. Contact Information: The principal investigator's name, title, organization, affiliation, location, and telephone number.

b. Experiment Information

(1) The location of the experiment.

(2) The names of personnel handling the biological material.

c. Biological Materials Information

(1) A detailed description of the biological materials and experimental protocol.

(2) The origin of the biological material.

(3) Indicate if the biological material poses any potential hazards to personnel.

(4) Indicate if humans are susceptible to infection by the biological material.

(5) Indicate if medical surveillance is required.

(6) Indicate if immunization is required.

(7) Indicate if animals will be used.

(8) Indicate if any type of regulated radiation will be used.

(9) The BSL of the biological material, if known.

(10) The maximum concentration of each biological sample and the maximum number of samples.

(11) The ATCC number(s) for the biological material(s), if known.

(12) Indicate if cell cultures of human origin are free of Hepatitis A, B, C, HTLV 1 and 2, and HIV 1 and 2.

(13) The proprietary nature of the biological data.

3.12 Submission of Information for Ground Based Experiment Assessment

The required information for ground-based experiment assessment shall be submitted online by filling out ground-based data submittal form located at, located at https://www.nasa.gov/feature/biosafety-review-board-brb

It is the responsibility of the submitter to verify the accuracy of the information. Inaccurate information may result in the delay of the assessment process. Questions regarding the submission of the form can be submitted to JSC-microbrb@mail.nasa.gov

3.13 Ground Based Experiment Assessment Process

Upon receipt of the completed ground-based data submittal form, the biological materials are reviewed by the BRB or a subcommittee composed of BRB members.

Information specific to biosafety assessments of biohazardous materials shall be used to consult data bases such as the ATCC to determine BSL of biohazardous material used in the experiment.

The actual risk associated with handling a biological agent shall depend not only on the nature of the agent, but also on the laboratory manipulations employed during its handling.

Once the biosafety assessment is completed, BRB shall send notification stating the designated NASA ground based BSL to the principal investigator and the supervisor of the laboratory where the work is to be conducted.

If sufficient information is not made available to the BRB, the designated NASA ground based BSL may be elevated to ensure safe conditions for laboratory workers.

3.15 Ground Based Experiment Information Submission Requirement

Ground based data submittal form shall be submitted to the BRB at least 2 weeks prior to the start of the experiment.

3.16 rDNA/RNA Experiment Assessment Requirements

All ground based and in-flight experiments involving recombinant DNA/RNA (rDNA/RNA) shall be assessed by the BRB.

For ground-based studies, the BRB shall compile a memorandum detailing the laboratory practices and techniques, safety equipment, and laboratory facilities that are required for the experiment according to the NIH Guidelines for Research Involving Recombinant DNA Molecules, which can be found online at https://osp.od.nih.gov/biotechnology/nih-guidelines/

For in-flight studies information shall be submitted and assessed through the e-HMST system

3.17 Required Information for rDNA/RNA Experiment Assessment

The following information shall be provided to the BRB in order to obtain an rDNA/RNA assessment and approval:

a. Contact Information: The principal investigator's name, title, affiliation, location, and telephone number.

b. Experiment Information

(1) The location of the experiment.

(2) The names of personnel handling the biological material.

(3) Has project been peer reviewed?

c. Biological Materials Information

(1) A detailed description of the biological materials.

(2) The origin of the biological material.

(3) The types of vector and the replication competency.

(4) The size and nature of inserted sequence.

(5) The nature of the encoded materials.

(6) Indicate if immunization is required.

(7) Indicate if animals will be used.

(8) Indicate if any type of regulated radiation will be used.

3.18 Submission of Information for rDNA/RNA Experiment Assessment

The required information for ground-based rDNA/RNA experiment assessment shall be submitted online by filling out the rDNA/RNA tab on the ground-based data submittal form, located at https://www.nasa.gov/feature/biosafety-review-board-brb

Questions and submission of the form can be submitted to JSC- microbrb@mail.nasa.gov.

It is the responsibility of the submitter to verify the accuracy of the information. Inaccurate information may result in the delay of the assessment process.

