State of California
Department of Fish and Wildlife

Received August 8, 2025

Memorandum

Date: August 6, 2025

To: Melissa Miller-Henson
Executive Director
Fish and Game Commission

From: Charlton H. Bonham
Director

Subject: **Agenda Item for the October 8-9, Meeting: Approval of Restricted Species Permit Application to Possess Transgenic Sea Urchins**

San Diego State University (SDSU) has applied for a Restricted Species Permit to possess transgenic painted sea urchins (*Lytechinus pictus*). According to the California Code of Regulations (CCR), Title 14, Section 671.1(a)(8)(H), all approved applications to possess a transgenic aquatic animal shall be reviewed by the California Fish and Game Commission (Commission) at a regularly scheduled meeting. The Commission may deny the issuance of a permit if it determines that the applicant is unable to meet the regulatory requirements for the importation, transportation, possession, and confinement of transgenic aquatic animals.

The transgenic painted sea urchins will be used for biological research. SDSU has outlined measures in their application materials that fulfill the containment and security requirements specified in CCR, Title 14, Section 671.1(a)(8). California Department of Fish and Wildlife (Department) Marine Region staff have coordinated with the Shellfish Health Lab in reviewing the permit. The Department recommends issuing SDSU a Restricted Species Permit to possess transgenic painted sea urchins.

If you have any questions or need additional information on this matter, please contact Dr. Craig Shuman, Marine Regional Manager at R7RegionalMgr@wildlife.ca.gov.

Attachment

ec: Chad Dibble, Deputy Director
Wildlife and Fisheries Division

Craig Shuman D.Env., Regional Manager
Marine Region

Kirsten Ramey, Program Manager
Marine Region

Adam Frimodig, Senior Environmental Scientist
Marine Region

Sara Briley, Environmental Scientist
Marine Region

Colleen Burge, PhD, Shellfish Pathologist and Research Scientist Supervisor
Fisheries Branch

State of California – Department of Fish and Wildlife

2025 RESTRICTED SPECIES PERMIT AMENDMENT REQUEST

DFW 1313b (REV. 01/29/2025) Page 1 of 2

IMPORTANT! YOU MAY NOT OBTAIN ANIMALS PRIOR TO AMENDMENT APPROVAL

Fees include a nonrefundable three percent (3%) application fee, not to exceed $7.50 per item. *(Section 700.4, Title 14, California Code of Regulations CCR).*

FEE: $78.54 *(Nonrefundable application fee must accompany this amendment request.)*

SEE INSTRUCTIONS ON PAGE 2. TYPE OR PRINT CLEARLY.

FIRST NAME	M.L	LAST NAME	PERMIT NUMBER
Rick		Gulizia	1726

BUSINESS NAME	DAY TELEPHONE
San Diego State University	619-594-5938

LOCATION OF ANIMAL(S) HOUSING: Note: Animals being held at multiple locations require inspection certification by the Department that each ofthose facilities meet the minimum applicable housing requirements as set forth in subsection 671.1(a)(8)(A-F), Sections 671.3-671.4 and/or 671.7(b), Title 14, of the CCR.

ADDRESS	CITY	STATE	ZIP CODE	COUNTY
[redacted]	San Diego	CA	92182	San Diego
ADDRESS	CITY	STATE	ZIP CODE	COUNTY

List all restricted animals **TO BE ACQUIRED** in the following order: mammals, birds, fish, or reptiles. Group animals by order, family, and species. Use the following letters to denote sex: M=Male, F=Female, and U=Neutered or Unknown. Mark an "X" in the TO **BE ACQUIRED** column for animals to be acquired within the next year. **Unique Identifiers:** Use the following letters to denote unique identifying methods (See Section 671.1(c)(3)(J), Title 14, of the CCR): M=Microchip, T=Tattoo, and A=Alternative Method. Aquaculture and fish permittees: Identify the actual number in the ID number field and identify either W=Weight, V=Volume or C=Count in the method field. Remember to complete the Importation Only Section below for animals being imported into California. For California Residents Only: **All native species obtained from a licensed California Wildlife Rehabilitation Facility require a Native Species Exhibiting Permit.** Contact the License and Revenue Branch at (916) 928-5846 or .SPU@wildlife.ca.gov if you need additional information.

COMMON NAME	SCIENTIFIC NAME	ID NUMBER	METHOD	SEX	AGE
Transgenic Sea Urchin	Transgenic Lytechinus pictus		C	M/F	adult

WILL ANIMALS BE IMPORTED INTO CALIFORNIA? ☐ YES, COMPLETE IMPORTATION SECTION ☑ NO, EXPLAIN:

IMPORT ONLY: COMPLETE THIS SECTION IF YOU ARE IMPORTING ANIMALS INTO CALIFORNIA

LIST SPECIES TO BE IMPORTED	NUMBER OF ANIMALS	ORIGIN *(State or Country)*

PERSON/BUSINESS SHIPPING ANIMALS	DAY TELEPHONE

ADDRESS	CITY	STATE	ZIP CODE

NAME OF CARRIER	POINT OF ENTRY INTO CALIFORNIA

I certify under penalty of perjury under the laws and regulations of the State of California that all information on this application is true and correct and I am not violating any city or county laws. I agree to comply with the provisions of Section 671, Title 14, of the CCR. I understand it is unlawful to use or possess a permit which was obtained by fraud or deceit (Fish and Game Code Section 1052b). I understand that in the event that this information is found to be untrue or incorrect, the permit will be considered invalid and must be surrendered where purchased and I will be subject to criminal prosecution. I further understand that failure to comply with the terms and conditions of a permit may result in revocation of current permit and/or denial of future permits. Violation of this section is a misdemeanor, punishable by fine of not more than $1,000.00, imprisonment in the county jail for not more than six months, or both the fine and the imprisonment. In addition, I may be subject to civil penalties as stated in Fish and Game Code Section 2125.

APPLICANT'S SIGNATURE *(Must be in ink)*	DATE
X [redacted]	3/11/2025

FOR DEPARTMENT OF FISH AND WILDLIFE USE ONLY

REVIEWED BY/DATE	TRANSACTION#	ISSUED BY/DATE

INSTRUCTIONS FOR COMPLETING THE RESTRICTED SPECIES PERMIT AMENDMENT REQUEST

Use this form to: 1) add species you are not currently authorized to possess; 2) increase the number of animals where there are condition limitations; or 3) add/change facility locations.

Please allow 45 business days for processing your request. Amendments for transgenic species must go before the Fish and Game Commission, so you must allow an additional 30 business days. Incomplete requests will be returned and could delay the issuance of your amendment. Contact the Department of Fish and Wildlife (Department), License and Revenue Branch at (916) 928-5846 or SPU@wildlife.ca.gov if you need additional information regarding Restricted Species Permits.

To complete this application, you must:

1. It is mandatory to complete all items unless exempted.
2. Sign and date the amendment request in ink (an **original** signature is required).
3. Provide a list of animals to be acquired.
4. Provide a statement of purpose describing in detail the planned use for each animal. Applicants shall include relevant materials, as appropriate, including any lists of prospective clients with their contact information or contracts with clients or websites, scripts, brochures or flyers promoting or describing the planned use of the animals. If the animals will be used in an educational program, the applicant shall provide an explanation why live restricted species are necessary and samples of the educational material and message that will be distributed (not required for animal care, AZA, breeding, research and single event breeding permittees).
5. Provide a resume that provides dates and details documenting you or your full-time employee's qualifying experience caring for restricted animals at a facility engaged in a similar or directly related activity to the permit requested and for the animal(s) to be acquired. This experience shall have been acquired within the previous five years and include a total of at least one year full-time, hands-on experience caring for a species in the same family or closely related taxonomic family as the species requested (required for breeding, exhibiting, nuisance bird abatement, shelter and single event breeding permittees only).
6. Provide a letter of recommendation, written within the previous five years on **letterhead stationery, with an original signature**, from the facility where you or your full-time employee gained the experience. Document the quality and extent of the knowledge and experience, as related to the species and permit requested (required for breeding, exhibiting, nuisance bird abatement, shelter and single event breeding permittees only).
7. Provide an updated copy of your Emergency Action Plan that includes the new species.
8. Provide an updated Breeding Plan that includes the new species (required for breeding and single event breeding permittees only).
9. Provide photograph(s) of the enclosure(s) for animal(s) to be acquired that includes all required elements of the minimum standards as specified in Section 671.3.
10. Provide any other supporting documentation required by regulations.
11. Mail the completed application and supporting documentation with a cashier's check, money order, personal or business check*, or credit card** authorization form with the appropriate fee to the Department of Fish and Wildlife, License and Revenue Branch, PO Box 944209, Sacramento, CA 94244-2090 or apply in person. **DO NOT SEND CASH**.

IMPORTANT INFORMATION FROM THE DEPARTMENT OF PUBLIC HEALTH

The Department of Public Health (CDPH) has regulatory authority over the importation of specified carnivores (including skunks and raccoons), nonhuman primates and bats, due to potential health hazards.

Section 2606.8, Title 17, of the CCR, prohibits the importation of skunks because the hazard to the public from exposure to rabies is extremely high. The CDPH is concerned that certain wild animals could carry rabies and introduce new strains of rabies into the state of California. Therefore, the Department routinely denies requests for the importation and possession of skunks and raccoons. Exceptions may rarely be made for zoological or research institutions demonstrating an extraordinary need. The importation of other specified carnivores, bats or nonhuman primates may be allowed under a CDPH permit in certain circumstances. **For more information on CDPH permits, please contact them at (916) 552-9740.**

NOTICE

Disclosure Statement—Under Section 671.1, Title 14, of the CCR, the Department of Fish and Wildlife is authorized to collect information from applicants to maintain a record of licensure. All information requested on this application is mandatory unless otherwise indicated. All information except the street address and telephone number of the applicant may be provided to the public, if requested. All information related to a business may be released, including the residence address if it is the same as the business address. Other personal information submitted on this application may be released for law enforcement purposes, pursuant to court order, or for official natural resources management purposes.

A licensee may obtain a copy of his/her license records maintained by the Department by submitting a written request to the Custodian of Records, at the Department of Fish and Wildlife, License and Revenue Branch, PO Box 944209, Sacramento, CA 94244-2090. All requests must include the requester's name, address, and telephone number.

PAYMENT POLICY

***Personal or business checks** will be accepted by the Department if name and address are imprinted on the check. Checks returned to the Department due to insufficient funds will render your permit invalid. The Department may also deny the issuance or renewal of any permit if a person has failed to reimburse the Department for the amount due. Any activity performed without a valid permit is a violation of the Fish and Game Code and therefore subject to enforcement action.
****Credit Cards—**Licenses, permits, tags, stamps, or registrations may be purchased with a Visa or MasterCard.

State of California – Department of Fish and Wildlife

2024 RESTRICTED SPECIES PERMIT AMENDMENT REQUEST

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RECEIVED
FEB 25 2025
BY LRB

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SEE INSTRUCTIONS ON PAGE 2. TYPE OR PRINT CLEARLY.

FIRST NAME	M.I.	LAST NAME	PERMIT NUMBER
Rick		Gulizia	1726

BUSINESS NAME: San Diego State University

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APPLI[redacted]	DATE
X	2/20/2025

FOR D[redacted]

REVIEWED BY/DATE	TRANSACTION#	ISSUED BY/DATE

State of California – Department of Fish and Wildlife
2024 RESTRICTED SPECIES PERMIT AMENDMENT REQUEST
DFW 1313b (REV. 10/23/2023) Page 2 of 2

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SDSU | Research Support Services

February 13, 2025

Alyssa Hayes
California Department of Fish and Wildlife
License and Revenue Branch
PO Box 944209
Sacramento, CA 94244-2090
916-902-9107

Re: SDSU Restricted Species Permit No. 1726 Amendment

Dear Alyssa Hayes,

Attached please find our application to amend SDSU Restricted Species permit 1726 to add transgenic *Lytechinus pictus* sea urchins in support of Dr. Catherine Schrankel's research program.

Transgenic sea urchins will be housed in Bioscience Center Transgenic Urchin facility at SDSU (previously the Bioscience Center Transgenic Zebrafish facility). Urchins will be housed in BSC 12 next to the associated water purification system in BSC 13.
Dr. Kari Sant closed her zebrafish colony at SDSU last year after relocating her research program to Michigan State University. Dr. Schrankel has adapted housing and water purification systems to ensure secure accommodation of transgenic sea urchins, as described in her Emergency Action Plan.

Included in this application, please find:

1) Cover Letter
2) Restricted Species Permit Form signed and dated by Rick Gulizia
3) Credit card payment form signed by Rick Gulizia
4) Dr. Schrankel's CV
5) Recommendation letter for Dr. Schrankel from Dr. Hamdoun at Scripps Institute of Oceanography
6) Dr. Schrankel's Emergency Action Plan
7) Pictures of BSC 12 and 13.
8) OLAW Annual Report Acknowledgement Fall 2024
9) Semi-Annual IACUC Inspection Report Fall 2024

Please let us know if further information is required to complete this application.

Sincerely,

Natalie Gude, Ph.D.
Asst. Director of Research Support Services
San Diego State University
ngude@sdsu.edu

CURRICULUM VITAE, December 2024

Catherine S. Schrankel, PhD
Department of Biology
San Diego State University
5500 Campanile Drive
San Diego, CA 92182-1308
(619) 594-1867
cschrankel@mail.sdsu.edu
www.schrankellab.com

EDUCATION

Nov 2017 PhD	University of Toronto Immunology
August 2010 MSc	The George Washington University Biological Sciences
May 2009 BSc	The George Washington University Biological Sciences

ACADEMIC POSITIONS HELD

Aug 2022 – Present San Diego State University	Assistant Professor Cell Biology
May 2017 – July 2022 Scripps Institution of Oceanography University of California, San Diego *Advisor, Dr. Amro Hamdoun*	NIH Ruth L. Kirschstein Postdoctoral Fellow Cell Biology and Toxicology

PROFESSIONAL GROWTH

****

REFEREED JOURNAL ARTICLES ***Post-doctoral work** ****Faculty work** **SDSU Trainees**

Before Tenure and Promotion

1. Nesbit K[1], Hargadon AC, Renaudin G; Kraieski N, Buckley KM, Darin E, Lee Y, Hamdoun A, **Schrankel CS**. Characterization of cellular and molecular immune components of the painted white sea urchin *Lytechinus pictus* in response to bacterial infection.** *In press, Immunology Cell Biology.* DOI:10.1111/imcb.12828.

