

National Aeronautics and Space Administration

Headquarters

Washington, DC 20546-0001



September 28, 2020

Reply to attn. of: Office of Communications

Russ Kick
New England Anti-Vivisection Society
333 Washington Street
Suite 850
Boston MA 02108

Re: FOIA Tracking Number 20-HQ-F-00697

Dear Mr. Kick:

This is our final response to your Freedom of Information Act (FOIA) request to the National Aeronautics and Space Administration (NASA), dated July 28, 2020, and received in this office on July 29, 2020. You seek:

For the most recent annual meeting of the Animal Policy Review Board (located within the Medical Policy and Ethics Division), we request: the agenda, the minutes, documents supplied to participants, all presentations (such as PowerPoint presentations), and all reports and memos issued based on this meeting.

In response to your request, we conducted a search of NASA's Office of The Chief Medical Office (OCHMO). That search identified records responsive to your request. We reviewed the responsive records under the FOIA to determine whether they may be disclosed to you. Based on that review, this office is providing the following:

17 page(s) are released in full (RIF);¹
11 page(s) are released in part (RIP);

Animal Policy Review Board

Meeting Agenda

March 18, 2020

9:00 AM PST

b6

MEMBERS

b7c, b7f, b6

b7c, b7f, b6

b7c, b7f, b6

GUESTS

b7c, b7f, b6

DISCUSSION ITEMS

Time	Item	Owner
9:00 a.m.	Opening Remarks	b7c, b7f, b6
9:10 a.m.	Center Updates	
	KSC	b7c, b7f, b6
	JSC	b7c, b7f, b6
	ARC	b7c, b7f, b6
	Flight	b7c, b7f, b6
	EVMS	b7c, b7f, b6
	Roskamp	TBD
9:50 a.m.	Review of September 2019 Minutes	b7c, b7f, b6
10:00 a.m.	Transportation	b7c, b7f, b6
10:10 a.m.	FOIA	b7c, b7f, b6
10:20 a.m.	Foodbar/DI Water	b7c, b7f, b6
10:30 a.m.	Roskamp Facility	b7c, b7f, b6

Animal Policy Review Board Meeting Agenda

March 18, 2020

9:00 AM PST

b6

10:40 a.m.	Future Manifest	b7c, b7f, b6
10:50 a.m.	BREAK	
11:10 a.m.	Changes in CASIS	b7c, b7f, b6
11:20 a.m.	JAXA	b7c, b7f, b6
11:30 a.m.	Housing Guidelines Discussion	b7c, b7f, b6
11:40 a.m.	Hardware Changes	b7c, b7f, b6
11:50 a.m.	VVC	b7c, b7f, b6
12:00 p.m.	Formulary	b7c, b7f, b6
12:10 p.m.	Occupational Health and Safety	b7c, b7f, b6
12:20 p.m.	NPR	b7c, b7f, b6
12:30 p.m.	Bion M2	b7c, b7f, b6
12:40 p.m.	International Standards and COSPAR	b7c, b7f, b6
12:50 p.m.	COVID-19	b7c, b7f, b6
1:00 p.m.	Looking Ahead	b7c, b7f, b6

**Animal Policy Review Board
Semi-Annual Meeting Minutes**

Teleconference
9:00 am- 1:00 pm PST
March 18, 2020

APRB Members:

[REDACTED], HQ
[REDACTED], HQ
[REDACTED], ARC
[REDACTED], KSC
[REDACTED]

[REDACTED], KSC
[REDACTED], KSC
[REDACTED], ARC
[REDACTED], JSC
[REDACTED]

[REDACTED], JSC
[REDACTED], JSC
[REDACTED], ARC
[REDACTED], ARC

APRB Guests:

[REDACTED], ARC
[REDACTED], JSC
[REDACTED], KSC
[REDACTED], KSC
[REDACTED], ARC
[REDACTED], ARC
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[REDACTED], KSC
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[REDACTED], JSC
[REDACTED], ARC
[REDACTED], EVMS
[REDACTED], HQ
[REDACTED], HQ
[REDACTED]
[REDACTED], KSC
[REDACTED], OZ
[REDACTED], KSC
[REDACTED]

Discussion Topics

Opening Remarks [REDACTED]