3.19 rDNA/RNA Experiment Assessment Process

Upon receipt of the completed ground-based data submittal form and or the combined data submittal form, the rDNA/RNA materials are reviewed by the BRB or a subcommittee composed of BRB members with expertise in rDNA/RNA.

When the rDNA/RNA biosafety assessment is completed, a BRB memorandum detailing the laboratory practices and techniques, safety equipment, and laboratory facilities that are required for the experiment according to the NIH Guidelines for Research Involving Recombinant DNA Molecules shall be sent to the principal investigator and the supervisor of the laboratory where the work will be performed.

If sufficient information is not made available to the BRB, the designated NASA ground based BSL may be elevated to ensure safe conditions for laboratory workers.

3.20 Handling of rDNA/RNA Experiment Proprietary Information

At the time when information is submitted to the BRB, the submitter shall designate, in writing with an appropriate notice affixed thereto, which information, if any, should be treated as proprietary. Proprietary information shall only be disseminated to NASA and/or contractor personnel that perform the assessment.

3.21 rDNA/RNA Experiment Information Submission Requirement

The ground-based data submittal form and/or combined data submittal form shall be submitted to the BRB at least 2 weeks prior to the experiment.

CHAPTER 4 BIOSAFETY INSPECTION OF JSC LABORATORIES UTILIZING BIOLOGICAL MATERIALS

4.1 JSC Laboratories Utilizing Biohazardous Materials

All JSC laboratories utilizing biohazardous materials shall be inspected. The Biosafety Inspection is to be conducted by members of the BRB annually.

4.2 Purpose of the Biosafety Inspection

The purpose of the annual Biosafety Inspection is to ensure that JSC laboratories storing/utilizing and disposing of biohazardous materials are in conformance with the biosafety guidelines as outlined in the latest edition of Biosafety in Microbiological and Biomedical Laboratories http://www.cdc.gov/biosafety/publications and to ensure that laboratory personnel are properly trained and are knowledgeable of the appropriate laboratory techniques, safety procedures, and hazards associated with handling biohazardous agents/materials.

4.3 Biosafety Inspection Checklist

The chairperson or executive officer of the BRB can provide a current biosafety inspection checklist prior to inspection. A review of the laboratory by the laboratory NASA Technical Monitor, Laboratory Supervisor or other designated laboratory personnel is recommended prior to the inspection.

CHAPTER 5 INVENTORY OF BIOHAZARDOUS MATERIALS

5.1 All JSC laboratories utilizing biohazardous biological materials shall submit a biohazardous materials inventory annually.

The NASA Technical Monitor, Laboratory Supervisor, or other designated laboratory personnel shall be responsible for submission of the inventory of biohazardous materials

5.2 Submission of Biohazardous Materials Inventory

The biohazardous materials inventory for each laboratory shall be submitted annually to the JSC BRB e-mail address at: microbrb@mail.nasa.gov.

The purpose of the annual biohazardous materials inventory is to maintain a centralized database where all biohazardous materials data can be stored, queried, and traced by the BRB.

5.3 Biohazardous Materials Information

The following information shall be submitted to the BRB annually for the Inventory of Biohazardous Materials:

a. Contact Information

(1) The name of the laboratory storing the biohazardous materials.

(2) The NASA Technical Monitor of the laboratory.

(3) The contract supervisor/manager of the laboratory.

b. Location of the Biohazardous Materials: The building and room number where the biohazardous materials are stored

c. Biohazardous Materials Information

(1) A detailed description of the biohazardous materials.

(2) BSLs, if known.

CHAPTER 6 BIOSAFETY TRAINING

6.1 Computer-based biosafety training

Shall be required for all new or current JSC or contract employees that work with biological materials.

6.2 Employees shall be required to take a refresher course every two years.

The “Basics of Biosafety” training module is available on System for Administration, Training, and Educational Resources (SATERN) (https://satern.nasa.gov).