   Impact Factor 4.0, CiteScore 9.9

   ****Corresponding author (Faculty):** Oversaw all research, animal husbandry, and data collection; performed some experiments and trained Nesbit, Hargadon and Darin in majority of data collection for manuscript; editing of manuscript (first draft written by Dr. Nesbit, Post-Doc); editing of figures and SI (all figures generated by co-authors); management of response to reviewers, final revisions and proofs (primary submission and first revision handled by Dr. Nesbit).

2. Tate HM, Barone V, **Schrankel CS****, Hamdoun A, Lyons DC. Localization and origins of juvenile skeletogenic cells in the sea urchin Lytechinus pictus. Dev Biol. 2024 Oct;514:12-27. doi: 10.1016/j.ydbio.2024.05.012. Epub 2024 Jun 9. PMID: 38862087.

   Impact Factor Impact Factor 2.7, CiteScore 5.6

   ****Co-author (Faculty):** Provided microscopy training to Tate HM (UCSD MSc student) onsite at SDSU (Schrankel Lab Echo Revolve microscope) to generate images used in several figures; editing of manuscript text (text first draft and figures written/created by Tate HM and Lyons DC).

3. Stoeltje L, Luc JK, Haddad T, **Schrankel CS**. The roles of ABCB1/P-gp drug transporters in regulating gut microbes and inflammation: Insights from animal models, old and new**. *Philos Trans R Soc Lond B Biol Sci.* 2024 May 6;379(1901):20230074. doi: 10.1098/rstb.2023.0074. Epub 2024 Mar 18. PMID: 38497255.

   Impact Factor 6.3, CiteScore 12.0

   ****Corresponding author (Faculty):** Oversaw literature review by MSc students; editing of manuscript (first drafts written by students); editing of figures (all figures generated by co-authors); management of submission, revisions and proofs.

4. Smith LC, Crow RS, Franchi N, **Schrankel CS**. The echinoid complement system inferred from genome sequence searches.** Dev Comp Immunol. 2023 Mar;140:104584. doi: 10.1016/j.dci.2022.104584. Epub 2022 Nov 4. PMID: 36343741.

   Impact Factor 2.9, CiteScore 5.7

   ****Co-author (Faculty):** Literature review and genomic analysis of MACPF proteins in sea urchin genomes; wrote full text of Section 10.1; generated data for and created Figures 7-9; helped edit full manuscript.

5. Vyas H, **Schrankel CS*,** Espinoza JA^, Mitchell KL, Nesbit KT^, Jackson E, Chang N^, Lee Y^, Warner J, Reitzel A, Lyons DC, Hamdoun A. (2022) **Generation of a homozygous mutant drug transporter (ABCB1) knockout line in the sea urchin *Lytechinus pictus***. Development. 2022 Jun 1;149(11):dev200644. doi: 10.1242/dev.200644. Epub 2022 Jun 6. PMID: 35666622. *^directly mentored graduate students.*

   Impact Factor 6.86, CiteScore 8.7

***Second author (Post-Doc):** I was part of the conceptual planning of how to genetically modify sea urchins and breed them to homozygosity. This included the spawning, care of, transport, and proper disposal of modified animals at all the life stages for the sea urchin (gametes, embryos, larvae, juveniles, and adults) that was necessary to complete this work. That also included the retrofitting of an enclosed freshwater rack system for zebrafish (Aquaneering) into a seawater recirculating system for juvenile and adult *L. pictus* containment, and creating an electronic inventory system for Tg animals.

For experimental work, I performed CRISPR-Cas9 microinjection experiments and assisted in animal husbandry for breeding to F_3 generation. I imaged and quantified over 1000 live individual F_2 larvae for their ABCB1-specific protein activity levels for data presented in Figures 3 and S7. I created the main and supplementary figures for the entire manuscript from my own and co-authors' data, excluding the genotyping analysis tables. I significantly contributed to draft writing, revisions, and final edits of the manuscript.

6. **Schrankel CS*** and Hamdoun A. (2021) **Early patterning of *ABCB*, *ABCC*, and *ABCG* transporters establishes unique territories of small molecule transport in the embryonic mesoderm and endoderm.** Dev Biol. 472:115-124. Doi: 10.1016/j.ydbio.2020.12.021. PMID: 33460641; PMCID: PMC8171262.

   Impact Factor 2.7, CiteScore 5.6

   ***First author (Post-Doc):** Performed all experiments for data in this manuscript including animal husbandry; created all main and supplementary figures/tables; wrote the first draft and performed iterative revisions/edits following Dr. Hamdoun edits; performed all requested revision experiments; performed all submission and response to Reviewers, and Proofs process.

7. **Schrankel CS*[1]**, Fleming TJ[1^], Vyas H[1], Rosenblatt HD, and Hamdoun A. (2021) **CRISPR/Cas9 mutagenesis reveals a role for ABCB1a in protection of sea urchin embryos from pathogenic gut bacteria.** J Exp Biol. 224(7):jeb232272. doi: 10.1242/jeb.232272. PMID: 33653719; PMCID: PMC8077557. [1]*co-first author;* [^]*mentored undergraduate*

   Impact Factor 3.2, CiteScore 5.5

   ***Co-first author (Post-Doc):** Performed all experiments for data in this manuscript including animal husbandry; created all main and supplementary figures/tables; wrote the first draft and performed iterative revisions/edits following Dr. Hamdoun edits; performed all requested revision experiments; performed all submission and response to Reviewers, and Proofs processes.

Refereed Publications from Doctoral Work

8. Schuh NW, Carrier TJ, **Schrankel CS**, Reitzel AM, Heyland A, and Rast JP. (2020) **Bacterial exposure mediates developmental plasticity and resistance to lethal *Vibrio lentus* infection in purple sea urchin (*Strongylocentrotus purpuratus*) larvae.** Front Immunol. 10:3014. doi:10.3389/fimmu.2019.03014

   Impact Factor 5.7, CiteScore 9.8

   Co-author: I helped perform bacterial exposure experiments and larval measurements for data presented in Figures 2-6; editing of manuscript (primary text written by lead author and Dr. Rast).

9. Buckley KM[1], Ho EC[1], Hibino T, **Schrankel CS**, Schuh N,Wang G, Rast JP. (2017) **IL-17 is the primary factor expressed in the gut epithelium during an invertebrate inflammatory response**. *Elife*. doi: 10.7554/eLife.23481. PMID 28447937 [1]co-first author.

   Impact Factor 7.7, CiteScore 12.3

Co-author: I cloned and microinjected IL-17 BAC reporters and scored data that are presented in Figures 3 and 5 and related Supplemental figures of each; editing of manuscript (primary text and figures written/created by lead co-first authors and Dr. Rast).

10. **Schrankel CS**[1], Solek CM[1], Buckley KM, Anderson MK, Rast JP. (2016) **A conserved alternative form of the purple sea urchin HEB/E2-2/E2A transcription factor mediates a switch in E-protein regulatory state in differentiating immune cells.** *Dev Biol.* 416(1):149-61. dio:10.1016/j.ydbio.2016.05.034. PMID 27265865. [1]co-first author.

    Impact Factor 2.7, CiteScore 5.6

    Co-First author: I performed RNA in-situs, cloned and microinjected E-protein-GFP and -mCherry BAC reporters and scored data that are presented in Figures 2-6 and related Supplemental figures and tables for each; wrote first draft of the manuscript and helped with editing; performed all revision experiments and revision edits; handled submission process.

11. Ho EC[1], Buckley KM[1], **Schrankel CS**, Schuh NW, Hibino T, Solek CM, Bae K, Wang G, Rast JP. (2016) **Perturbation of gut bacteria induces a coordinated cellular immune response in the purple sea urchin larva.** *Immunol Cell Biol.* 94(9):861-874. PMID 27192936. [1]co-first author

    Impact Factor 4.0, CiteScore 9.9

    Second Author: I performed gene annotation and cloned and imaged reporter constructs for immunocytes (data within several main and supplemental figures). I assisted with bacterial exposure experiments; editing of manuscript (primary text written by lead authors and Dr. Rast).

12. Solek CM, Oliveri P, Loza-Coll M, **Schrankel CS**, Ho EC, Wang G, Rast JP. (2013) **An ancient role for Gata-1/2/3 and Scl transcription factor homologs in the development of immunocytes.** *Dev Biol.* 382(1):280-92. PMID 23792116

    Impact Factor 2.7, CiteScore 5.6

    Co-author: I performed RNA in-situ hybridization, imaging, and quantification for Gata and Scl; performed Gata-1/2/3 morpholino knockdown and qPCR analysis of immunocyte marker *MacpfA2* (data within several main and supplemental figures). I assisted with editing of the manuscript (primary text written by Dr. Solek and Dr. Rast).

13. Lun CM, **Schrankel CS**, Chou HY, Sacchi S, Smith LC. (2016) **A recombinant Sp185/333 protein from the purple sea urchin has multitasking binding activities towards certain pathogens and PAMPs.** *Immunobiology*.221(8):889-903. dio: 10.1016/j.imbio.2016.03.006. PMID: 27020848

    Impact Factor 2.5, CiteScore 5.0

    Second author: I performed recombinant expression and isolation of Sp185/333 protein and optimized the bacterial binding assays (by Western and FACS) that the primary data are based on. I assisted with final editing of the manuscript (primary text written by Drs Lun and Smith).

14. Sherman LS, **Schrankel CS**, Brown KJ, Smith LC. (2015) **Extraordinary Diversity of Immune Response Proteins among Sea Urchins: Nickel-Isolated Sp185/333 Proteins Show Broad Variations in Size and Charge**. *PLoS ONE*. 25;10(9). doi: 10.1371/journal.pone.0138892. PMID: 26406912.

    Impact Factor 2.5, CiteScore 5.0

    Second author: I performed recombinant expression and isolation of Sp185/333 protein and optimized the bacterial binding assays (by nickel column isolation and Western blot) that the primary data are based on. I assisted with final editing of the manuscript (primary text written by Sherman LS and Dr. Smith).

Undergraduate work:

15. Ghosh J, Lun CM, Majeske AJ, Sacchi S, **Schrankel CS**, Smith LC. (2011) **Invertebrate immune diversity.** *Dev Comp Immunol.*35(9):959-74. DOI: 10.1016/j.dci.2010.12.009. PMID: 21182860. *All equal contributors (Review).*

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REFEREED BOOK CHAPTERS

Before Tenure and Promotion

1. Smith LC, Arriza V, Barela Hudgell MA, Barone G, Bodnar AG, Buckley KM, Cunsolo V, Dheilly N, Franchi N, Fugmann SD, Furukawa R, Garcia-Arraras J, Henson JH, Hibino T, Irons ZH, Li C, Lun CM, Majeske AJ, Oren M, Pagliara P, Pinsino A, Raftos DA, Rast JP, Samasa B, Schillaci D, **Schrankel CS**, Stabili L, Stensväg K, Sutton E. (2018) **Complexity of the Immune System in Echinoderms.** In: Cooper EL, editor. *Comparative Immunology*. Springer Publisher. *All equal contributors.*

2. Smith LC, Ghosh J, Buckley KM, Clow LA, Dheilly NM, Haug T, Henson JH, Li C, Lun CM, Majeske AJ, Matranga V, Nair SV, Rast JP, Raftos DA, Roth M, Sacchi S, **Schrankel CS**, Stensvag K. (2010) **Echinoderm immunity.** In: Söderhäll K, editor. *Adv Exp Med Biol. Chapter 14: Invertebrate Immunity*. Landes Bioscience and Springer Science+Business Media. PMID 21528703. *All equal contributors.*

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REFEREED PROCEEDINGS ***Post-doctoral work** ****Faculty work** **SDSU Trainees**

Before Tenure and Promotion

1. Hanson MA, Westlake HE, **Schrankel CS**. Sculpting the microbiome**. *Philos Trans R Soc Lond B Biol Sci.* 2024 May 6;379(1901):20230057. doi: 10.1098/rstb.2023.0057. Epub 2024 Mar 18. PMID: 38497263.

   ****Co-author:** Co-wrote our editorial overview of our Guest Edited Special Issue.

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UNPUBLISHED, REFEREED PAPERS BEFORE PROFESSIONAL CONFERENCES

Before Tenure and Promotion

Faculty

1. INVITED

April 2025 Building the Echinoderm Model for the cross-talk between immunity and development.
[Invited Keynote Talk]
28th Meeting of the Developmental Biology of the Sea Urchin and other Marine Invertebrates
Marine Biological Laboratory, Woods Hole, MA

2. INVITED

Feb 2025 A novel role for AMPs in marine invertebrate developmental transitions and metamorphosis
Gordon Research Conference on Antimicrobial Peptides
Feb 23-28, 2025
Ventura, CA

3. Oct 2023 Building an Echinoderm Model for the role of drug transporters in host-microbe interactions.
[Invited Talk]

27th Meeting of the Developmental Biology of the Sea Urchin and other Marine Invertebrates
Marine Biological Laboratory, Woods Hole, MA

4. Mar 2023 A new model system for testing the role of drug transporters in host-microbe interactions.
[Invited Plenary Seminar]
The DC Local Immunology Conference. Department of Biological Sciences, GWU. Washington, DC.

5. July 2022 Illuminating the role of drug transporters in host-microbe interactions.
[Plenary Seminar]
Symposium: Animal immunity at the interface of development and the microbial environment
8th Meeting of the European Society for Evolutionary and Developmental Biology
Naples, Italy

Postdoctoral:

6. Apr 2022 Drug transporters in embryo-environment interactions. **[Plenary Seminar]**
26th Meeting of the Developmental Biology of the Sea Urchin. (Virtual)

7. Mar 2021 Imaging the ontogeny and activity of small molecule transporters in gut epithelia.
[Invited Future Investigator Presentation]
4D Cellular Physiology Workshop: *Epithelial Biology*
Janelia Research Campus (Virtual)

8. Feb 2021 Small molecule transporters in development and host-environment interactions.
[Invited Departmental Seminar]
University of South Carolina. Department of Environmental Health (Virtual)

9. Oct 2020 Spatial patterning and CRISPR/Cas9 mutagenesis of small molecule transporters: A role for ABCB1 in the protection of sea urchin embryos against *Vibrio* bacteria.
Oceans and Human Health, Virtual Meeting.

10. Oct 2019 Patterning and activity of multidrug ABC transporters during embryogenesis.
5th Congress of the Meredith Gould Symposium. Ensenada, Mexico.