KSC, JSC, ARC, Flight, Roskamp, EVMS Center Updates [REDACTED]
[REDACTED]

Approval and Review of Sep 2019 Minutes All

Transportation [REDACTED]

FOIA [REDACTED]

Foodbar/DI Water	b7c, b7f, b6
Roskamp Facility	b7c, b7f, b6
Future Manifest	b7c, b7f, b6
Changes in CASIS	b7c, b7f, b6
JAXA	b7c, b7f, b6
Housing Guidelines Discussion	b7c, b7f, b6
Hardware Changes	b7c, b7f, b6
VVC	b7c, b7f, b6
Formulary	b7c, b7f, b6
Occupational Health and Safety	b7c, b7f, b6
NPR	b7c, b7f, b6
Bion M2	b7c, b7f, b6
International Standards and COSPAR	b7c, b7f, b6
COVID-19	b7c, b7f, b6
Looking Ahead	b7c, b7f, b6

Opening Remarks/Updates

b7c, b7f, b6 called the meeting to order at 9:05 am PST. Members and guests were thanked for participating. The animal program is dynamic, and many new issues have come up since the September 2019 meeting.

Center Updates

- **KSC,** [REDACTED]
Submitted annual report for AAALAC. USDA Annual Report of Research Facilities was submitted December 1. Scientist and Alt-AV were added to IACUC members. SpaceX-19 Launched 12/5/2019, and SpaceX-20 launched 3/6/2020. JAXA contingency plan has not been implemented yet, but the PI team is staying in the US to improve chances of continuing project upon LAR. 15 total protocols for FY 2020: 5 flight, 1 ground, 1 pre-flight trial run, 8 wildlife.
- **JSC,** [REDACTED]
Crew training protocol is the main AUP. Two new AUPs approved. Animal care personnel are considered essential and are allowed onsite during Stage 3 to care for animals. Animals will be dispositioned if the center moves to Stage 4. Training is considered mission critical at this point. AUP approved to investigate alternatives for RR22 skin biopsy on orbit. Possible other AUP with liver mice delayed.
- **ARC,** [REDACTED]
40 active AUPs with several USDA species. Full AAALAC accreditation. Filed annual report with USDA. Completed semi-annual review over telecom and facility inspection by subcommittee. Several procedures were modified in ACF due to COVID-19, including increased PPE and minimizing time spent onsite.
- **Flight,** [REDACTED]
VVC policy developed, and 3 requests approved by VVC. 2 new protocols were approved, 1 renewal. MOU with OLAW in progress. Photo doc policy and AUP review in progress. No new departures.
- **EVMS,** [REDACTED]
The school is closed to students currently due to COVID-19. Otherwise up to date.
- **Roskamp,** [REDACTED]
The Roskamp Institute is a nonprofit neuroscience institute, once part of University of Southern Florida. Readiness review is scheduled for the beginning of June. They still hope to be ready for Fall launches of RR23 and RR10, assuming current events do not necessitate a later launch date.

Review and Approval of September 2019 APRB Minutes

Members suggested edits to the September minutes.

Action: Members will email edits and points for clarification to [REDACTED]

Transportation

The board discussed effects of transporting controls from KSC to Roskamp. PIs are concerned this trip could impact animals and data. Roskamp and Leidos are drafting requirements for transport with commercial vendors. Requirements will be reviewed by IACUCs prior to implementation.

One transportation requirements document was levied on Leidos contract. Leidos found discrepancies between this document and what their contract stipulated.

In the future, we should encourage PIs to accommodate Atlantic splashdown and work in KSC. While this approach may not work for some studies, this may overall reduce the strain of transportation.

Action: b7c, b7f, b6 will share transportation document with group.

FOIA

Photos and videos are records and thus subject to FOIA requests. The legal office determines what will be released after receiving a request. There was some confusion about how a FOIA request is handled at NASA, so b7c, b7f, b6 will clarify the process. We anticipate requests will increase as the program grows.

A guest asked if there was a requirement to archive health check videos. This was discussed, and b7c, b7f, b6 said that while no requirement exists, the videos are valuable and should be kept.