CHAPTER 7 RECORDS

Records Description	Custodian	Retention Schedule
8/116 Program/Project Records spanning multiple programs	Biosafety Lead	Temporary. Destroy/Delete between 0 and 30 years after termination of last applicable program/project

APPENDIX A TERMS AND DEFINITIONS

TERM	DEFINITION
ACF	Animal Care Facility
ATCC	American Type Culture Collection
BRB	Biosafety Review Board
BSL	Biosafety Level
CARB	Cilia Associated Respiratory Bacillus
CDC	Centers for Disease Control and Prevention
CDMS	Center Directives Management System
COTS	Commercial Orbital Transportation System
DNA	Deoxyribonucleic acid
ECTRO	Ectromelia Virus
EDIM	Mouse Group-A Rotavirus
eHMST	Electronic Hazardous Materials Summary Table
FELASA	Federation of European Laboratory Animal Science Association
GFE	Government Furnished Equipment
HH&P	Human Health and Performance
HIV	Human Immunodeficiency Virus
HMST	Hazardous Materials Summary Table
HTLV	Human T-lymphotropic virus
IACUC	Institutional Animal Care and Use Committee
ICLAS	International Council for Laboratory Animal Science

TERM	DEFINITION
ISRP	International Space Station (ISS) Safety Review Panel
ISS	International Space Station
JSC	Johnson Space Center
K	K-virus
KSC	Kennedy Space Center
LCMV	Lymphocytic Choriomeningitis Virus
LDV	Lactate Dehydrogenase Elevating Virus
MAV	Mouse Adenovirus
MCMV	Mouse Cytomegalovirus
MHV	Mouse Hepatitis Virus
MNV	Murine Norovirus
MPV	Mouse Parvovirus
MTLV	Mouse Thymic Virus
MVM	Minute Virus of Mice
MYCO	Mycoplasma pulmonis
N/A	Not Applicable
NASA	National Aeronautics and Space Administration
NCR	Non-compliance Report
NIH	National Institutes of Health
OSB	Outside of board
PD	Payload Developer
PI	Principle Investigator
POLY	Polyoma Virus

TERM	DEFINITION
PSF	Program Science Forum
PVM	Pneumonia Virus of Mice

Appendix B GUIDELINES FOR USE OF EXPERIMENTAL ANIMALS - JOINT REQUIREMENTS AND RECOMMENDATIONS WITH THE AGENCY VETERINARIAN

This guideline summarizes the JSC BRB current requirements and recommendations regarding experimental animal standards and procedures as viewed in the context of past advisory group meetings on this and related topics.

All animal holding facilities and/or breeding colonies shall adhere to the guidelines and recommendations of the current National Research Council's Guide for Care and Use of efLaboratory Animals, National Academy Press (currently 2011), and the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC, Int.).

Only NASA Specific Pathogen Free (SPF) rodents shall be utilized for crewmember flight activities. The SPF criteria for mice are given in Chapter 7.

Standard SPF mice from approved vendors, as outlined in Chapter 7, per the Agency Veterinarian, shall be utilized for all crew training activities.

Other animal species proposed for flight experiments shall be considered by the JSC BRB and the Flight Institutional Animal Care and Use Committee (IACUC) on an individual basis.

Animals which are not colony or captive reared, may carry a greater variety of pathogens some of which may have undetermined zoonotic potential. The use of feral or non-colony born animals is discouraged.

Standard Microbiological Practices:

- Work Surfaces shall be decontaminated with a suitable disinfectant, that has been approved by the BRB, before and after use.
- All waste liquids, solids, tissues, syringes, and needles shall be placed in durable, leak proof, sealed containers for eventual autoclaving, incineration, or other appropriate decontamination/disposal procedure post-training, post-simulation, or post- flight. Such materials will not be transported between the animal investigation area and crew living quarters.
- Hypodermic needles and syringes shall be used only for the parenteral injection or aspiration of fluids from laboratory animals and diaphragm bottles.
- Only needle-locking syringes or disposable needle syringe units (i.e., the needle is integral to the syringe) are to be used for the injection or aspiration of fluids.
- Needles shall not be bent, sheared, or removed from the syringe following use except if an aspirate is to be transported within a syringe.
- The needle shall be removed from the syringe and appropriately discarded.
- Syringe tips shall be appropriately capped.
- Needles shall not be replaced in the plastic sheath or guard prior to disposal.
- Needle and syringe shall be promptly placed in puncture-proof container for eventual decontamination, preferably by autoclaving, before final discard.
- Personnel shall use appropriate antiseptic wet wipes or other available means for cleaning hands after handling animals, when departing the laboratory, and especially before eating.
- Street clothing, a laboratory coat (or equivalent) and appropriate protective gloves shall be worn when animals are handled.
- Facilities may have more stringent requirements for attire when working with or around laboratory animals; these standards shall apply within those facilities.