11. July 2019 Patterned expression and activity of ABC Transporters during embryogenesis. **[Invited Institutional Seminar]**
Institute de la Mer Villefranche. Villefranche, France.

12. May 2019 Patterned expression of cellular defense systems in the sea urchin embryo. **[Plenary Seminar]**
Guest Symposium: *Deuterostome Immune Innovations from Echinoderms to Mammals*
American Association of Immunology 2019 Meeting. San Diego, CA.

13. Oct 2018 Patterned expression and activity of ABC Transporters during gut morphogenesis. **[Plenary Seminar]**
25th Meeting of the Developmental Biology of the Sea Urchin. Woods Hole, MA.

14. Mar 2018 ABC Transporters are differentially regulated during gut development and gut epithelial immune responses. **[Lightning Poster Presentation; winner]**

15. Oct 2017 7th FEBS Special Meeting on ABC Proteins. Innsbruck, Austria.
ABC Transporters are differentially regulated during development.
4th Congress of the Meredith Gould Symposium. Ensenada, Mexico.

****

NON-REFEREED BOOK CHAPTERS ***Post-doctoral work** ****Faculty work** **SDSU Trainees**

Before Tenure and Promotion

1. **Schrankel CS*,** Gökirmak T, Lee CW, Chang G, and Hamdoun A. (2019) **Generation, expression and utilization of single-domain antibodies for *in-vivo* protein localization and manipulation in sea urchin embryos.** In: Hamdoun A, Foltz KR, editors: *Methods in Cellular Biology, Volume 151.* PMID: 30948018

   Impact Factor 1.4, CiteScore 3.1

   ***First author (Post-doctoral work):** I performed literature review, wrote the text, and created all figures; final editing and proofs. Submission handled by Dr. Hamdoun.

2. Hamdoun A, **Schrankel CS*,** Nesbit K, Espinoza JE. (2018) **Sea urchins as lab animals for reproductive and developmental biology.** In: Skinner M, Swanson P, editors. *Encyclopedia of Reproduction, Second Edition.* San Diego: Academic Press.

   ***First author (Post-doctoral work):** I performed literature review, wrote the majority of text, and created all figures and tables; performed final editing and proofs. Submission handled by Dr. Hamdoun.

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PUBLICATIONS IN PROCESS

Before Tenure and Promotion ****Faculty, corresponding author.** Underlined = Direct SDSU trainees of mine.

1. Haddad T, Plascencia P, Anderson C, Mitchell KL, Tjeerdema, E, Lee Y, Dominko T, Hamdoun A, Schrankel CS**. Changes in expression and localization of ABC transporters during the transition from human embryonic stem cells to primordial germ cells suggest developmental roles for ABCC1. *In preparation.*

2. Stoeltje E, Horkan E, Stenzel S, Hamdoun A, and Schrankel CS**. ABCB1 knockout sea urchins reveal a conserved role for ABCB1 in preventing gut epithelial inflammation and microbial dysbiosis. *In preparation.*

3. Luc JK, Hajama H, Horkan E, Stenzel S, Andrew M, and Schrankel CS**. Microbial origins of black spot disease in adult sea urchins. *In preparation.*

4. Hargadon AC, Hunter D, Stenzel S, Nyugen K, and Schrankel CS**. A novel role for antimicrobial peptides in transducing bacterial cues for animal metamorphosis. *In preparation.*

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SCHOLARLY and FOUNDATION AWARDS (including those of trainees)

Before Tenure and Promotion

Faculty:

1. Nov 2024 **Maxson Foundation Award, SDSU Research Foundation**
Schrankel CS. **$15,000.**
Support for students and projects focused on understanding the evolution of cellular defense mechanism against urban pollutants.

2. Oct 2024 **Nominated, University Senate Teaching Award, SDSU**
Schrankel CS
Nominated by students and lab trainees. Award winners announced Spring 2025.

The Senate's Excellence in Teaching Award recognizes an SDSU faculty member for contributions made to students, respective academic disciplines, and the campus communities. The primary criterion of this award is teaching excellence. The awardee receives the title Senate Distinguished Professor and a stipend. Qualified nominees may be tenured or tenure-track.

3. Oct 2024 **Nominated, CSUBIOTECH Don Eden Graduate Student of the Year**
Haddad, T. First year PhD student, Schrankel Lab. **$2,000.**
"Preservers of Reproductive Integrity: Identifying the role of ABC transporters in the Human Germline."

Awarded to one of **five** finalists from all 23 Cal State University schools; Winner announced Jan 11, 2025 after poster and talk competitions at the annual CSUBIOTECH Research Symposium. The Don Eden Graduate Student Research Award fosters excellence in graduate student research throughout the CSU system, covering a broad range of topics in the life sciences and biotechnology. The award is designed to recognize and promote successful scientific communication to general audiences, to celebrate the work of outstanding graduate student researchers, and to highlight the pioneering work of collaborative faculty-student research groups.

4. Oct 2024 **CSUBIOTECH 2025 Crellin Pauling Student Teaching Award**
Haddad, T. First year PhD student, Schrankel Lab. **$2,000.**
*Awarded to **two** CSU students annually.*

The Crellin Pauling Student Teaching Award acknowledges outstanding student teaching achievement by a CSU student in biotechnology-related settings, courses and programs. These awards honor Professor Crellin Pauling (San Francisco State University), a co-founder of CSUBIOTECH, for his extraordinary contributions to the training of teachers and scientists and his commitment to the creation of a scientifically literate electorate.

5. Mar 2024 **Research Award for Diversity, Inclusion and Social Justice, SDSU S^3 Symposium**
Luc, J. Masters Student

6. Mar 2024 **Best Student Poster Prize, Aquatic and Soil Systems Annual Meeting.**
Luc, J. Masters Student. **$1,000.**
Microbial origins of black spot disease in adult sea urchins

Postdoctoral:

1. Nov 2019 **Company of Biologists Scientific Meeting Grant, £2000**
Schrankel CS and Rast JP
Symposium: Animal immunity at the interface of development and the microbial environment
8th Meeting of the European Society for Evolutionary and Developmental Biology
Naples, Italy. July 2020 ***Rescheduled to May 2022*

2. June 2019 **European ASSEMBLE Grant**
"Comparative studies on xenobiotic metabolism in tunicates"
Hamdoun A and Schrankel CS.
Host: Institute de la Mer Villefranche. Villefranche, France. June-July 2019.

3. Dec 2018 **Runner-up, Elevator Speech.** American Society of Cell Biology | EMBO Meeting.

4. April 2018 Nominated, Governor General Gold Medal. Department of Immunology, U of T

5. Mar 2018 Best Poster Bulletin, €280. 7th FEBS Meeting on ABC Proteins. Innsbruck, Austria

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FUNDED RESEARCH GRANTS

Before Tenure and Promotion

1. $7,500 - **CSUBIOTECH Faculty-Graduate Student Research Collaboration award:** *Preserver of reproductive integrity: Identifying the role of ABC transporters in the germline*
   June 2024 – June 2025
   Role: Faculty Advisor
   Granting agency and Grant acceptance rate: CSUBIOTECH; 35%.

2. $135,000 - **Ruth L. Kirschstein NIH National Research Service Award:** *"Identifying the ABCs of xenobiotic metabolism in protecting the germ line lineage"*
   Dec 2018 – July 2022
   Role and Percent Effort: PI. 85% Research Effort, 15% Professional Development (Post-doctoral Stage)
   Granting Agency and Acceptance Rate: National Institute of Environmental Health Sciences (NIEHS), National Institute of Health; 28%

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GRANTS SUBMITTED

Before Tenure and Promotion

1. **$1.375 M: NIH R35 MIRA-ESI. A new animal model system for identifying conserved mechanisms of the drug transporter ABCB1 in host-microbe interactions.**
   Submission for Jan 30 2025 deadline.
   Potential Dates of funding: 12/2025 to 12/2028
   Role and Percent Effort: Principal Investigator, 51%
   Granting Agency and Acceptance Rate: Directorate For Biological Sciences (BIO) - Div Of Biological Infrastructure (DBI), NFE-New Faculty Enhancement; variable %

2. $499,588. **BRC-BIO: An integrative lab and classroom approach to test the adaptive potential of the sea urchin *Lytechinus pictus* to local urban pollution.**
   Potential Dates of funding: 01/2025 to 12/2028
   Role and Percent Effort: Principal Investigator, 51%
   Granting Agency and Acceptance Rate: Directorate For Biological Sciences (BIO) - Div Of Biological Infrastructure (DBI), NFE-New Faculty Enhancement; variable %

3. *$499,588: Not awarded; Panel Review ranking, Highly Meritorious*
   BRC-BIO: An integrative approach to test the adaptive potential of the xenobiotic defense gene ABCB1 in the sea urchin *Lytechinus pictus.*
   Potential Dates of funding: 01/2024 to 12/2027
   Role and Percent Effort: Principal Investigator, 51%
   Granting Agency and Acceptance Rate: Directorate For Biological Sciences (BIO) - Div Of Biological Infrastructure (DBI), NFE-New Faculty Enhancement; variable %

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PARTICIPATION IN PROFESSIONAL ASSOCIATIONS

Before Tenure and Promotion

1. 2015—present: Member, Society of Developmental Biology
2. 2018—present: Member, American Society of Cell Biology
3. 2008—2013: Member, International Society of Developmental and Comparative Biology
4. 2017—present: Reviewer for journals *iScience, Developmental Biology, Phil. Trans. R. Soc. B.*

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TEACHING EFFECTIVENESS

Direct Mentorship and Thesis Chair

Aug 2024 – present
Kaeyln Nyugen, Undergraduate Student, CMB and Marine Biology BSc, SDSU
Project: *Identifying conserved ABC transporter functions in the primordial germ line of Echinoderms and Mammals*

Feb 2024 – present
Samantha Stenzel, Undergraduate Student, CMB and Marine Biology BSc, SDSU
Fall 2024 SDSU Undergraduate Research Program (SURP) Award: **$3,600**
Summer 2024 SURP Award: **$3,600**
Project: *Identifying differential bacterial accumulation in ABCB1-knockout Lytechinus pictus larvae*

Feb – Aug 2024
Courtney Anderson, Undergraduate Student, CMB, SDSU
Project: *Identifying conserved ABC transporter functions in the primordial germ line of Echinoderms and Mammals*
Current position: PhD Student, JDP-CMB at SDSU (2024-2025 Rotations)

Feb – May 2024
Tatiana Guillen, Undergraduate Volunteer, CMB BSc, SDSU
Merrill Willis, Undergraduate Volunteer, Marine Biology BSc, SDSU
Ivy Santos, Undergraduate Volunteer, CMB BSc, SDSU

Dec 2023 – present
Erin Horkan, MSc Student, Microbiology, SDSU
Thesis Chair
Thesis Title: *Identifying new larval pathogens of the sea urchin* Lytechinus pictus.

Feb 2023 – present
Priscilla Plascencia,
MSc Student, CMB, SDSU
August 2024 – present
Scholar, Bridges to Stem Cell Research Internship Program (BSCRIP)
SDSU Home Mentor: Dr. Catherine Schrankel
Home Lab project (SDSU): *The role of GSTs in primordial germ cell development and protection*
BSCRIP Host Mentor: Dr. Evan Snyder (MD/PhD), Sanford Burnham Prebys Consortium of Regenerative Medicine
Host Lab Project (SBPCRM): *Differentiation of Kabuki Syndrome patient-derived iPSCs to Cortical Neurons*

Lab volunteer, SDSU
Feb 2023 – July 2024

Advisor
Project: *The role of ABC transporters and GSTs in primordial germ cell development and protection*

Feb 2023 – present **Tim Haddad, PhD student,** JDP-CMB, SDSU/UC San Diego
Thesis Chair, August 2024 – present
Project: *The role of ABCC1 in primordial germ cell development and protection from toxicants*

Tim Haddad, MSc, CMB SDSU
Thesis Chair; Feb 2023 – July 2024
Thesis Title: *Preserver of reproductive integrity: Identifying the role of ABC transporters in the human germline*
Defended July 21st, 2024.
Current position: PhD Student, JDP-CMB at SDSU (Schrankel Lab)

Jan 2023 – May 2024 **Juan Manansala, Undergraduate Volunteer,** CMB BSc, SDSU

Feb – August 2023 **Larsa Gorges, Undergraduate Student,** CMB BSc, SDSU
Summer 2023 SURP Award: **$3,600**
Project: *Helping identify the role of ABC transporters in the human germline*

Jan – May 2023 **Janna Bawwab, Undergraduate Volunteer,** Biology/EB BSc, SDSU
DJ Schab, Undergraduate Volunteer, CMB BSc, SDSU

Nov 2022 – present **Lauren Stoeltje, MSc Student,** CMB SDSU
Thesis Chair
Thesis Title: *ABCB1 knockout in the sea urchin Lytechinus pictus drives gut inflammation and altered microbiome community profiles*
Target Graduation: Fall 2024 (Oct 22nd, 2024 Defense date)

Aug 2022 – Aug '24 **Jenna Luc, MSc,** Microbiology, SDSU
Thesis Chair
Thesis Title: *Identifying the microbial origins of Black Spot Disease in the sea urchin Lytechinus pictus.*
Defended July 21st, 2024. **(Teaching Item #2)**
Current position: PhD Student, Microbiology; University of Hawaii Monoi

Student Thesis Committee Membership

May 2023 – present **Candyd Lace Velasquez, PhD Candidate**, CMB-JDP, SDSU (Luallen Lab)
UG Thesis Committee Member
Thesis Title: *Identification of resistant alleles to intracellular bacterial infection in Oscheius tipulae*

Feb 2023 – present **Emily Darin, PhD student**, JDP-CMB, SDSU/UC San Diego
Lab Rotation Advisor, Feb-May 2023
Committee Member, June 2023—present.
Project: *Immune systems and metamorphosis of marine invertebrates*

Feb 2023 – present **Caden Unholz, PhD Student**, Chemistry, SDSU (Huxford Lab)
Thesis Committee Member
Thesis Title: *Development of an in-vitro fluorescence-based protein-protein interaction assay utilizing known interactions in the NF-κB pathway*

Jan – May 2023 **Megan Daneman, Undergraduate student**, CMB SDSU (Zayas Lab)
UG Thesis Committee Member
Thesis Title: *Analysis of a barh-like homeodomain 2 homolog in planarian Schmidtea mediterranea neuronal regeneration and maintenance*
Graduated 2023.