Action: b7c, b7f, b6 and b7c, b7f, b6 will draft a summary document detailing how FOIA process is handled, and the proper route to take when a FOIA request is received

Food Bar/DI Water

With the release of the Food bar Report, changes are currently being implemented to prevent the issue from happening again. Currently, new vendors are being evaluated. The plan is to reduce moisture content and move toward industry standard composition. Ideally, we could use a commercially available product. A member stated the importance of finding literature to support significant changes such as this.

A member asked if it was possible to switch to pelleted rodent chow which is more in line with industry standards. b7c, b7f, b6 said this is possible, and there are no concerns from a functional perspective. The goal is to find an option with the least number of modifications to reduce risk of complications. Another mold incident could shut down the RR program.

Concerns were raised for incisor growth on long duration missions utilizing soft food.

OZ will update contract to include RO water. Roskamp and EVMS use RO. ARC and JSC use tap water. KSC uses both RO and DI.

Action: b7c, b7f, b6 and b7c, b7f, b6 will discuss RO/DI water at a later date.

Roskamp Facility

Roskamp is a nonprofit neuroscience institute, which was once part of USF. Research includes Alzheimer's, TBI, and other neurological abnormalities. They collaborate frequently with the commercial sector.

Future Manifest

RR23 and RR10 will fly together on same vehicle. This will be the first time male and female mice are housed concurrently (not co-housed) on orbit (males for one protocol, female for another). While literature shows a risk of pheromone interactions to housing males and females in proximity, the practical reality is that the risk is not enough to prevent the experiments from flying together.

The program will likely see overlapping missions in the future. No anticipated mission delays due to COVID-19 because RR missions are classified as essential. Setbacks are only anticipated if there is an infection risk to flight crew.

Changes in CASIS

There are no drastic changes in CASIS. An independent review team has been implemented.

Rats were requested, but the team determined that mice are a satisfactory model for the study in question. There is no restriction on flying rats. The habitat can accommodate small rats in small numbers, but they need regular handling to reduce bite risk. Contracts might need updating to include rats. A better definition of timeline must be developed if rats are to be used. It was also noted that HRP is considering using rats.

Will wait until return of RR23 and RR10 to make any official changes to guidance regarding flying mixed sexes.

JAXA

Japanese Department of Agriculture treated JAXA mouse carcasses as agricultural supply. Process was very slow, but the carcasses were eventually returned to JAXA.

Housing Guidelines Discussion

Science requirements will change hardware configuration. Need to inform CVO and FIACUC prior to engaging engineering for anticipated changes. There may be deviations from standard housing, which will need to be justified, in addition to addressing animal welfare concerns that may come from changing the current housing.

Xenogriss **b4**

b4

Hardware Changes

Hardware changes need to be run by CVO before implementation, before even consulting engineering.

VVC

Veterinary Verification and Consultation (VVC) policy was approved by the FIACUC in December 2019. This policy allows for small changes to pass quickly and efficiently, thus making it easier for the PI team and stakeholders to continue their studies. The FIACUC requires documentation of the process within 5 days of veterinary consultation.

The FIACUC approved VVC policies to extend food bar change-out, water refill, and habitat changeout. So far, these policies have introduced flexibility when the crew schedule is in conflict.

Formulary

OLAW allows IACUCs to develop drug formularies. The FIACUC is developing a formulary for anesthesia and analgesics to be used in orbit. The veterinarians from each site will meet in the near future to finalize the formulary.

Occupational Health and Safety

The IACUC has a mandate to ensure OHS program exists and covers workers adequately. Recently, a habitat cleaning was observed. The engineers wore minimal PPE by animal user standards, and the cleaning process raised several concerns. OHS Code Q was brought in to evaluate and are currently in the process of revising ATOPs to address the concerns.

Personnel cannot waive compliance with PPE requirements once informed of the risks. They must either comply or refuse all tasks related to exposure. The same OHS requirements need to be levied on all contracts.

Action: b7c, b7f, b6 to draft common OHS language to apply to all contracts

NPR

The NPR will be finalized in a few weeks. The APRB Charter is now on the OCHMO website, along with the Sundowner report.

Websites for the CVO and FIACUC are currently in the works. A NASA moratorium is in effect against the creation of new websites, so administration is exploring various workarounds.