- Shorts, sandals, or opened toed shoes shall not be worn under a laboratory coat in the Animal Care Facility.

Animal Certification:

- Animals shall be certified SPF by the supplier for the organisms listed in Chapter 7.
- Rodents shall be housed appropriately in filtered cages.
- The crew shall not be exposed to animals if the sampled animals are positive for a proscribed organism.
- Animals used for crew training purposes only, shall be certified SPF by the supplier at the minimum barrier level available.
- Health reports shall be reviewed from the vendors prior to shipment to ensure that animals are free of pathogens tested for.
- Mice shall not be shipped if positive for a monitored pathogen.

In-flight Guidelines for Animal Housing Units, Animal Transportation Modules and Gloveboxes or Work Stations:

- With the improved integrity of animal enclosures and associated flight procedures, THE ROUTINE USE OF LABORATORY ATTIRE IS NOT REQUIRED.
- If anomalous situations should develop which produce free contaminants, all crewmembers shall use suitable protective measures (viz., NIOSH- approved respirator) until the particular experiment or procedure is terminated and the contaminant is satisfactorily removed from the spacecraft. This precaution is necessary in the closed microgravity environment since contamination does not remain localized in the continuous atmosphere of spacecraft.
- Particular care shall be exercised during the following procedures: Rats/Mice: Waste tray and food canister change out; cage removal; condensate bottle changes out; Glovebox/Work Station operations involving animals.
- Animal Housing Units and Glovebox/Work Stations shall be designed to filter particulate matter and keep it from exhausting into the spacecraft.
- Biological samples from animals shall not contaminate the spacecraft or crew at any time during collection, transport, and storage procedure.
- Animals transported between Animal Housing Units and Glovebox/Work Stations shall be enclosed in a carrier.
- Equipment and procedures for the housing, transport, and experimental protocol shall preclude any possibility of animal escape into the spacecraft.

Appendix C SPECIFIC PATHOGEN FREE (SPF) REQUIREMENTS FOR FLIGHT CERTIFICATION OF MICE – PER THE AGENCY VETERINARIAN

Mouse

Veterinary treatment of rodents harboring pathogens on the SPF list is generally impractical. Infected rodents may pose a risk to crew members and animal handling personnel and may pose a risk to animal welfare and jeopardize science objectives. Careful monitoring of the rodent group health is important; the recognition of an SPF- listed agent must be early enough to permit replacement of the rodent or, if necessary, the entire colony. Rodents are frequently group-caged in the vendor's barrier colony and are part of routine health monitoring programs.

Animals from Approved Vendors

Upon review by the NASA Chief Veterinarian, BRB and JSC, Kennedy Space Center (KSC) and Ames Flight IACUCs, the following commercial vendors are considered to be approved vendors for NASA SPF mice:

a. Charles River Laboratories International Incorporated (Inc.),
b. Envigo,
c. The Jackson Laboratory, and
d. Taconic Biosciences, Inc.

Approved vendors shall be selected based on their rodent health monitoring programs and significant history of maintaining healthy mouse colonies.

Approved vendor SPF verification shall consist of:

a. examination of the latest health monitoring reports from the commercial supplier to verify compliance for all pathogens (outlined in Table 7-1)

b. verification testing at the launch Animal Care Facility (ACF).

The vendor of choice shall be provided the required SPF list prior to ordering animals to assure they can provide enough animals that comply with the SPF requirement to meet mission requirements.

The health status of the animals shall be confirmed prior to placing orders. Health Verification Pre-Shipment.

Prior to shipment, vendor health reports from the preceding 18 months shall be reviewed for the areas from which the purchased animals will be shipped.

The most recent report shall be no greater than 3 months old.

Health reports shall indicate that the animals being shipped are free from the organisms specified in Table 1.

The health report review shall be conducted a minimum of 2 weeks prior to animal receipt.

Copies of health reports shall be obtained from the vendor.