Dec 2022 – Jun 2024 **Sarah Warner, MSc Student**, CMB SDSU (Zayas Lab)
Thesis Committee Member
Thesis Title: *The Role of Ephrin Signaling in Neural Patterning in Planarians*
Graduated Summer 2024.

Oct 2022 – Oct 2023 **Julia Goebel, MSc,** School of Public Health, SDSU (Sant Lab)
Thesis Committee Member
Thesis Title: *Comparative Assessment of the Fungicide Boscalid with its Primary Metabolite M510F01 in Zebrafish Embryos*
Graduated Dec 2023.

Teaching Fellowships, Awards, and Innovations

May—June 2023 Inclusive Excellence Faculty Fellow, CIE (Center for Inclusive Excellence)

Fall 2024
Spring 2024
Spring 2023 Teaching Innovations: Immunology Group Activity for BIOL 567 **(Teaching Item #1)**

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COURSES TAUGHT

Course #	Course Name	Level	Modality	Co-Taught?
M BIO 601 *Fall 2024*	Colloquium in Molecular Biology Research	Graduate	In-Person	No
BIOL 567 *Fall 2024*	Advanced Biochemistry, Cell, and Molecular Biology	Undergraduate, Upper division; some graduate	In-Person	No
BIOL 567 *Spring 2024*	Advanced Biochemistry, Cell, and Molecular Biology	Undergraduate, Upper division; some graduate	In-Person	Yes, with Dr. Carrie House
BIOL 567 *Spring 2023*	Advanced Biochemistry, Cell, and Molecular Biology	Undergraduate, Upper division	In-Person	Yes, with Dr. Carrie House
M BIO 600 *Fall 2023*	Seminar in molecular biology:	Graduate	In-Person	Yes, with Dr. Maya Capelson

	Advanced topics in modern cell biology			
M BIO 600 *Fall 2022*	Seminar in molecular biology: Advanced topics in modern cell biology	Graduate	In-Person	Yes, with Dr. Maya Capelson
Guest Lectures ***BIOL 576*** *Fall 2024 Spring 2024 Fall 2023 Fall 2022*	**Developmental Biology** ***Lecture and Group Activity Lead:*** *Discussion of Vyas et al 2021 (Generation of a homozygous mutant ABCB1 knockout line in the sea urchin L.pictus)*	Undergraduate, Upper division	In-Person	No for Guest Lecture (main course content taught by Dr. Ricardo Zayas)
Guest Lecture ***BIOL 485*** *Spring 2023*	**Principles of Immunology** ***Guest Lecture****: Evolution of Immune Systems*	Undergraduate, Upper division	In-Person	No for Guest Lecture (main course content taught by Dr. Robert Luallen)
Guest Lecture ***M BIO 610*** *Fall 2022*	**Bioethics, Bioinformatics, and Molecular Biology** ***Guest Lecture****: Ethical considerations when working with invertebrates*	Graduate	In-Person	No for Guest Lecture (main course content taught by Dr. Cristal Zuniga)
Guest Lecture ***BIOL 462*** *Fall 2022*	**Zoology** ***Guest Activity****: Sea urchin spawning and early development*	Undergraduate, Lower division	In-Person	No for Guest Lecture (main course content taught by Dr. Nick Barber)

SERVICE

Service for the Department

1. 2 years (Fall 2022 – present) — Cell and Molecular Biology Joint Doctoral Program (CMB-JDP) Selection Committee; 5-year commitment. **(Service Item #1)**
2. 1 year (Fall 2023 – present) — CMB JDP Program Review: Provide input on program documents
3. 0.5 years (Spring 2024 – present) — Biology Core Curriculum Committee **(Service Item #2)**
4. 1 month (Sept 2024 – present) — CMIL Director Search Committee member; 9-month commitment

Service for the College

1. 4 days (Mar 2023; 2024) — S3 SDSU Symposium. Judge in 2023; attended 2023 and 2024
2. 1 day (Nov 2023) — Panelist, *Thematic conversation on the intersection of arts, wellness, and public health.* College of Professional Studies and Fine Arts (PSFA) and Division in Research and Innovation (DRI). **(Service Item #3)**.

Service for the University

1. 1 days (Sept 2024) — Panelist, MCTEN *"What I Wish I Knew When I Started My Faculty Position"*. Zoom-based Q+A Session for incoming and new SDSU Faculty. Recorded and shared by MCTEN, a Faculty Success Group.
2. 2 days (April 2024 – present) — SDSU representative for the CSUBIOTECH Faculty Consensus Group; 4-year commitment. **(Service Item #4)**.

Service for the Profession

1. 5 years 2019 – present — Reviewer: *iScience*; *DevBio; PLoS ONE*

Service for the Community

1. 2 years (Fall 2022 – present) — **Marine Science Day Contributor;** Annual San Deigo science outreach event hosted by the SDSU Coastal and Marine Institute Laboratory (CMIL). **(Service Item #5)**.

UNIVERSITY OF CALIFORNIA, SAN DIEGO
SCRIPPS INSTITUTION OF OCEANOGRAPHY

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Phone: 858.822.5839

Email: hamdoun@ucsd.edu
Web: hamdounlab.org

20 DEC 2024

To: California Department of Fish and Wildlife; San Diego State University Institutional Review Committee.

I am writing to provide my enthusiastic support for Dr. Catherine Schrankel's proposed transgenic sea urchin (*Lytechinus pictus*) research at San Diego State University (SDSU).

I can confirm the extensive qualifying experience of Dr. Catherine Schrankel for the handling and care of transgenic *L. pictus*. Dr. Schrankel was a full-time post-doctoral scholar in my lab at Scripps Institution of Oceanography (SIO), UC San Diego, from May 2017 to July 2022.

Starting in April 2020, she was instrumental in developing our scientific strategies, husbandry, and containment approaches for the future development of a genetically modified *L. pictus* colony in my lab. This included the spawning, care of, transport, and proper disposal of modified animals at all the life stages for the sea urchin (gametes, embryos, larvae, juveniles, and adults). It also included the retrofitting of an enclosed freshwater rack system for zebrafish (Aquaneering) into a seawater recirculating system for juvenile and adult *L. pictus* containment.

While working in my lab (and as a visiting collaborator after July 2022, while her own lab was getting set up), Dr. Schrankel has had over three years of experience directly related to the activities described in her permit and BUA amendment requests for sustaining transgenic lines at her lab at SDSU.

If you have any questions about her qualifications for safely creating and maintaining transgenic sea urchins, please do not hesitate to contact me.

Sincerely yours,

Amro M. Hamdoun
Professor and Associate Director Center for Marine Biotechnology and Biomedicine

EMERGENCY ACTION PLAN FOR Transgenic Sea Urchins
San Diego State University 2025

a. List of the re-capture equipment available, including but not limited to darting equipment, nets, traps, and chemical immobilization drugs for animals listed on your inventory.

Juvenile and adult sea urchins: Animals will be kept inside a re-circulating saltwater aquarium system in Biosciences 12 (BSC 12), which is located within the BSC basement vivarium. This room is secured from public access, with only approved and trained individuals permitted to enter and exit the room via key card (entrance to BSC Vivarium) and physical keys (entrance to BSC 12).

All juveniles (>2 mm diameter) and adult animals (0.5-3 cm diameter) are to be housed inside individual flow-through tanks that are connected to a large, fully enclosed rack system with constant re-circulating seawater. Each container has its own lid and baffle (mesh filter screen, 0.4 mm size) to prevent sea urchin escape or movement between containers.

In the rare event that a sea urchin does escape its individual enclosure, it would get transported with the re-circulating water flow (a series of covered troughs, hoses and piping) into the rack's internal reservoir (the sump), serving as secondary containment. Individual tanks, the sump, and all circulation troughs and hoses will be inspected daily for rogue animals or leaks.

In the case of an emergency, such as a severe earthquake able to dislodge the secure rack system from the walls and building infrastructure, escaped urchins could possibly fall to the ground of the laboratory. Any urchins falling to the floor would ultimately perish within 30 minutes once outside of water.

The floor has one drain that feeds into to the municipal wastewater system; a grate is present on the drain to prevent any possible surviving urchins from entering the drain. The drainage system combines with freshwater, which kills urchins within a few minutes. The floors and drain are to be inspected whenever personnel are in the room (expected multiple times per weekday; at least once daily on both weekend days). Finally, a detailed inventory will be kept for all animals in the system and cross-referenced and updated every time animals enter or exit individual enclosures (*e.g.* scanned barcodes) for specific handling and experiments.

Animals at any life cycle stage will not be shared with any other lab or researchers inside or outside of SDSU without prior written approval from CDFW, the SDSU IBC, and the receiving labs' institutional IBC and state permits as needed.

Gametes, Embryos and Larvae: Sea urchin spawning and fertilizations for experiments and breeding are performed inside the room housing the adult urchins, which is locked 24-7 and accessible only to limited, trained personnel. Eggs are collected directly into 20-100 mL size beakers of seawater by inverting the female so the eggs stream into the water. Sperm is collected dry directly off the males by pipets equipped with barrier filter tips, such that sperm cannot get aspirated into the pipet. The dry sperm is collected into 0.5 mL tubes. Sperm can be cryopreserved in a DMSO-seawater mixture and stored in liquid nitrogen dewars. The Schrankel Lab Dewar is located in LSN 321A, inside a separate locked room within the main Schrankel Lab space in LSN 321. Only trained personnel are permitted to enter 321A and to handle cryogenic storage. All cryopreserved sperm will be inventoried and cross-referenced when removed for experiments (e.g. barcode scanning).

Embryos and larvae will be grown in 2-4 L beakers of seawater for up to 3 weeks if growing through metamorphosis. Beakers will be covered by fitted lids that allow for an air pick and a 5 rpm paddle insert for circulation. The cultures undergo a 30% water change every other day (see *section b* for culturing water disposal specifics). Animals can naturally metamorphose inside these beakers, or they will be induced to metamorphose with standard 5M KCl treatments or by the introduction of plastic petri dishes that have been coated with adult tank biofilms. Metamorphosed juveniles will continue to be grown in their larval-home beakers, until they reach a size of ~2 mm. Once 2 mm or larger in diameter, they are moved into the recirculating system into the tanks equipped with lids and a baffle (0.4 mm size) to prevent sea urchin escape or movement between containers. All beakers, paddles and dishes used during culturing will be scrubbed and soaked in RO water for 24 hours to enable re-use without risk of contamination.

Should transgenic adults spawn gametes inside the system, gametes and embryos cannot survive the physical and UV-light filtering processes active during aquarium/rack internal re-circulation. Therefore, if seawater is ever released from the system itself into the floor drains, there are no live gametes or embryos able to escape out of the room.

Collectively, these conditions ensure that risk of escape from the vivarium is VERY low for all stages of the sea urchin life cycle.

b. Description of humane lethal dispatch methods for various animals and a list of qualified personnel who are trained to carry out the methods.

Juvenile and adult sea urchins: Live juvenile and adult sea urchins that are transgenic and no longer needed will be frozen (euthanized) and disposed of in red BioHaz waste bags; animals that die naturally in the recirculating system will also be disposed of in red BioHaz bags.

Gametes, Embryos and Larvae: Any leftover gametes not used for spawning are to be neutralized by pouring them directly into a separate container with a 5x volume amount of RO water, with a final concentration of 10% bleach and left therein for 15 min. This will lyse and destroy the cells/animals and any microorganisms harbored in/on the animals or gametes. Dead gametes are poured down the sink drain. During embryo and larval culturing, the seawater removed during this change is to be treated as per the gamete destruction protocol before dumping into the sink. Any unused embryos and larvae are to be destroyed and disposed of in the same manner.

All laboratory personnel will be trained in these methodologies, and all protocols and personnel will be approved by the San Diego State University Institutional Biosafety Committee.

Current personnel trained for this work once permit and IBC-BUA approved is secured:

Catherine Schrankel (PI)
Erin Horkan, master's student
Brad Hunter, PhD rotation student (months of Feb/March 2025)
Samantha Stenzel, Undergraduate student
Kae Nyugen, Undergraduate student

c. List of medical supplies/first aid kits (both animal and human) and where they are located.

First aid kits for laboratory personnel are located inside BSC 12 (vivarium) and LSN 321(lab). Medical supplies for sick animals include separate vessels and ampicillin salt baths to quarantine animals and treat potential bacterial infections.

d. Description and number of mobile transport cages and equipment on hand to accommodate all animals listed on your inventory.

No adult urchins will be allowed outside of the vivaria as they are only maintained as breeding populations on the automated system. Spawning of transgenic urchins is only allowed in BSC 12.

Any transgenic embryos, larvae, or juveniles required for further research or live imaging performed in LSN 321 (main lab) will be collected into covered plastic beakers, placed into a polypropylene secondary containment bin, and transported to the research laboratory in LSN. Sperm to be cryopreserved will be collected in BSC 12 and transported on ice; the ice bucket will transported in a polypropylene secondary containment bin. Secondary containment bins will be moved by rolling cart by trained personnel only. Sperm Cryopreservation will occur by flash freezing in liquid nitrogen in LSN 321A.

Any embryos, larvae or juveniles brought to LSN 321 for experiments are going to be either destroyed by routine molecular biology tissue collection processes that do not permit further life (e.g., DNA/RNA extractions; paraformaldehyde fixation of whole embryos or juveniles), or in the case of some juveniles, returned to BSC 12 using the same containment methods described above. The movement and return of juveniles will be recorded by scanning barcodes and cross-referencing electronic inventories of all animals and stages present in BSC 12.

e. List of emergency telephone numbers that includes 911, the local Department of Fish and Game regional office (find telephone number at www.wildlife.ca.gov/regions), and animal control agencies.