Bion M2

Bion M2 is a joint project with Russia. Eight projects have been selected to fly. This vehicle will fly mice 3 times higher than the ISS. We must ensure that activities do not require pre or post-intervention, as there will no opportunity to intervene during flight. Some projects need refinement in this regard.

Russians will collect video, though NASA will not have access to this without negotiations. A member noted that some videos were posted to YouTube after the last mission.

International Standards and COSPAR

International partners are only bound by our regulations if they are using NASA crew and hardware. Otherwise, our regulations do not apply.

COVID-19

COVID-19 will impact how we conduct business over the next months. Since animal projects are minimal at this time, facilities have been asked if they have a surplus of masks and PPE to share with the clinic.

Looking Ahead

b7c, b7f, b6 will be transitioning to **b7c, b7f, b6** position in OZ, as he takes on a new role. She has 10 years of experience in ON, and some rodent experience working with NG projects. **█**
b7c, b7f, b6 thanked **b7c, b7f, b6** for his contributions to the program.

APRB will meet again in fall 2020 for a 2-day, in-person conference. A date will be set after the centers reopen from COVID-19.



JACOBS
TOSC Team

Animal Policy Review Board KSC Animal Care Program

[REDACTED], IACUC Chair
[REDACTED], Attending Veterinarian
[REDACTED], Animal Care Program Lead

March 18, 2020

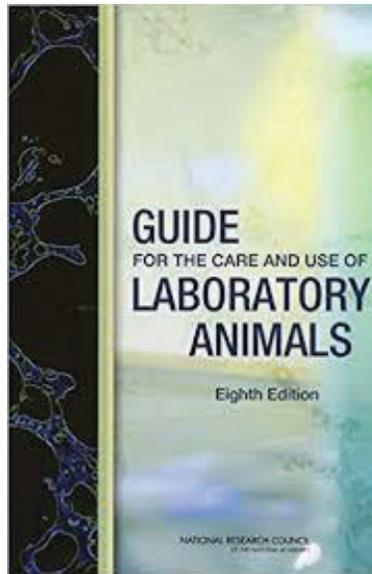
KSC Animal Care Program

- AAALAC International Status
 - Site Visit: Summer Trimester 2020
 - Program Description Update Complete
 - Annual Report Submitted January 2020
- Current PHS - OLAW Status
 - Assurance Letter Approved 2018 (Expiration: September 30, 2022)
 - Annual Report Submitted January 2020
- USDA
 - Annual Report of Research Facilities Submitted December 1, 2019
 - No species were housed at KSC that are regulated by the Animal Welfare Act, however reported the wild mice.



KSC Animal Care Program

- IACUC Membership Changes
 - Alternate to the KSC Attending Veterinarian
 - Scientist



KSC Animal Care Program

- FY 2020 Flight Activities

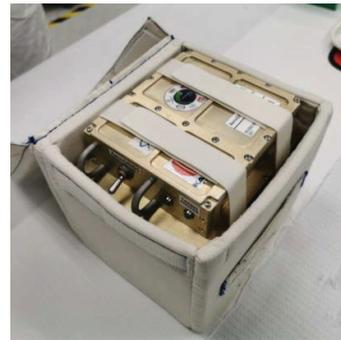
- SpaceX-19 Launch 12/5/2019

- Rodent Research-19
 - XenoGRISS



- SpaceX-20 JAXA MHU5 Launch 3/6/2020

- Coronavirus Pandemic Preparedness



KSC Animal Care Program

- Protocols FY 2020: 15 Total
 - Flight: 5 Total – Mice, Cephalopod(Squid)
 - 2 RR Series (RR-19 *complete*, RR-10 SpaceX-21 Roskamp preflight)
 - 2 JAXA Series (MHU5 *complete*, MHU6 *in review*)
 - 1 Squid (SpaceX-22; Flight includes an EVT and SVT– review in process)
 - Ground (Flight Related): 1 Total – Cephalopod(Squid)
 - 1 Squid Ground protocol – review in process
 - Squid will be added to the KSC ACP
 - Pre-Flight Facility Trial Run: 1 Total - Mice
 - 1 JAXA Series (MHU6 FTR *complete*)



5



JACOBS
TOSC Team

KSC Animal Care Program

- Wildlife Studies: 8 Total (long-term)



- Herpetological Surveys on KSC

- Gopher Tortoise Relocations and Research on KSC

- Long-term Population Dynamics of the Florida Scrub-Jay (*Aphelocoma coerulescens*) on KSC

- Assessment of the American Alligator (*Alligator mississippiensis*) at the KSC

- Small mammal community dynamics, demography, gene flow, homerange, habitat management, and occupancy of the southeastern beach mouse (*Peromyscus polionotus niveiventris*) and the Florida mouse (*Peromyscus floridanus*) on the KSC/Merritt Island Wildlife Refuge.