Health reports shall be examined by the PD and Launch Facility Attending Veterinarian (or their designees) to assure compliance with SPF requirements prior to arrival of the animals at the NASA ACF.

Table 1 Approved Vendor SPF Requirements Pre-Shipment

MICROORGANISM	COMMENTS
Zoonotic Viruses	
Lymphocytic Choriomeningitis Virus (LCMV)	
Hantavirus	
Non Zoonotic Viruses	
Minute Virus of Mice (MVM)	
Mouse Group-A Rotavirus (Enteric Disease of Infant Mice)	
Mouse Hepatitis Virus (MHV)	
Mouse Parvovirus (MPV)	
Murine Norovirus (MNV)	
Mouse Adenovirus (MAV)	
Theiler's Mouse Encephalomyelitis Virus (TMEV)	
Sendai Virus (SV)	
Pneumonia Virus of Mice (PVM)	
Polyoma Virus (POLY)	
K-virus (K)	
Reovirus (REO)	
Ectromelia Virus (ECTRO)	
Lactate Dehydrogenase Elevating Virus (LDV)	
Mouse Cytomegalovirus (MCMV)	
Mouse Thymic Virus (MTLV)	
Zoonotic Bacteria - Primary Pathogens	
Salmonella spp.	
Streptobacillus moniliformis	
Helicobacter bilis	Screening for Helicobacter spp. is sufficient
*Spirillum minus	*Any signs of infection or concerns for exposure to Spirillum minus will mandate screening for Spirillum minus
Non- Zoonotic Bacteria - Primary Pathogens	
Bordetella. bronchiseptica	
Cilia Associated Respiratory Bacillus (CARB)	

Citrobacter rodentium	
Clostridium piliforme (Tyzzer's Disease)	
Corynebacterium kutscheri	
Helicobacter spp.	
Mycoplasma pulmonis (MYCO)	
Bacteria - Opportunistic Pathogens	
Beta Hemolytic Streptococcus. spp.	Screening for Streptococcus spp. is sufficient
Streptococcus pneumoniae	Screening for Streptococcus spp. is sufficient
Klebsiella oxytoca	Screening for Klebsiella spp. is sufficient
Klebsiella pneumoniae[1]	Screening for Klebsiella spp. is sufficient Positive result does not stop shipments for lowest barrier at Charles River, Taconic, or Jackson Labs; therefore, higher barrier mice are required.[1]
Pasteurella multocida	
Pasteurella pneumotropic	
Proteus mirabilis[1]	Screening for Proteus spp. is sufficient Not tested for at the lowest barrier at Charles River or Envigo; tested for but positive result does not halt shipping for lower two barriers at Taconic or Jackson Labs; therefore, higher barrier mice are required. [1]
Pseudomonas aeruginosa	Screening for Pseudomonas spp. is sufficient
Staphylococcus aureus[1]	Tested for but positive result does not stop shipments for lowest barrier at Charles River, Taconic, Envigo or Jackson Labs; therefore, higher barrier mice are required. [1]
Pneumocystis murina[1]	Screening for Pneumocystis spp. is sufficient Tested for but positive result does not stop shipments for lowest barrier at Charles River, Taconic, or Jackson Labs; therefore, higher barrier mice are required. [1]
Parasites	
All Endoparasites	
All Ectoparasites	
All Pathogenic Dermatophytes	

NOTE 1: Lower barrier rooms utilize different standards for animal handling than high barrier rooms, increasing the risk of infection with the noted pathogens during handling prior to shipment despite previous clean room report. The lowest barrier rooms acceptable for procurement of flight mice shall bethose that restrict shipment for a positive result of these pathogens.

Testing of Animals Post Receipt

Following receipt of the animals at a NASA launch facility, the mice that are intended for launch on or to a manned spacecraft shall be tested at receipt plus 5 to 7 days and again at Turnover (T) minus 11 days for the organisms listed in Table 7-2 SPF Test Requirements after Receipt (which is a subset of Table 7-1).

At receipt plus 5 to 7 days, fecal samples, oral swabs and body swabs shall be collected from 5% of the mice received. A minimum of one sample per shipping container is required. Samples may be pooled within a cage. These samples will be used to verify the full list of pathogens in Table 7-2.