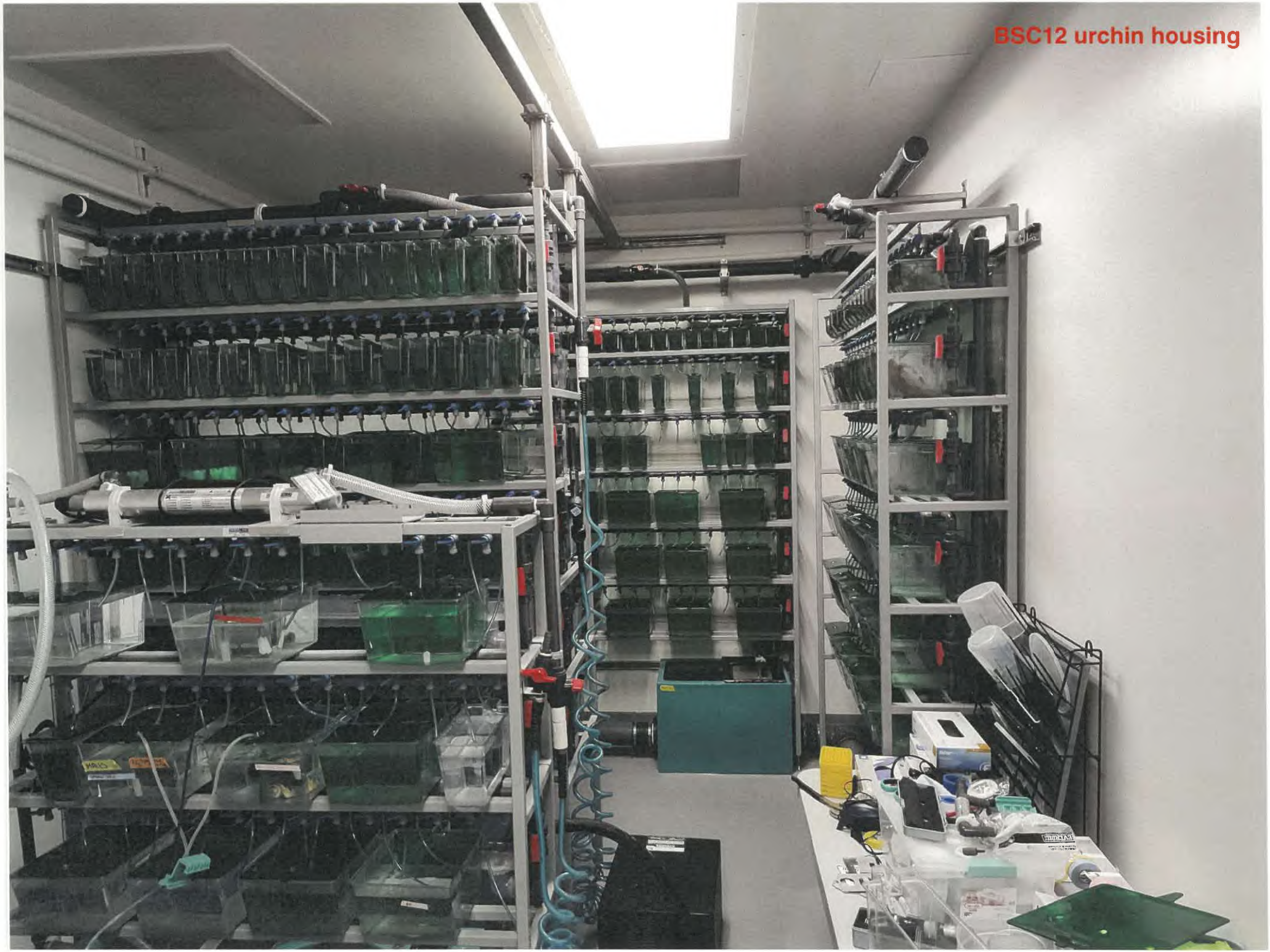
1 - 911
2 - CA Fish & Game Regional office: South Coast Regional Office: (858) 467-4201
3 - County/City Animal Control Agencies (insert here name/telephone number)
San Diego County Department of Animal Services, Emergency Line: (619) 236-2341
County Department of Animal Services, Emergency Line: (619) 236-2341
4 - Veterinarian -
(insert here name/telephone number)
Mari Bray, mbray@lavcs.onmicrosoft.com, Phone: (858) 663-6107

f. Written plan of action for various emergencies (i.e. animal escape, animal evacuation, animal attack).

Sea urchins are very unable to escape the facility due to various physical and physiological barriers, including mesh baffles and individual tank lids, floor drain covers, secure vivarium and room entrance, euthanization protocols for juveniles and adults, and the inability of the sea urchin embryos and gametes to survive the filtering processes during aquarium/rack internal re-circulation. Any required evacuation of animals can be controlled by placing their tanks into polypropylene secondary containment bins kept on a mobile cart.

Sea urchins are not physically harmful to humans, and therefore pose no risk for bite attacks. They do not harbor diseases that are infectious to humans. Handling some sea urchin

species poses a risk of puncture wound and/or venom from spines, but *L. pictus* spines are not venomous and are too dull to pierce through human skin. To prevent the rare event where a spine could get caught under a fingernail, adults are to be handled while wearing gloves. If gloves tear in this context, a hot water soak, sterile removal of the spine, and sterile band aid application can be performed with tools in the first aid kits located in BSC 12. Personnel are trained to report any such case to the PI and IBC as soon as safe for them to do so.


BSC12 urchin housing


BSC13 Water Purification System
for urchins

DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
Division of Assurances
6700B Rockledge Drive
Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
Home Page: https://olaw.nih.gov

FOR EXPRESS MAIL:
Office of Laboratory Animal Welfare
Division of Assurances
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163

10/17/2024

Re: Annual Report for Assurance: D16-00430 (A3728-01)
Report to OLAW for FY 2024

Hala Madanat, Ph.D., M.S.
AVP Research Support Services
San Diego State University
5500 Campanile Drive
San Diego, CA 92182-8220

Dear Dr. Madanat:

This notice is to acknowledge that the Division of Assurances, Office of Laboratory Animal Welfare (OLAW) received and reviewed your institution's Annual Report that was submitted in accordance with Part IV.F. of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, revised 2015.

The Annual Report to OLAW is a key document in a continuing relationship with the PHS. It contains pertinent information regarding the policies and procedures in place to provide for the appropriate care and use of laboratory animals.

We look forward to receiving your next report for the period October 1, 2024 through September 30, 2025 by December 1 (but no earlier than September 30). Please include your Assurance number on your Annual Report and in all correspondence to OLAW.

Thank you for your attention to these matters.

Sincerely,

ANDREW P. COLLINS -S

Digitally signed by ANDREW P. COLLINS -S
Date: 2024.10.17 12:21:38 -04'00'

Program Analyst, OLAW
National Institutes of Health

cc: IACUC Contact
POC

Annual Report to OLAW

Institution:	San Diego State University
Assurance Number:	D16-00430
Reporting Period: October 1, 2023 – September 30, 2024	

This institution's Institutional Animal Care and Use Committee (IACUC), through the Institutional Official, provides this annual report to the Office of Laboratory Animal Welfare (OLAW).

I. Program Changes [*Select A or B*]

[□]	A. There have been **no changes** in this institution's program for animal care and use as described in the Assurance. [*Skip to Item II.*]		
[☒]	B. Change(s) in this institution's program for animal care and use as described in the Assurance have occurred during this reporting period.		
	Select all that apply:		
	[□]	This institution's AAALAC accreditation status has changed (PHS Policy IV.A.2.).	
		[□]	AAALAC Accredited – Category 1
		[□]	Non-Accredited – Category 2
	[□]	This institution's program for animal care and use has changed (PHS Policy IV.A.1.a-i.). [*Attach a full description of the changes.*]	
	[□]	The individual designated by this institution as the Institutional Official has changed. [*Provide name, title(s), address, e-mail, phone, and fax numbers in Item V.*]	
	[☒]	The membership of this institution's IACUC has changed. [*Provide current roster of members in Item VI.*]	

II. Semiannual Evaluations

This IACUC has conducted semiannual evaluations of the institution's program and inspections of the institution's facilities (including satellite facilities) on the dates below. Reports of the evaluations and inspections have been submitted to the Institutional Official. The reports include any IACUC-approved departures from the *Guide* with a reason for each departure, any deficiencies (significant or minor) that were identified, and a plan and schedule for correction of each deficiency. [*Do not provide semiannual reports unless they include a minority view.*]

A. Program Evaluations

[*Two dates (month/day/year) must be provided to satisfy the PHS Policy requirement that evaluations be done at 6-month intervals. If the IACUC conducted more than 2 evaluations of the program during the reporting period, please attach a list showing the dates.*]

Date 1: 04-02-2024	Date 2: 09-25-2024 Date 3: 10-01-2024

B. **Facility Inspections**

[*Two dates (month/day/year) must be provided to satisfy the PHS Policy requirement that facility inspections be done at 6-month intervals. If the IACUC conducted more than 2 inspections of each site during the reporting period, please attach a list showing the dates.*]

Date 1: 04-02-2024	Date 2: 09-25-2024 Date 3: 10-01-2024

III. Minority Views [*Select A or B*]

[☒]	A. There were **no minority** views during this reporting cycle.
[☐]	B. Any minority views submitted by members of the IACUC regarding reports filed under PHS Policy IV.F. for this reporting cycle are attached.

IV. Signatures

IACUC Chairperson	**Institutional Official**
Name: Susan Brasser, Ph.D.	Name: Hala Madanat, Ph.D.
 Signature:	 Signature:
Date: 10-08-2024	Date: 10-08-2024

V. Change in Institutional Official

Name:	
Title:	Degree/Credentials:
Name of Institution: San Diego State University	
Address: [*street, city, state, zip code*]	
Phone:	Fax: N/A
E-mail:	

SDSU Research Support Services

DATE: October 17, 2024

TO: Dr. Hala Madanat
Vice President for Research and Innovation

VIA: Rick Gulizia
Asst. Vice President Research and Innovation

FROM: Susan Brasser, Chair
Institutional Animal Care and Use Committee

SUBJECT: Fall 2024 Semi-annual Facility Inspection and Program Review Reports

Our Institution adheres to the recommendations of the Guide, the PHS Policy, and the Animal Welfare Act and Regulations, all of which are used as a foundation for the development, implementation, and continual improvement of a comprehensive animal care and use program based on humane care and use of animals.

Subcommittees of the IACUC met to perform the facility inspections. The OLAW Semi-annual Facility Inspection Checklist (based on the 8th Edition ILAR Guide for the Care and Use of Laboratory Animals) was used as a guideline. The following definitions were used to determine the categories of compliance: A= acceptable; met or exceeded USDA and NIH standards; M= minor deficiency; items not affecting animal health or safety; S= significant deficiency (items that are or may be a direct threat to human or animal health and safety where animals are involved in the research); C=Change which will be submitted to OLAW; N/A=Not applicable. There is a list of minor deficiencies found during these inspections and which are outlined in the attached documents. These reports were discussed and approved by the IACUC at the convened meeting on October 14, 2024.

Additionally, the IACUC reviewed and approved the program review at the convened meeting on October 14, 2024. The OLAW Semiannual Program Review Checklist based on the 8th Edition of the ILAR Guide for the Care and Use of Laboratory Animals was used as a guideline. There have not been any departures from the regulations submitted, reviewed and/or approved by the IACUC over the last 6 months.

Research Support Services
Division of Research and Innovation
5250 Campanile Drive
San Diego, CA 92182-1933
Tel: 619/594-0905
Email: iacuc@sdsu.edu

Semiannual Program Review and Facility Inspection Checklist

About the checklist

The Semiannual Program Review and Facility Inspection Checklist is provided to assist institutions in conducting their semiannual reviews of programs and facilities for the care and use of animals. The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), section IV.B.1.-2., requires the Institutional Animal Care and Use Committee (IACUC) to review the institution's program for humane care and use of animals and inspect all of the institution's animal facilities at least once every 6 months using the *Guide for the Care and Use of Laboratory Animals: Eighth Edition (Guide)* as a basis for evaluation.

How to use the checklist

This checklist is a tool to assist IACUCs in conducting thorough semiannual reviews. IACUCs are not required to use this checklist but are encouraged to amend it as necessary to reflect institutional programs and needs, or to develop their own checklist. If the checklist is modified, periodic review of the checklist is recommended to ensure relevant topics are considered as the animal care and use program changes.

The checklist covers the major topics of the *Guide* and the requirements of the PHS Policy. The checklist does not replace the *Guide*, but should be utilized in conjunction with the *Guide*. The *Guide* provides the standards, recommendations, and descriptions of desired outcomes necessary to evaluate and inspect an animal care and use program. Relevant references for the *Guide* and the PHS Policy are noted. Endnotes are included to reference specific U.S. Department of Agriculture (USDA) regulatory requirements that differ from the PHS Policy. A column to identify changes that have occurred in the institution's program for animal care and use (PHS Policy IV.A.1.a.-i.) since the last review is also included.

It is recommended that the Program Review section be completed during an IACUC meeting. Because physical aspects of a program require visual observation to evaluate, it is recommended that the Facility Inspection section be completed during an inspection of the facilities, including satellite facilities.

A table, "Semiannual Program Review and Facility Inspection Deficiencies," is provided as a format for the IACUC to organize and track information regarding deficiencies and plans and schedules for correction. IACUCs may choose to attach the table to the Semiannual Report to the Institutional Official (IO), but it is not a substitute for the Semiannual Report to the IO. For more information about the Semiannual Report to the IO and to obtain a sample document, visit here.

Questions or comments?

Suggestions or comments about this checklist should be e-mailed to: olawdpe@mail.nih.gov.

A new feature of this checklist is the Table of Contents, provided in entirety on the next page. The Table of Contents allows you to use Control+Click (in WORD) or Click (in PDF) to go directly to a particular section of the checklist.