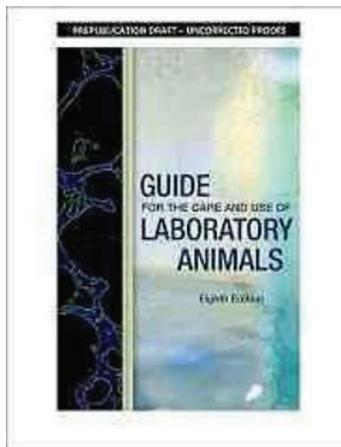
KSC Animal Care Program

- Relative Abundance and Distribution of Marine Turtles Inhabiting Mosquito Lagoon (Chelonia mydas and Caretta caretta)
- Applying Autonomous Acoustic Telemetry to Evaluate Seasonal and Daily Movements of Estuarine Sportfish at KSC, FL.”
- Small mammal community responses to NASA, contractor, and commercial operations and restoration projects on KSC



KSC Animal Care Program

- Departures from the Guide
 - Rodent Research
 - Caging Size: Ground Transporter & Habitat
 - JAXA
 - No Enrichment
 - Single Housing



FIACUC Veterinary Verification and Consultation (VVC) Policy
and
Administrative Animal Number Increases (AANI) Policy

I. Background

The Office of Laboratory Animal Welfare (OLAW) issued a “Guidance on Significant Changes to Animal Activities” (NOT-OD-14-126) which was developed to support the use of performance standards and professional judgment to reduce regulatory burden on the Institutional Animal Care and Use Committee (IACUC) without the need for Full Committee Review (FCR) or Designated Member Review (DMR). The Guidance describes two new administrative processes that allow some significant modifications to be incorporated into previously approved protocols without having to utilize FCR or DMR. These eligible modifications must be clearly supported by FIACUC-approved policies (e.g., guidance documents, standard operating procedures, drug formularies), which must be written, reviewed and approved by the FIACUC at least every 3 years. Their incorporation into an approved animal care or use activity and their documentation must follow established FIACUC-approved processes described in this policy.

Per NOT-OD-14-126, significant modifications to animal activities may be managed by three methods:

1. **Classic Process - Full Committee Review (FCR) or Designated Member Review (DMR):** Some specific significant modifications, defined by OLAW and the USDA, **MUST** be reviewed and approved by either FCR or DMR. All FIACUC members must be given the opportunity to request FCR. If any FIACUC member requests FCR, the modification must be review at a convened meeting of a quorum of the membership. In the absence of a request for FCR, the FIACUC Chair may designate at least one trained and qualified FIACUC member to conduct the review on the FIACUC’s behalf.
2. **Veterinary Verification and Consultation (VVC):** Some significant modifications, defined by OLAW and the USDA, **MAY** be administratively managed using an IACUC-established mechanism of VVC as long as the modifications are eligible for VVC and are within the scope of a corresponding FIACUC policy and appropriate for the animals on study.
3. **Administrative Animal Number Increases (AANI):** Requests for increases in animal numbers **MAY** be administratively managed using an IACUC-established mechanism of allowing additional numbers of animals as long as the increase is covered by an existing FIACUC policy on allowable increases.

The two administrative review methods, which are embraced by both OLAW and USDA, require established FIACUC-approved processes and corresponding FIACUC-approved policies that address the corresponding significant modifications. These administrative review methods do not change what constitutes a significant modification. They have no impact on veterinary interventions. They are optional.

The VVC method is to be used to manage eligible significant modifications, designated by OLAW and the USDA, to procedures already described in an approved protocol. VVC may not be used to add new procedures. New procedures must be reviewed and approved by FCR or DMR methods.