At T-11 days, fecal pellets, oral swabs, and body swabs shall again be collected from a minimum of 5% of mice, using the same methodology as described in 7.4.2, to verify the full list of pathogens in Table 7-2.

This sampling shall be conducted 11 days prior to the nominal T date and the results from these tests will be considered valid even if there are delays in T or Launch (L).

In the event the experimental requirements dictate a late delivery of mice (i.e., the age of mice required will not allow for an earlier delivery) then:

a. The T-11 tests may be waived if there is <5 days between the R + 5 to 7 days test and the planned T-11 tests. If the amount of time between R+ 5 to 7 and T-11 is 5 days or longer, the T-11 tests shall be required.

b. If the samples cannot be collected at T-11 days due to this day falling on a weekend or holiday, the nearest day which is feasible will be used, but sample collections shall not exceed T-15 days.

Samples shall be taken from representative mice from both flight and flight contingency (scrub/turnaround) groups, with the priority of this testing to certify mice destined for flight. These groups selected for flight are from the same colony, receipt group, and flight pool as the mice used for ground controls, so they will share the flora.

All samples shall be tested by a lab that adheres to either the International Council for Laboratory Animal Science's (ICLAS) or the Federation of European Laboratory Animal Science Association's (FELASA) guidelines.

Animals shall be maintained inside a barrier facility until the time of cage load or experiment termination.

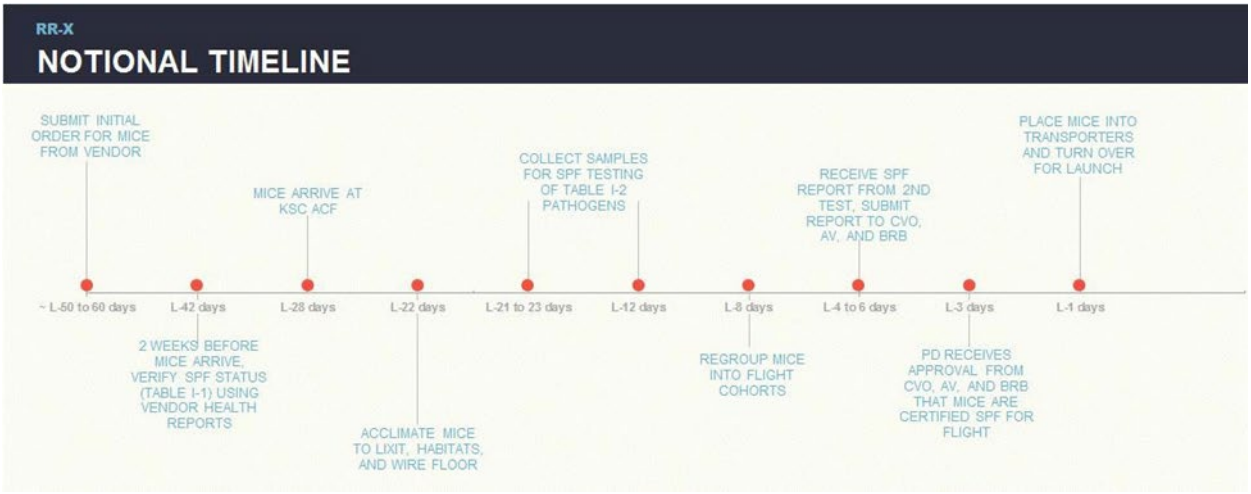

Figure 1 Notional Timeline
Certification for Flight

The PD shall confirm whether the flight candidates satisfy SPF criteria. Additional testing may be required on selected groups, at the discretion of the PD.

The PD shall prepare and submit a letter confirming the SPF status of the flight candidate animals to the NASA Chief Veterinarian, NASA Flight Attending Veterinarian, Launch Facility Attending Veterinarian and JSC BRB Chair (or their designees).

The NASA Chief Veterinarian, Flight Attending Veterinarian, and JSC BRB Chair (or their designees) shall respond with the animal SPF certification status.

The letter confirming SPF certification status shall constitute the final flight SPF certification for the animals.

The letter shall be submitted nominally by two days before turnover (T-2), but not later than T-1.

Turnover is nominally no earlier than 25 hours before launch, so T-1 corresponds to two days before launch (L-2).