Table of Contents

I. Semiannual Program Review Checklist [i]

Institutional Policies and Responsibilities

Date: 10/01/2024

1. Animal Care and Use Program	A*	M	S	C	NA
• Responsibility for animal well-being is assumed by all members of the program (*Guide*, p 1) [must]	X				
• IO has authority to allocate needed resources (*Guide*, p 13)	X				
• Resources necessary to manage program of veterinary care are provided (*Guide*, p 14) [must]	X				
• Sufficient resources are available to manage the program, including training of personnel in accord with regulations and the *Guide* (*Guide*, pp 11, 15)	X				
• Program needs are regularly communicated to IO by AV and/or IACUC (*Guide*, p 13)	X				
• Responsibilities for daily animal care and facility management are assigned to specific individual(s) when a full-time veterinarian is not available on site (*Guide*, p 14) [must]	X				
• Inter-institutional collaborations are described in formal written agreements (*Guide*, p 15)	X				
• Written agreements address responsibilities, animal ownership, and IACUC oversight (*Guide*, p 15)	X				

2. Disaster Planning and Emergency Preparedness	A*	M	S	C	NA
• Disaster plans for each facility to include satellite locations are in place (*Guide*, p 35, p 75) [must]	X				
• Plans include provisions for euthanasia (*Guide*, p 35) [must]	X				
• Plans include triage plans to meet institutional and investigators' needs (*Guide*, p 35)	X				
• Plans define actions to prevent animal injury or death due to HVAC or other failures (*Guide*, p 35)	X				
• Plans describe preservation of critical or irreplaceable animals (*Guide*, p 35)	X				
• Plans include essential personnel and their training (*Guide*, p 35)	X				
• Animal facility plans are approved by the institution and incorporated into overall response plan (*Guide*, p 35)	X				
• Law enforcement and emergency personnel are provided a copy and integration with overall plan is in place (*Guide*, p 35)	X				

3. IACUC	A*	M	S	C	NA
• Meets as necessary to fulfill responsibilities (*Guide*, p 25) [must]	X				
• IACUC Members named in protocols or with conflicts recuse themselves from protocol decisions (*Guide*, p 26) [must]	X				
• Continuing IACUC oversight after initial protocol approval is in place (*Guide*, p 33)	X				
• IACUC evaluates the effectiveness of training programs (*Guide*, p 15)	X				

4. IACUC Protocol Review - Special Considerations	A*	M	S	C	NA
• Humane endpoints are established for studies that involve tumor models, infectious diseases, vaccine challenge, pain modeling, trauma, production of monoclonal antibodies, assessment of toxicologic effects, organ or system failure, and models of cardiovascular shock (*Guide*, p 27)	X				
• For pilot studies, a system to communicate with the IACUC is in place (*Guide*, p 28)	X				
• For genetically modified animals, enhanced monitoring and reporting is in place (*Guide*, p 28)	X				
• Restraint devices are justified in the animal use protocols (*Guide*, p 29) [must]	X				

• Alternatives to physical restraint are considered (*Guide*, p 29)	X				
• Period of restraint is the minimum to meet scientific objectives (*Guide*, p 29)	X				
• Training of animals to adapt to restraint is provided (*Guide*, p 29)	X				
• Animals that fail to adapt are removed from study (*Guide*, p 29)	X				
• Appropriate observation intervals of restrained animals are provided (*Guide*, p 29)	X				
• Veterinary care is provided if lesions or illness result from restraint (*Guide*, p 30) [must]	X				
• Explanations of purpose and duration of restraint are provided to study personnel (*Guide*, p 30)	X				
• Multiple surgical procedures on a single animal are justified and outcomes evaluated (*Guide*, p 30)	X				
• Major versus minor surgical procedures are evaluated on a case-by-case basis (*Guide*, p 30)	X				
• Multiple survival procedure justifications in non-regulated species conform to regulated species standards (*Guide*, p 30)	X				
• Animals on food/fluid restriction are monitored to ensure nutritional needs are met (*Guide*, p 31)	X				
• Body weights for food/fluid restricted animals are recorded at least weekly (*Guide*, p 31)	X				
• Daily written records are maintained for food/fluid restricted animals (*Guide*, p 31)	X				
• Pharmaceutical grade chemicals are used , when available, for animal-related procedures (*Guide*, p 31)	X				
• Non-pharmaceutical grade chemicals are described, justified, and approved by IACUC (*Guide*, p 31)	X				
• Investigators conducting field studies know zoonotic diseases, safety issues, laws and regulations applicable in study area (*Guide*, p 32)	X				
• Disposition plans are considered for species removed from the wild (*Guide*, p 32)	X				
• Toe-clipping only used when no alternative, performed aseptically and with pain relief (*Guide*, p 75)	X				

5. IACUC Membership and Functions	**A***	**M**	**S**	**C**	**NA**
• IACUC is comprised of at least 5 members, appointed by CEO (PHS Policy, IV.A.3.)	X				
• Members include a veterinarian, a scientist, a nonscientist, and a nonaffiliated non-lab animal user (*Guide*, p 24)[ii]	X				
• IACUC authority and resources for oversight and evaluation of institution's program are provided (*Guide*, p 14)	X				
• IACUC conducts semiannual evaluations of institutional animal care and use program (PHS Policy, IV.B.)	X				
• Conducts semiannual inspections of institutional animal facilities (PHS Policy, IV.B.)	X				
• IACUC organizationally reports to the Institutional Official (PHS Policy, IV.A.1.b.)	X				
• Methods for reporting and investigating animal welfare concerns are in place (*Guide*, p 23) [must]	X				
• Reviews and investigates concerns about animal care and use at institution[iii] (PHS Policy, IV.B.)	X				
• Procedures are in place for review, approval, and suspension of animal activities[iv] (PHS Policy, IV.B.)	X				
• Procedures are in place for review and approval of significant changes to approved activities (PHS Policy, IV.B.)	X				
• Policies are in place for special procedures (e.g., genetically modified animals, restraint, multiple survival surgery, food and fluid regulation, field investigations, agricultural animals) (*Guide*, p 27-32)	X				
• Requests for exemptions from major survival surgical procedure restrictions are made to USDA/APHIS[v] (*Guide*, p 30) [must]					X

6. IACUC Training	**A***	**M**	**S**	**C**	**NA**
• All IACUC members should receive:					

○ Formal orientation to institution's program (*Guide*, p 17)	X				
○ Training on legislation, regulations, guidelines, and policies (*Guide*, p 17)	X				
○ Training on how to inspect facilities and labs where animal use or housing occurs (*Guide*, p 17)	X				
○ Training on how to review protocols as well as evaluate the program (*Guide*, p 17)	X				
○ Ongoing training/education (*Guide*, p 17)	X				

7. IACUC Records and Reporting Requirements[vi]	**A***	**M**	**S**	**C**	**NA**
• Semiannual report to the IO (PHS Policy, IV.B.)					
○ Submitted to IO every 6 months	X				
○ Compiles program review and facility inspection(s) results (includes all program and facility deficiencies)	X				
○ Includes minority IACUC views	X				
○ Describes IACUC-approved departures from the *Guide* or PHS Policy and the reasons for each departure[vii]	X				
○ Distinguishes significant from minor deficiencies	X				
○ Includes a plan and schedule for correction for each deficiency identified[viii]	X				
• Reports to OLAW (PHS Policy, IV.F.)					
○ Annual report to OLAW documents program changes, dates of the semiannual program reviews and facility inspections and includes any minority views	X				
○ Promptly advises OLAW of serious/ongoing *Guide* deviations or PHS Policy noncompliance (NOT-OD-05-034)	X				
○ Institute must promptly advise OLAW of any suspension of an animal activity by the IACUC (NOT-OD-05-034)	X				
• Reports to U.S. Department of Agriculture (USDA) or Federal funding agency[ix]					
○ Annual report to USDA contains required information including all exceptions/exemptions	X				
○ Reporting mechanism to USDA is in place for IACUC-approved exceptions to the regulations and standards	X				
○ Reports are filed within 15 days for failures to adhere to timetable for correction of significant deficiencies	X				
○ Promptly reports suspensions of activities by the IACUC to USDA and any Federal funding agency	X				
• Records (PHS Policy, IV.E.)					
○ IACUC meeting minutes and semiannual reports to the IO are maintained for 3 years	X				
○ Records of IACUC reviews of animal activities include all required information[x]	X				
○ Records of IACUC reviews are maintained for 3 years after the completion of the study	X				

8. Veterinary Care (See also next section - Veterinary Care)	**A***	**M**	**S**	**C**	**NA**
• An arrangement for veterinarian(s) with training or experience in lab animal medicine is in place including backup veterinary care[xi]	X				
• Veterinary access to all animals is provided (*Guide*, p 14) [must]	X				
• Direct or delegated authority is given to the veterinarian to oversee all aspects of animal care and use (*Guide*, p 14) [must]	X				
• Veterinarian provides consultation when pain and distress exceeds anticipated level in protocol (*Guide*, p 5) [must]	X				
• Veterinarian provides consultation when interventional control is not possible (*Guide*, p 5) [must]	X				
• If part time /consulting veterinarian, visits meet programmatic needs (*Guide*, p 14)	X				
• Regular communication occurs between veterinarian and IACUC (*Guide*, p 14)	X				
• Veterinarian(s) have experience and training in species used (*Guide*, p 15) [must]	X				
• Veterinarian(s) have experience in facility administration/management (*Guide*, p 15)	X				

9. Personnel Qualifications and Training	A*	M	S	C	NA
• All personnel are adequately educated, trained, and/or qualified in basic principles of laboratory animal science. Personnel included: [must]					
○ Veterinary/other professional staff (*Guide*, p 15-16)	X				
○ IACUC members (*Guide*, p 17)	X				
○ Animal care personnel (*Guide*, p 16)	X				
○ Research investigators, instructors, technicians, trainees, and students (*Guide*, pp 16-17)	X				
• Continuing education for program and research staff provided to ensure high quality care and reinforce training (*Guide*, pp 16-17)	X				
• Training is available prior to starting animal activity (*Guide*, p 17)	X				
• Training is documented (*Guide*, p 15)	X				
• Training program content includes: (*Guide*, p 17)					
○ Methods for reporting concerns (*Guide*, p 17)	X				
○ Humane practices of animal care (e.g., housing, husbandry, handling) [xii]	X				
○ Humane practices of animal use (e.g., research procedures, use of anesthesia, pre- and post-operative care, aseptic surgical techniques, and euthanasia (*Guide*, p 17)[xiii]	X				
○ Research/testing methods that minimize numbers necessary to obtain valid results (PHS Policy, IV.A.1.g.)	X				
○ Research/testing methods that minimize animal pain or distress (PHS Policy, IV.A.1.g.)	X				
○ Use of hazardous agents, including access to OSHA chemical hazard notices where applicable (*Guide*, p 20)	X				
○ Animal care and use legislation (*Guide*, p 17)	X				
○ IACUC function (*Guide*, p 17)	X				
○ Ethics of animal use and Three Rs (*Guide*, p 17)	X				

10. Occupational Health and Safety of Personnel	A*	M	S	C	NA
• Program is in place and is consistent with federal, state, and local regulations (*Guide*, p 17) [must]	X				
• Program covers *all* personnel who work in laboratory animal facilities (*Guide*, p 18)	X				
• Changing, washing, and showering facilities are available as appropriate (*Guide*, p 19)	X				
• Hazardous facilities are separated from other areas and identified as limited access (*Guide*, p 19)	X				
• Personnel training is provided based on risk (e.g., zoonoses, hazards, personal hygiene, special precautions, animal allergies) (*Guide*, p 20)	X				
• Personal hygiene procedures are in place (e.g., work clothing, eating/drinking/smoking policies) (*Guide*, p 20)	X				
• Procedures for use, storage, and disposal of hazardous biologic, chemical, and physical agents are in place (*Guide*, p 21)	X				
• Personal Protective Equipment for the work area is appropriate and available (*Guide*, p 21)	X				
• Program for medical evaluation and preventive medicine for personnel includes:					
○ Pre-employment evaluation including health history (*Guide*, p 22)	X				
○ Immunizations as appropriate (e.g., rabies, tetanus) and tests as appropriate (*Guide*, p 22)	X				
○ Zoonosis surveillance as appropriate (e.g., Q-fever, tularemia, Hantavirus, plague) (*Guide*, p 23)	X				
○ Procedures for reporting and treating injuries, including accidents, bites, allergies, etc. (*Guide*, p 23)	X				
○ Promotes early diagnosis of allergies including preexisting conditions (*Guide*, p 22)	X				
○ Considers confidentiality and other legal factors as required by federal, state and local regulations (*Guide*, p 22) [must]	X				
○ If serum samples are collected, the purpose is consistent with federal and state	X				

laws (*Guide*, p 22) [must]						
• Waste anesthetic gases are scavenged (*Guide*, p 21)	X					
• Hearing protection is provided in high noise areas (*Guide*, p 22)	X					
• Respiratory protection is available when performing airborne particulate work (*Guide*, p 22)	X					
• Special precautions for personnel who work with nonhuman primates, their tissues or body fluids include:						
○ Tuberculosis screening provided for all exposed personnel (*Guide*, p 23)	X					
○ Training and implementation of procedures for bites, scratches, or injuries associated with macaques (*Guide*, p 23)	X					
○ PPE is provided including gloves, arm protection, face masks, face shields, or goggles (*Guide*, p 21)	X					
○ Injuries associated with macaques are carefully evaluated and treatment implemented (*Guide*, p 23)	X					
• Occupational safety and health of field studies is reviewed by OSH committee or office (*Guide*, p 32)	X					

11. Personnel Security	**A***	**M**	**S**	**C**	**NA**
• Preventive measures in place include pre-employment screening, and physical and IT security (*Guide*, p 23)	X				

12. Investigating & Reporting Animal Welfare Concerns	**A***	**M**	**S**	**C**	**NA**
• Methods for investigating and reporting animal welfare concerns are established (*Guide*, p 23) [must]	X				
• Reported concerns and corrective actions are documented (*Guide*, p 24)	X				
• Mechanisms for reporting concerns are posted in facility and at applicable website with instructions (*Guide*, p 24)	X				
○ Includes multiple contacts (*Guide*, p 24)	X				
○ Includes anonymity, whistle blower policy, nondiscrimination and reprisal protection (*Guide*, p 24)	X				

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NA = not applicable

NOTES:

Veterinary Care

Date:

1. Clinical Care and Management	A*	M	S	C	NA
• Veterinary program offers high quality of care and ethical standards (*Guide*, p 105) [must]	X				
• Veterinarian provides guidance to all personnel to ensure appropriate husbandry, handling, treatment, anesthesia, analgesia, and euthanasia (*Guide*, p 106)	X				
• Veterinarian provides oversight to surgery and perioperative care (*Guide*, p 106)	X				
• Veterinary care program is appropriate for program requirements (*Guide*, pp 113-114)	X				
• Veterinarian(s) is familiar with species and use of animals and has access to medical and experimental treatment records (*Guide*, p 114)	X				
• Procedures to triage and prioritize incident reports are in place (*Guide*, p 114)	X				
• Procedures are in place to address:					
○ Problems with experiments to determine course of treatment in consultation with investigator (*Guide*, p 114)	X				
○ Recurrent or significant health problems with the IACUC and documentation of treatments and outcomes (*Guide*, p 114)	X				
○ Veterinary review and oversight of medical and animal use records (*Guide*, p 115)	X				
• Procedures established for timely reporting of animal injury, illness, or disease (*Guide*, p 114) [must]	X				
• Procedures established for veterinary assessment, treatment, or euthanasia (*Guide*, p 114) [must]	X				
• Veterinarian is authorized to treat, relieve pain, and/or euthanize (*Guide*, p 114) [must]	X				