During the VVC process, the Attending Veterinarian (AV) or other authorized veterinarian(s) serves as a subject matter expert to consult with the Principal Investigator (PI) and to verify that the significant modification is in compliance with a FIACUC-reviewed and approved policy and the significant modification is appropriate for the animals in the specific circumstance. This veterinary consultation must be documented and retained on file with the corresponding FIACUC-approved protocol.

During the verification step, if a request for a significant modification does not comply with a FIACUC-approved policy, the authorized veterinarian may consult with the PI to recommend a revision to the desired modification that is within the scope of the policy and the species and circumstance are appropriate. If the significant modification is not supported by a FIACUC-approved policy or cannot be

revised to do so, the veterinarian must refer the request to the FIACUC. Note, the authorized veterinarian is at liberty to defer a request for a significant modification to the FIACUC for review at any time and for any reason even if a corresponding FIACUC-approved policy exists.

II. Purpose

This policy defines those significant modifications that must be reviewed and approved by FCR or DMR.

This policy defines those significant modifications that are eligible for management by the VVC process.

This policy describes the FIACUC-established VVC process that authorizes the Attending Veterinarian (AV) or other trained and qualified veterinarian authorized by the FIACUC to allow the initiation of eligible significant modifications, supported by specific FIACUC-approved policies.

This policy describes the FIACUC established Administrative Animal Number Increases (AANI) process that allows Increases in animal numbers to be managed administratively according to an existing FIACUC policy WITHOUT additional consultation or IACUC-notification.

Overall, the VVC and AANI methods of review are intended to help avoid delays, reduce the risk of compromising research, permit a modification to be extended to all animals under a given protocol, and reduce regulatory burden.

III. Significant modifications that must be reviewed by FCR or DMR methods

Per NOT-OD-14-126, significant modifications that must be reviewed and approved by the classic methods of FCR or DMR include, but are not necessarily limited to:

1. A change from non-survival to survival surgery
2. Any change resulting in greater pain, distress, or degree of invasiveness
3. A change in housing and/or use of animals in a location that is not part of the animal program overseen by the FIACUC
4. A change in species
5. A change in study objectives
6. A change in Principal Investigator
7. A change that impacts the safety of personnel
8. A change in the method of euthanasia to a method not approved by the current AVMA Guidelines
9. Addition of a new procedure not described in the approved protocol

While the FIACUC is at liberty to add other significant changes that require review and approval by the FCR or DMR methods, the FIACUC cannot remove or modify the modifications in the list above or develop and approve policies that allow these modifications to be managed administratively. These significant modifications, as designated by OLAW and USDA, must be reviewed and approved by the FCR or DMR methods.

Per the FIACUC's authority to do so, other significant modifications that must be reviewed and approved by the classic methods of FCR or DMR include, but are not limited to:

10. Addition of a non-pharmaceutical grade drug or change from a pharmaceutical grade to a non-pharmaceutical grade drug

11. Changes in animal care activities that increase the duration between food bar change-outs, water refills and/or habitat changes above the maximum durations described in the corresponding FIACUC-approved VVC policies

12. Significant deviations from the ISS Standard Housing Guidelines that have no corresponding FIACUC-approved policies to make them eligible for review by the VVC method

IV. Significant Modifications that are allowed under the VVC method

The following significant modifications may be administratively managed with verification and consultation by a FIACUC-authorized veterinarian and must be supported by corresponding and specific FIACUC-approved policies.

1. Change in anesthesia, analgesia, sedation, or experimental substances
2. Change in euthanasia to any AVMA approved method including those approved with conditions (as long as the conditions are met)
3. Change in duration, frequency, type, or number of procedures performed on an animal
4. Change in standard animal care activities (e.g., frequencies of food change-outs, water replenishments, cage changes)

In the absence of FIACUC-approved policies that specifically address each of the significant modifications listed above, the modification is not eligible for VVC. Without such a policy, the significant modification must be reviewed and approved by FCR or DMR.