Table 2 SPF Test Requirements After Receipt

MICROORGANISM	VERIFICATION METHOD
Zoonotic Viruses	
LCMV	Fecal PCR/ Oral swab/ Body swab
Hantavirus	Fecal PCR/ Oral swab/ Body swab
Non Zoonotic Viruses	
Minute Virus of Mice (MVM)	Fecal PCR/ Oral swab/ Body swab
Mouse Group-A Rotavirus (EDIM)	Fecal PCR/ Oral swab/ Body swab
MICROORGANISM	VERIFICATION METHOD
Mouse Hepatitis Virus (MHV)	Fecal PCR/ Oral swab/ Body swab
Mouse Parvovirus (MPV)	Fecal PCR/ Oral swab/ Body swab
Murine Norovirus (MNV)	Fecal PCR/ Oral swab/ Body swab

Mouse Adenovirus (MAV)	Fecal PCR/ Oral swab/ Body swab
Theiler's Mouse Encephalomyelitis Virus (TMEV)	Fecal PCR/ Oral swab/ Body swab
Zoonotic Bacteria	
Campylobacter spp.	Fecal PCR/ Oral swab/ Body swab
Leptospira spp.	Fecal PCR/ Oral swab/ Body swab
Salmonella spp.	Fecal PCR/ Oral swab/ Body swab
Streptobacillus moniliformis	Fecal PCR/ Oral swab/ Body swab
Non-Zoonotic Bacteria	
Clostridium piliforme (Tyzzer's Disease)	Fecal PCR/ Oral swab/ Body swab
Helicobacter spp.	Fecal PCR/ Oral swab/ Body swab
Pasteurella pneumotropic	Fecal PCR/ Oral swab/ Body swab
Zoonotic Ecto Parasites	
Fur mite - Mobia musculi	Fecal PCR/ Oral swab/ Body swab
Fur mite - Myocoptes musculinus	Fecal PCR/ Oral swab/ Body swab
Fur mite - Radfordia spp.	Fecal PCR/ Oral swab/ Body swab
Zoonotic Endo Parasites	
Protozoan - Giardia spp.	Fecal PCR/ Oral swab/ Body swab
Protozoan - Spironucleus spp.	Fecal PCR/ Oral swab/ Body swab
Non- Zoonotic Endo Parasites	
Pinworm - Syphacia obvelata	Fecal PCR/ Oral swab/ Body swab
Pinworm - Aspiculuris tetráptera	Fecal PCR/ Oral swab/ Body swab

Table 3 SPF Testing and Related Activities Schedule of Mice for Sentinels and Launch Nominal Group (LNG)

Date	AnimalGroup	Sample Size	Activity and Comments
PRIOR TO ANIMAL RECEIPT (VENDOR TESTING)			
Prior to order	N/A	N/A	Provide vendor with NASA SPF requirements in Table 7-1.
A minimum of 2 weeks prior to receipt	Vendor	N/A	Review of vendor health status reports for routinely tested pathogens (Table 7-1).
UPON ANIMAL RECEIPT PLUS 5-7 days			
5 to 7 days after receipt of animals	All Received	Collect fecal pellets, oral swabs and body swabs for a minimum of 5% of mice.	Perform SPF testing for pathogens in Table 7-2 on animal feces and swabs; no serology required.

11 DAYS BEFORE TURNOVER			
11 days before turnover (T) [1]	All	Collect fecal pellets, oral swabs, and body swabs for a minimum of 5% of mice.	Perform SPF testing for pathogens in Table 7-2 on animal feces and swabs; no serology required.
T-5 to T-3			Payload Developer (PD) submit SPF testreport to NASA Chief Veterinarian, FlightAttending Veterinarian, Launch Facility Attending Veterinarian and JSC BRB Chair.
T-2 days			PD receives approval from NASA Chief Veterinarian, Flight Attending Veterinarian and BRB Chair. Mice are certified as SPF.
Turnover (L-25 hrs.)			Turnover of mice for Transporter loadingand Launch.
NOTE 1: If the samples cannot be collected at T-11 days due to this day falling on a weekend or holiday, the nearest day, which is feasible will be used, but sample collection shall not exceed T-15 days.			