V. VVC Process

- A. In the event a significant modification to a FIACUC-approved activity is needed, the PI or POC must bring it to the attention of the FIACUC support staff, FIACUC Chair and/or authorized veterinarian as soon as possible.
- B. Notification can be by phone, email, written memo, text message, or completed amendment form.
- C. If the significant modification is one that must be reviewed by FCR or DMR, the PI must submit a completed amendment form to the FIACUC support staff as soon as possible.
 - a. If the significant modification is urgent, the FIACUC support staff will make every effort to immediately contact all FIACUC members for the opportunity to request FCR.
 - b. If all members are successfully reached and no member requests FCR, the FIACUC Chair will designate at least one trained and qualified FIACUC member to conduct the review on the FIACUC's behalf. The designated reviewer(s) can approve the amendment, require modifications in order to secure approval or send the amendment to FCR.
 - c. If any FIACUC member requests FCR, the amendment must be reviewed and approved at a convened meeting of a quorum of the FIACUC. If necessary, the FIACUC may convene an emergency meeting to consider the amendment.
- D. If the significant modification is eligible for VVC, an authorized veterinarian may initiate the VVC process
 - a. An authorized veterinarian verifies that the significant modification is addressed and permitted under a corresponding FIACUC policy.
 - b. If yes, the authorized veterinarian determines if the requested modification is appropriate for the species under the given circumstances.

- c. If appropriate, the authorized veterinarian may consult with the PI to recommend revisions or adjustments to the requested change, if deemed more suitable for the animal(s) under the circumstances. Any such revisions must also be covered under the relevant policy.
- d. The authorized veterinarian may defer the request and ask the PI to submit an amendment to the FIACUC for review and approval. Deferring may be necessary in, but not limited to, the following situations:
 - i. If the requested change is one that can only be approved by FCR or DMR.
 - ii. If the change is not covered or permitted under a FIACUC-approved policy.
 - iii. If there are concerns that the change may NOT be appropriate for the animals under the particular circumstances.
 - iv. If it cannot be ascertained that personnel are trained and qualified to perform the change.
 - v. If the change may introduce possible safety issues to personnel.
- E. Ultimately, a significant modification that is permitted via the VVC process must be documented in writing, provided to the FIACUC within five business days, and include the following information for the protocol file:
 - a. The protocol number and title, the PI name and contact information
 - b. A description of the modification
 - c. Justification for the significant modification
 - d. Signature/date: PI
 - e. Date(s) of consultation with authorized veterinarian
 - f. Date of permission to proceed from the authorized veterinarian
 - g. Corresponding FIACUC-policy title and version number
 - h. Signature/date: IACUC Chair
- F. Paperwork (hard-copy or electronic) associated with the request for significant modification must be retained in the corresponding protocol file.
- G. Significant modifications managed through the VVC process must be brought to the attention of the FIACUC at the next IACUC meeting, if possible, and recorded in the meeting minutes.
- H. All FIACUC members must be familiar with FIACUC-approved policies.
- I. The VVC process and its corresponding policies must be reviewed by the FIACUC at least every 3-years.

VI. AANI Process

- A. The AANI process requires a FIACUC-approved policy that delineates allowable increases in animal numbers
 - a. The policy may be written broadly for all species or specifically by species or genus.

- b. The policy may be reviewed and approved by FCR or DMR (best practice), by polling or by some other mechanism that makes policies available for FIACUC member review and input.
 - c. All FIACUC members must be familiar with the policy.
 - d. The policy should address the rationale for the increase in animal numbers and include language that ensures the rationale continues to align with the one presented in the approved protocol. If not, an acceptable revised rationale should be a condition for permitting additional animals.
 - e. The policy should designate the individuals or positions authorized to conduct the administrative review on behalf of the FIACUC.
 - f. The policy should make clear that authorized individuals can at any time and for any reason defer the request for additional animals to the FIACUC for review.
 - g. The AANI policy must be reviewed by the FIACUC at least every 3-years.
- B. Requests for additional animals above the number approved on the original protocol must be documented on a protocol amendment form or other appropriate form. The form must include:
- a. The protocol number and title, the PI name and contact information
 - b. The number of animals approved for use in the original protocol and the rationale for that number as it appears in the approved protocol
 - c. The number of additional animals requested and the justification for that increase.
 - d. A field that designates the FIACUC-policy and version number that permits the increase in animal numbers.
 - e. Fields for the type of review (FCR, DMR, VVC, AANI) and the approval date.
 - f. Signature/date fields for the PI, Administrative reviewer(s) and IACUC Chair.
- C. Paperwork (hard-copy or electronic) associated with the request for additional animals must be retained in the corresponding protocol file.
- D. Increases in animal numbers managed through the AANI process must be brought to the attention of the FIACUC at the next IACUC meeting, if possible, and recorded in the meeting minutes.
- E. The AANI process must be reviewed by the FIACUC at least every 3-years or more often, if needed.

History of Revisions

Date	Summary
12Dec2019	Initial Approval
13Feb2020	Section V.E: VVC documentation required within five business days



Requirements

**NASA Ames Research Center
Space Biosciences Division**

**Rodent Research
Flight Transporter Operational Requirements and Constraints
Doc. No. 7610 Rev. -**

Prepared by

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10/3/18

Date

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Approved by

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10/3/2018

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10/3/18

Date

NASA SS&MA



Revision History

Rev.	Date	Affected Pages	Description of Change
-	10/3/2018	All	Initial Release

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Flight Transporter Operational Requirements and Constraints

Doc No. 7610 Rev. -

1.0 Purpose

The purpose of this document is to provide orientation and handling requirements for Flight Transporters from the time on animal load through integration into the launch vehicle. Subsequent revisions of this document will include Transporter operations requirements for on-orbit operations, ground controls, and Live Animal Return (LAR)

2.0 Scope

The following requirements are applicable to pre-flight operations of the flight Transporter from the time of animal loading through installation in the launch vehicle and in the event of a scrub for deintegration and transport back to the Animal Care Facility.

3.0 Definitions and Acronyms

ACF	Animal Care Facility
ARC	Ames Research Center
ERC	Engineering Release Center
IVT	Integration Verification Test
LAR	Live Animal Return
QA	Quality Assurance, also referred to as SS&MA

4.0 Requirements

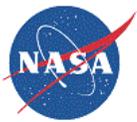
4.1. Orientation

4.1.1. The Transporter shall be maintained in the front face up or down orientation prior to animal load. Exceptions are during functional testing, pre-flight preparation and during animal load when Transporter is required to be horizontal.

4.1.2. The Transporter shall be maintained in the front face down orientation during transport to the launch site and until loading into the launch vehicle.

Rationale: The Transporter filters are designed to operate in an exhaust filter (front face) down while the unit is in a 1 G environment.

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Flight Transporter Operational Requirements and Constraints

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Due to launch vehicle configuration the Transporter can be in a different orientation once it is integrated into the launch vehicle.

4.2. Handling

4.2.1. Orientation changes shall be minimized during hardware movement from the transport vehicle, to the loading platform, and installation into the vehicle.

4.2.2. Orientation changes shall be handled in a slow smooth and controlled manner to prevent injury to the animals.

4.3. Power

4.3.1. Power off time for the Transporter shall be limited to no more than 30 minutes. Goal for power off is no more than 15 minutes

4.3.2. 28 volt power shall be supplied for operation of the Transporter.

Power can be provided by battery pack(s) or facility power (a calibrated 28 volt power supply is required for facility power)

4.3.3. If battery packs are used spare battery packs shall be available

4.3.4. All personnel shall be grounded during all power connection mate and demate operations.

4.4. Environment

4.4.1. The Transporter shall be maintained in an environmentally controlled area from turnover through launch.

4.4.2. The Transporter shall not be out of the environmentally controlled area for more than 15 minutes during transfer from the ACF to the transport vehicle and to the launch vehicle loading platform.

4.4.3. Temperature shall be maintained from 22° and 25°C.

4.4.4. Humidity shall be maintained from 30 to 70%

4.5. Miscellaneous

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Flight Transporter Operational Requirements and Constraints

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4.5.1. The Transporter shall not be left unattended for periods longer than 30 minutes from turnover through installation in the launch vehicle (weather permitting).

4.5.2. A “Just in Time” turnover is preferable from an animal welfare perspective.

4.5.3. A Rodent Research Team member should be present during IVT at the pad.

5.0 Metrics

Not applicable to this document.

6.0 Forms

Not applicable to this document

7.0 Applicable Documents

None

8.0 Reference Documents

None

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