Animals from Non-Approved Vendors

Occasionally, a certain strain of mouse may be required that is only available from a non-approved vendor such as a university or biotech facility.

The SPF requirements are the same, regardless of the source of the animals.

Upon initial consideration of the use of a non-approved vendor, the non- approved vendor shall be provided the NASA SPF requirements so that an assessment can be made with regard to the vendor's ability to comply.

The NASA Flight Attending Veterinarian and Attending Veterinarian at the receiving facility shall be notified of this consideration.

Health reports for a minimum of the previous 18 months, with the latest report having been conducted within the last 3 months shall be obtained.

The vendor shall be required to complete additional testing if their routine health monitoring does not address all organisms on the NASA SPF list.

All testing shall be performed at an independent lab, approved by NASA for SPF testing and that adheres to either ICLAS or FELASA diagnostic guidelines.

Testing of these animals shall be completed in sufficient time to quarantine or re-derive animals if required.

If the animals are determined to be compliant with the NASA SPF list, the vendor may be approved for use on the specific mission and the SPF confirmation shall be followed per Table 7-3.

If the initial health report from a non-approved vendor indicates a positive test result for any excluded NASA SPF pathogen or if direct transfer of the animals from the non-approved vendor to the receiving facility is not approved by the Flight Attending Veterinarian or the receiving facility Attending Veterinarian, the principal investigator (PI) shall be given the option to re-derive the strain at a commercial vendor.

It is important to note that if an animal is coming from a non-approved vendor and there is a concern about the accuracy of the health report, re-derivation may be the best method to ensure compliance.

Re-derivation shall be considered on a case-by-case basis, as there will be variations in time required, cost, the number and age of the animals that are needed depending on the strain and experimental requirements.

Investigators that are not obtaining animals from approved vendors shall factor this time and expense into their schedule.

SPF Waiver Process

All rodent payloads shall be subject to the requirements outlined in this chapter.

If a PD cannot meet the requirements as outlined for scientific reasons and wishes to seek a waiver, the process as outlined in Table 7-4 shall be followed.

For Non-Zoonotic Species Pathogen waivers, approval shall be obtained from the NASA flight IACUC, the launch site ACF IACUC, the Vehicle Control Board (VCB) if the experiment is conducted in NASA provided facilities, and the Program Science Forum (PSF) for science impact determination.

For Zoonotic and Opportunistic Species Pathogen waivers, approval from the ISRP shall be obtained.

The approvals may shall be sought concurrently.

Responses to time critical requests may be needed within less than 24 hours, and may be confirmed outside of board (OSB) (for ISS Program boards) or via a designated member review of the IACUC.

Table 4 SPF Waiver Approving Boards and Methods

Approving Authority	PD Process	Approval Method
		Non-Zoonotic Species
NASA Flight IACUC	PD submits a request to include pathogen waiver in IACUC protocol (or protocol amendment)	Approval from IACUC or designated member review.
ACF IACUC	PD submits a request to include pathogen waiver in IACUC protocol (orprotocol amendment)	Approval from IACUC or designated member review.
VCB	PD presentation to board for review of impacts to NASA research facilities.	Approval at Board, or by chair OSB
PSF	PD representative presents proposed SPF violation with BRB assessment. VCB representative presents hardware	Approval to proceed with waiver request is by consensus of PSF board.

	and facility impacts with cleaning plan.	
Zoonotic and Opportunistic Species		
NASA Flight IACUC	PD submits a request to include pathogen waiver in IACUC protocol (orprotocol amendment).	Approval from IACUC or designated member review.
ACF IACUC	PD submits a request to include pathogen waiver in IACUC protocol (orprotocol amendment).	Approval from IACUC or designated member review.
VCB	PD presentation to board for review of impacts to NASA research facilities.	Approval at Board, or by chair OSB
PSF	PD representative presents proposed SPF violation with BRB assessment. VCB representative presents hardware and facility impacts with cleaning plan.	Approval to proceed with waiver request is by consensus of PSF board.
ISRP	PD submits a Non-compliance Report (NCR) to ISRP.	ISRP recommends acceptance or non-acceptance of NCR after consultation with BRB. May require ISS Program Manager Approval.