2. Animal Procurement and Transportation/Preventive Medicine	A*	M	S	C	NA
• Procedures for lawful animal procurement are in place (*Guide*, p 106) [must]	X				
• Sufficient facilities and expertise are confirmed prior to procurement (*Guide*, p 106)	X				
• Procurement is linked to IACUC review and approval (*Guide*, p 106)	X				
• Random source dogs and cats are inspected for identification (*Guide*, p 106)	X				
• Population status of wildlife species is considered prior to procurement (*Guide*, p 106)	X				
• Appropriate records are maintained on animal acquisition (*Guide*, p 106)	X				
• Animal vendors are evaluated to meet program needs and quality (*Guide*, p 106)	X				
• Breeding colonies are based on need and managed to minimize numbers (*Guide*, p 107)	X				
• Procedures for compliance with animal transportation regulations, including international requirements, are in place (*Guide*, p 107) [must]	X				
• Transportation is planned to ensure safety, security and minimize risk (*Guide*, p 107)	X				
• Movement of animals is planned to minimize transit time and deliveries are planned to ensure receiving personnel are available (*Guide*, pp 107- 108)	X				
• Appropriate loading and unloading facilities are available (*Guide*, p 109)	X				
• Environment at receiving site is appropriate (*Guide*, p 109)	X				
• Policies in place on separation by species, source, and health status (*Guide*, pp 109, 111-112)	X				
• Procedures in place for quarantine to include zoonoses prevention (*Guide*, p 110)	X				
• Quarantined animals from different shipments are handled separately or physically separated (*Guide*, p 110)	X				
• Procedures in place for stabilization/acclimation (*Guide*, pp 110-111)	X				
• Policies in place for isolation of sick animals (*Guide*, p 112)	X				
• Program is in place for surveillance, diagnosis, treatment, and control of disease to include daily observation (*Guide*, p 112)	X				

• Diagnostic resources are available for preventive health program (*Guide*, p 112)	X					

3. Surgery	A*	M	S	C	NA
• Surgical outcomes are assessed, and corrective changes instituted (*Guide*, p 115)	X				
• Researchers have appropriate training to ensure good technique (*Guide*, p 115) [must]	X				
• Pre-surgical plans are developed and include veterinary input (e.g., location, supplies, anesthetic and analgesic use, peri-operative care, recordkeeping) (*Guide*, p 116)	X				
• Aseptic surgery is conducted in dedicated facilities or spaces, unless exception justified and IACUC approved (*Guide*, p 116)	X				
• Surgical procedures including laparoscopic procedures are categorized as major or minor (*Guide*, pp 117-118)	X				
• For nonsurvival surgery, the site is clipped, gloves are worn and instruments and area are clean (*Guide*, p 118)	X				
• Aseptic technique is followed for survival surgical procedures (*Guide*, pp 118-119)	X				
• Effective procedures for sterilizing instruments and monitoring expiration dates on sterile packs are in place (*Guide*, p 119)	X				
• Procedures for monitoring surgical anesthesia and analgesia are in place (*Guide*, p 119)	X				
• For aquatic species, skin surfaces are kept moist during surgical procedures (*Guide*, p 119)	X				
• Post-operative monitoring and care are provided by trained personnel and documented (e.g., thermoregulation, physiologic function, analgesia, infection, removal of skin closures) (*Guide*, pp 119-120)	X				

4. Pain, Distress, Anesthesia, and Analgesia	A*	M	S	C	NA
• Guidelines for assessment and categorization of pain, distress and animal wellbeing are provided during training (*Guide*, p 121)	X				
• Selection of analgesics and anesthetics is based on professional veterinary judgment (*Guide*, p 121)	X				
• Painful procedures are monitored to ensure appropriate analgesic management (*Guide*, p 122)	X				
• Nonpharmacologic control of pain is considered as an element of postprocedural care (*Guide*, p 122)	X				
• Procedures are in place to assure antinociception before surgery begins (*Guide*, p 122) [must]	X				
• Guidelines for selection and use of analgesics and anesthetics are in place and regularly reviewed and updated (*Guide*, p 122)	X				
• Special precautions for the use of paralytics are in place to ensure anesthesia[xiv] (*Guide*, p 123)	X				

5. Euthanasia	A*	M	S	C	NA
• Methods are consistent with AVMA Guidelines on Euthanasia unless approved by the IACUC (*Guide*, p 123)	X				
• Standardized methods are developed and approved by the veterinarian and IACUC that avoid distress and consider animal age and species (*Guide*, pp 123-124)	X				
• Training is provided on appropriate methods for each species and considers psychological stress to personnel (*Guide*, p 124)	X				
• Procedures and training are in place to ensure death is confirmed (*Guide*, p 124) [must]	X				

6. Drug Storage and Control	A*	M	S	C	NA
• Program complies with federal regulations for human and veterinary drugs (*Guide*, p 115) [must]	X				
• Drug records and storage procedures are reviewed during facility inspections (*Guide*, p	X				

115)						
• Procedures are in place to ensure analgesics and anesthetics are used within expiration date (*Guide*, p 122) [must]	X					
• Anesthetics and analgesics are acquired, stored, and their use and disposal are recorded legally and safely (*Guide*, p 122)	X					

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NA = not applicable

NOTES:

II. Semiannual Facility Inspection Checklist

Terrestrial Animal Housing and Support Areas

Date:
Location:

	A*	M	S	C	NA
• **Location:**					
○ animal areas separate from personnel areas (*Guide*, p 134)	X				
○ separation of species (*Guide*, p 111)	X				
○ separation by disease status (*Guide*, p 111)	X				
○ security and access control (*Guide*, p 151)	X				
• **Construction:**					
○ corridors (*Guide*, p 136)	X				
○ animal room doors (*Guide*, p 137)	X				
○ exterior windows (*Guide*, p 137)	X				
○ floors (*Guide*, p 137)	X				
○ drainage (*Guide*, p 138)	X				
○ walls and ceilings (*Guide*, p 138)	X				
○ heating ventilation and air conditioning (*Guide*, p 139)	X				
○ power and lighting (*Guide*, p 141)	X				
○ noise control (*Guide*, p 142)	X				
○ vibration control (*Guide*, p 142)	X				
○ environmental monitoring (*Guide*, p 143)	X				
• **Room/Cage:**					
○ temperature and humidity (*Guide*, p 43)	X				
○ ventilation and air quality (*Guide*, p 45)	X				
○ illumination (*Guide*, p 47)	X				
○ noise and vibration (*Guide*, p 49)	X				
• **Primary Enclosure:**					
○ space meets physiologic, behavioral [xv], and social[xvi] needs (*Guide*, pp 51, 55-63)	X				
○ secure environment provided (*Guide*, p 51)	X				
○ durable, nontoxic materials in good repair and no risk of injury (*Guide*, p 51)	X				
○ flooring is safe and appropriate for species (*Guide*, p 51)	X				
○ adequate bedding and structures for resting, sleeping, breeding (*Guide*, p 52)	X				
○ objective assessments of housing and management are made (*Guide*, p 52)	X				
○ procedures for routine husbandry are documented (*Guide*, p 52)	X				
○ socially housed animals can escape or hide to avoid aggression (*Guide*, p 55)	X				
○ cage height provides adequate clearance (*Guide*, p 56)	X				
○ animals express natural postures, can turn around, access food and water, and rest away from urine and feces (*Guide*, p 56) [must]	X				
○ rationale[xvii] for *Guide*/USDA space exceptions approved by IACUC and based on performance indices (*Guide*, p 56)	X				
○ dogs and cats allowed to exercise and provided human interaction (*Guide*, p 58)					X
○ nonhuman primates are socially housed except for scientific, veterinary or behavior reasons (*Guide*, pp 58-59)					X
○ single housing of nonhuman primates is for shortest duration possible (*Guide*, p 60)					X
○ opportunities for release into larger enclosures is considered for single caged nonhuman primates (*Guide*, p 60)					X
○ agricultural animals are housed socially (*Guide*, p 60)					X
○ food troughs and water devices for agricultural animals allow access for all					X

animals (*Guide*, p 60)	
• **Environmental Enrichment, Behavioral and Social Management:**	
○ structures and resources promote species typical behavior (*Guide*, pp 52-54)	X
○ novelty of enrichment is considered (*Guide*, p 53)	X
○ species specific plans for housing including enrichment, behavior and activity are developed and reviewed regularly by IACUC, researchers and veterinarian (*Guide*, pp 53, 58, 60, 63)	X
○ animal care personnel receive training to identify abnormal animal behaviors (*Guide*, p 53)	X
○ stability of pairs or groups is monitored for incompatibility (*Guide*, p 64)	X
○ single housing is justified for social species (*Guide*, p 64)	X
○ single housing is limited to the minimum period necessary (*Guide*, p 64)	X
○ additional enrichment for single housed animals is provided (*Guide*, p 64)	X
○ single housing is reviewed regularly by IACUC and veterinarian (*Guide*, p 64)	X
○ habituation to routine procedures is part of enrichment program (*Guide*, p 64)	X
• **Sheltered or Outdoor Housing:** (e.g., barns, corrals, pastures, islands)	
○ weather protection and opportunity for retreat (*Guide*, p 54) [must]	X
○ appropriate size (*Guide*, p 54)	X
○ ventilation and sanitation of shelter (no waste/moisture build-up) (*Guide*, p 54)	X
○ animal acclimation (*Guide*, p 55)	X
○ social compatibility (*Guide*, p 55)	X
○ roundup/restraint procedures (*Guide*, p 55)	X
○ appropriate security (*Guide*, p 55)	X
• **Naturalistic Environments:**	
○ animals added /removed with consideration of effect on group (*Guide*, p 55)	X
○ adequate food, fresh water, and shelter ensured (*Guide*, p 55)	X
• **Food:**	
○ feeding schedule and procedures including caloric intake management (*Guide*, pp 65-67)	X
○ contamination prevention (*Guide*, p 65)	X
○ vendor quality control (*Guide*, p 66)	X
○ storage in sealed containers (*Guide*, p 66)	X
○ expiration date labeling (*Guide*, p 66)	X
○ vermin control (*Guide*, p 66)	X
○ rotation of stocks (*Guide*, p 66)	X
• **Water:**	
○ ad libitum unless justified (*Guide*, pp 67-68)	X
○ QC procedures (*Guide*, pp 67-68)	X
• **Bedding and Nesting Materials:**	
○ species appropriate (*Guide*, pp 68-69)	X
○ keeps animals dry (*Guide*, pp 68-69)	X
○ QC procedures (*Guide*, pp 68-69)	X
○ minimizes scientific variables (*Guide*, pp 68-69)	X
• **Sanitation:**	
○ frequency of bedding/substrate change (*Guide*, p 70)	X
○ cleaning and disinfection of microenvironment (*Guide*, pp 70-71)	X
○ cleaning and disinfection of macroenvironment (*Guide*, p 72)	X
○ assessing effectiveness (*Guide*, p 73)	X
• **Waste Disposal:**	
○ procedures for collection (*Guide*, pp 73-74)	X
○ procedures for storage and disposal (*Guide*, pp 73-74)	X
○ hazardous wastes are rendered safe before removal from facility (*Guide*, pp 73-74) [must]	X
○ animal carcasses (*Guide*, pp 73-74)	X
• **Pest Control:**	
○ regularly scheduled (*Guide*, p 74)	X

○ documented program including control of rodent pests and insecticide use (*Guide*, p 74)	X
• **Emergency, Weekend, and Holiday Animal Care:**	
○ care provided by qualified personnel every day (*Guide*, p 74)	X
○ provision for accessible contact information (*Guide*, p 74)	X
○ monitoring of backup systems (*Guide*, p 143)	X
○ veterinary care available after hours, weekends, and holidays (*Guide*, pp 74, 114) [must]	X
○ a disaster plan that takes into account both personnel and animals (*Guide*, p 75)	X
• **Identification:**	
○ cage/rack cards contain required information (*Guide*, p 75)	X
○ genotype information included and standardized nomenclature used when applicable (*Guide*, p 75)	X
• **Recordkeeping:**	
○ clinical records accessible and contain appropriate information (*Guide*, pp 75-76)	X
○ records are provided when animals are transferred between institutions (*Guide*, p 75)	X
• **Breeding Genetics and Nomenclature:**	
○ appropriate genetic records, management and monitoring procedures (*Guide*, p 76)	X
○ phenotypes that affect wellbeing are reported to IACUC and effectively managed (*Guide*, p 77)	X
• **Storage:**	
○ adequate space for equipment, supplies, food, bedding and refuse (*Guide*, p 141)	X
○ bedding in vermin-free area and protected from contamination(*Guide*, p 141)	X
○ food in vermin-free, temperature and humidity controlled area and protected from contamination (*Guide*, p 141)	X
○ refuse storage is separate (*Guide*, p 141)	X
○ carcass and animal tissue storage is separate, refrigerated below 7°C and cleanable (*Guide*, p 141)	X
• **Personnel:**	
○ adequate space for locker rooms, administration and training (*Guide*, p 135)	X

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NA = not applicable

NOTES:

Aquatic Animal Housing and Support Areas

Date: 09/25/2024
Location: CMIL

	A*	M	S	C	NA
• **Location:**					
○ animal areas separate from personnel areas (*Guide*, p 134)	X				
○ separation of species (*Guide*, p 111)	X				
○ separation by disease status (*Guide*, p 111)	X				
○ security and access control (*Guide*, p 151)	X				
• **Construction:**					
○ corridors (*Guide*, p 136)	X				
○ animal room doors (*Guide*, pp 137, 150)	X				
○ exterior windows (*Guide*, p 137)	X				
○ floors (*Guide*, pp 137, 150)	X				
○ drainage (*Guide*, pp 138, 150)	X				
○ walls and ceilings (*Guide*, pp 138, 150)	X				
○ heating ventilation and air conditioning (*Guide*, pp 139, 150-151)	X				
○ power and lighting (*Guide*, pp 141, 150)	X				
○ noise control (*Guide*, p 142)	X				
○ vibration control (*Guide*, p 142)	X				
○ environmental monitoring (*Guide*, p 143)	X				
• **Water Quality:**					
○ standards for acceptable quality are established (*Guide*, p 78)	X				
○ chlorine, chloramines, chemical, and reactive bioproducts are removed or neutralized prior to use in aquatic systems (*Guide*, pp78, 86) [must]	X				
• **Life Support System:**					
○ water source is based on appropriate controls and research requirements (*Guide*, p 79)	X				
○ biofilter is of sufficient size to process bioload (*Guide*, p 80) [must]	X				
• **Temperature, Humidity and Ventilation/Illumination/Noise and Vibration:**					
○ temperature and humidity (*Guide*, pp 43, 80-81)	X				
○ ventilation and air quality (*Guide*, pp 45, 81)	X				
○ illumination (*Guide*, pp 47, 81)	X				
○ noise and vibration (*Guide*, pp 49, 81)	X				
• **Primary Enclosure:**					
○ allows for normal physiological and behavioral needs (*Guide*, p 82)	X				
○ allows social interaction for social species (*Guide*, p 82)	X				
○ provides a balanced, stable environment (*Guide*, p 82)	X				
○ provides appropriate water quality and monitoring (*Guide*, p 82)	X				
○ allows access to food and waste removal (*Guide*, p 82)	X				
○ restricts escape and entrapment (*Guide*, p 82)	X				
○ allows undisturbed observation (*Guide*, p 82)	X				
○ constructed of nontoxic materials (*Guide*, p 82)	X				
○ prevents electrical hazards (*Guide*, p 82)	X				
○ space needs of species are evaluated by IACUC during program evaluations and facility inspections (*Guide*, p 83)	X				
• **Environmental Enrichment, Social Housing, Behavioral and Social Management:**					
○ enrichment elicits appropriate behaviors and is safe (*Guide*, p 83)	X				
○ semi-aquatic reptiles are provided terrestrial areas (*Guide*, p 83)	X				
○ handling is kept to a minimum and appropriate techniques are in place at facility	X				

	or protocol level (*Guide*, p 84)					
○	nets are cleaned, disinfected and managed to avoid contamination of systems (*Guide*, p 84)	X				
•	**Food:**					
○	storage to prevent contamination, preserve nutrients and prevent pests (*Guide*, p 84)	X				
○	delivery ensures access to all , minimizing aggression and nutrient loss (*Guide*, p 84)	X				
○	storage times are based on manufacturer recommendations or accepted practice (*Guide*, p 84)	X				
○	a nutritionally complete diet is provided (*Guide*, p 84)	X				
•	**Substrate:**					
○	amount, type, and presentation of substrate is appropriate for the system and the species (*Guide*, p 85)	X				
•	**Sanitation, Cleaning and Disinfection**					
○	frequency of tank/cage cleaning and disinfection is determined by water quality, permits adequate viewing and health monitoring (*Guide*, p 86)	X				
○	cleaning and disinfection of macroenvironment (*Guide*, p 86)	X				
•	**Waste Disposal:**					
○	procedures for collection (*Guide*, pp 73-74)	X				
○	hazardous wastes are rendered safe before removal from facility (*Guide*, pp 73-74) [must]	X				
○	animal carcasses (*Guide*, pp 73-74)	X				
•	**Pest Control:**					
○	regularly scheduled (*Guide*, p 74)	X				
○	documented program including control of pests and insecticide use (*Guide*, p 74)	X				
•	**Emergency, Weekend, and Holiday Animal Care:**					
○	care provided by qualified personnel every day (*Guide*, pp 74, 87)	X				
○	provision for accessible contact information (*Guide*, pp 74, 87)	X				
○	emergency response plans in place to address major system failures (*Guide*, 87)	X				
○	veterinary care available after hours, weekends, and holidays (*Guide*, pp 74, 114) [must]	X				
•	**Identification:**					
○	cage/tank cards contain required information (*Guide*, pp 75, 87)	X				
○	genotype information included and standardized nomenclature used when applicable (*Guide*, pp 75, 87)	X				
•	**Recordkeeping:**					
○	water quality parameters and frequency of testing recorded (*Guide*, p 88)	X				
○	records kept on feeding, nonexpired food supplies, live cultures (*Guide*, p 88)	X				
•	**Storage:**					
○	adequate space for equipment, supplies, food, substrate, and refuse (*Guide*, p 141)	X				
○	substrate protected from contamination (*Guide*, p 141)	X				
○	food in vermin-free, temperature and humidity-controlled area and protected from contamination (*Guide*, p 141)	X				
○	refuse storage is separate (*Guide*, p 141)	X				
○	carcass and animal tissue storage is separate, refrigerated below 7ºC and cleanable (*Guide*, p 141)	X				
•	**Personnel:**					
○	adequate space for locker rooms, administration, and training (*Guide*, p 135)	X				

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NOTES:

Cagewash

Date:
Location:

	A*	M	S	C	NA
• **Construction and Operation:**					
○ dedicated central area for sanitizing cages and equipment is provided (*Guide*, p 143)	X				
○ cage-washing equipment meets need (*Guide*, p 143)	X				
○ doors, windows, floors, drainage, walls, ceilings (*Guide*, pp 136-138)	X				
○ convenient to animal areas/waste disposal (*Guide*, p 143)	X				
○ ease of access (including door size) facilitates use (*Guide*, p 143)	X				
○ sufficient space for staging and maneuvering (*Guide*, p 143)	X				
○ safety precautions/clothing/equipment used for waste disposal/prewash/acid wash ((*Guide*, p 143)	X				
○ traffic flow clean to dirty with no contamination of clean equipment by dirty equipment and appropriate air pressurization (*Guide*, p 143)	X				
○ insulation and/or sound attenuation present as needed (*Guide*, p 143)	X				
○ utilities are appropriate (*Guide*, p 143)	X				
○ ventilation meets heat and humidity load (*Guide*, p 143)	X				
○ safety features (e.g., SOPs, warning signs, eyewash stations) are in use (*Guide*, p 143)	X				
○ functioning safety devices to prevent entrapment in washer/sterilizers (*Guide*, p 143)	X				
○ cage wash temperatures are monitored and records are available (*Guide*, p 73)	X				
○ appropriate clean cage storage (*Guide*, p 141)	X				

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NA = not applicable

NOTES:

Special Facilities: Aseptic Surgery

Date:
Location:

	A*	M	S	C	NA
• **General Considerations:**					
○ location minimizes traffic/contamination (*Guide*, p 144)	X				
○ functional components (surgical support, animal preparation, surgeon scrub, operating room, postoperative recovery) are designed and separated (physically or otherwise) (*Guide*, p 144)	X				
○ appropriate drug storage, control, expiration date monitoring (*Guide*, pp 115, 122)	X				
○ safe sharps disposal system (*Guide*, p 74)	X				
○ adequate records of anesthesia and perioperative care (*Guide*, p 122)	X				
○ aseptic procedures in use for all survival surgery (*Guide*, pp 118-119)	X				
• **Operating Room:**					
○ effective contamination control procedures (*Guide*, p 144)	X				
○ effective cleaning procedures/dedicated tools (*Guide*, p 145)	X				
○ interior surfaces smooth and impervious to moisture (*Guide*, p 145)	X				
○ HVAC system meets *Guide* requirements (*Guide*, p 145)	X				
○ lighting safe and appropriate (*Guide*, p 145)	X				
○ outlets safe and appropriate (*Guide*, p 145)	X				
○ scavenging of anesthetic gases implemented (*Guide*, p 145)	X				
• **Surgical Support:**					
○ facility for washing, sterilizing, storing instruments and supplies (*Guide*, p 145)	X				
○ autoclave monitoring procedures are implemented (*Guide*, pp 119, 145)	X				
○ storage of autoclaved materials maintains sterility (*Guide*, p 145)	X				
○ cold sterilization procedures are appropriate (*Guide*, p 119)	X				
• **Animal Preparation:** contains large sink to facilitate cleaning of animal and operative site (*Guide*, p 145)	X				
• **Surgeon Scrub:** outside operating room, non-hand-operated sink (*Guide*, p 145)					X
• **Postoperative Recovery:** allows adequate observation, easily cleaned, supports physiologic functions, minimizes risk of injury (*Guide*, p 145)	X				
• **Dressing Area:** place for personnel to change (*Guide*, p 145)	X				

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NOTES:

Special Facilities: Procedure Areas, Non-survival Surgeries, Laboratories, Rodent Surgeries, Imaging, Whole Body Irradiation, Hazardous Agent Containment, Behavioral Studies

Date:
Location:

	A*	M	S	C	NA
• **General Considerations:**					
○ labs used to house animals only when scientifically required and limited to minimum period necessary (*Guide*, p 134)	X				
○ drug storage, control, and expiration dates (*Guide*, pp 115, 122)	X				
○ sharps disposal (*Guide*, p 74)	X				
○ anesthetic monitoring (*Guide*, p 120)	X				
○ scavenging of anesthetic gases (*Guide*, p 21)	X				
○ safety features (e.g., SOPs, safety signs, eyewash stations, secure gas cylinders) are in place (*Guide*, p 19)	X				
○ carcass disposal (*Guide*, pp 73-74)	X				
• **Additional Concerns for Survival Surgery:** (rodent and minor procedures only)					
○ rodent survival surgery clean and uncluttered, not used for anything else during surgery (*Guide*, p 144)	X				
○ records of peri-operative care (*Guide*, p 120)	X				
○ aseptic procedures (*Guide*, pp 118-119)	X				
○ autoclave monitoring procedures (*Guide*, pp 119, 145)	X				
○ storage of autoclaved materials (*Guide*, p 145)	X				
○ cold sterilization procedures are appropriate (*Guide*, p 119)	X				
• **Imaging/Whole Body Irradiation:**					
○ location of resource limits contamination risk (*Guide*, p 147)	X				
○ appropriate transportation methods are in place (*Guide*, p 147)	X				
○ gas anesthesia provision, scavenging and monitoring are appropriate (*Guide*, p 147)	X				
○ appropriate sensors and ventilation are provided for cryogen gases (*Guide*, p 147) [must]					X
○ imaging console is located away from radiation source (*Guide*, p 147)					X
• **Hazardous Agent Containment:**					
○ facility adheres to APHIS, USDA and CDC Select Agent Regulations and other federal, state and local regulations including security measures (*Guide*, p 148) [must]	X				
• **Behavioral Studies:**					
○ facility minimizes airborne transmission of noise and ground-borne transmission of vibration (*Guide*, p 149)	X				
○ floor coverings reduce sound transmission (*Guide*, p 149)	X				
○ testing equipment allows for surface disinfection (*Guide*, p 150)	X				
○ components that cannot be cleaned are not in ready contact with animals and kept covered when not in use (*Guide*, p 150)	X				
○ housing areas are contiguous with testing areas when appropriate (*Guide*, p 150)	X				

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NOTES:

III. Semiannual Program Review and Facility Inspection Deficiencies

This table is provided as a format for the IACUC to organize and track information regarding deficiencies and plans and schedules for correction. This is not a substitute for the Semiannual Report to the IO. For more information about the Semiannual Report to the IO and to obtain a sample document, visit here.

Date:
Members in Attendance:

Deficiency Category*	√	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete

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M = minor deficiency
S = significant deficiency (is or may be a threat to animal health or safety)
C = change in program (PHS Policy IV.A.1.a.-i.) (include in semiannual report to IO and in annual report to OLAW)
NA = not applicable

√ Check if repeat deficiency

IV. Endnotes

[i] The PHS Policy requires that Assured institutions comply with the regulations (9 CFR, Subchapter A) issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act, as applicable. The endnotes below are specific USDA regulatory requirements that differ from or are in addition to the PHS Policy. This list is not intended to be all inclusive. For additional information please refer to 9 CFR Subchapter A - Animal Welfare.

[ii] Part 2 Subpart C - Research Facilities
- 2.31(b)(2) - "The Committee shall be composed of a Chairman and at least two additional members;... at least one shall not be affiliated in any way with the facility...such person will provide representation for general community interests in the proper care and treatment of animals." [PHS policy requires 5 members]

[iii] 2.32(c)(4) - "...No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act." [USDA requirement additional to PHS Policy]

[iv] 2.31(d)(5) - "...shall conduct continuing reviews of activities...not less than annually." [PHS Policy requires a complete new review every 3 years utilizing all the criteria for initial review]

[v] 2.31(d)(1)(x) - "...no animal will be used in more than one major operative procedure from which it is allowed to recover unless...(it is) justified for scientific reasons...(or is) required as routine veterinary procedure...or other special circumstances as determined by the Administrator on an individual basis." [this last point is an additional USDA justification for multiple survival surgeries]

[vi] 2.36 - "...each reporting facility shall submit an annual report to the APHIS, AC sector supervisor for the State where the facility is located on or before December 1 of each calendar year." [The USDA annual report has a list of requirements which differ from PHS annual report]

[vii] 2.36(b)(3) - "...exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the IACUC. A summary of all such exceptions must be attached to the facility's annual report." [Refers to USDA annual report]

[viii] 2.31(c)(3) - "...Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the institutional official, to APHIS and any Federal agency funding that activity." [PHS Policy requires prompt reporting to OPRR of serious or continuing noncompliance with the PHS Policy or serious deviations from the provisions of the *Guide*]

[ix] 2.36 - "...each reporting facility shall submit an annual report to the APHIS, AC sector supervisor for the State where the facility is located on or before December 1 of each calendar year." [The USDA annual report has a list of requirements which differ from PHS annual report]

[x] In addition to PHS requirements for IACUC review/application for funding, USDA regulations require:

2.31(d)(1)(ii) - "The principal investigator (PI) consider alternatives to procedures that cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources...used to determine that alternatives were not available."

2.31(d)(1)(iii) - "The PI has provided written assurance that the activities do not unnecessarily duplicate previous experiments."

2.31(d)(1)(iv) - "Procedures that may cause more than momentary or slight pain or distress to the animals will:
- involve in their planning, consultation with the attending veterinarian or his or her designee; [PHS Policy does not specify veterinary consultation]
- not include paralytics without the use of anesthesia;"

2.31(d)(1)(x) - "No animal will be used in more than one major operative procedure from which it is allowed to recover, unless justified for scientific reasons by the principal investigator, in writing..."

[xi] 2.33(a)(1) - "In the case of a part-time attending veterinarian or consultant arrangements, the formal arrangements shall include a written program of veterinary care and regularly scheduled visits to the research facility." [USDA requirement additional]

[xii] 2.32(c) - "Humane methods of animal maintenance and experimentation, including the basic needs of each species, proper handling and care for the various species of animals used by the facility, proper pre-procedural and post-procedural care of animals, and aseptic surgical methods and procedures."

[xiii] 2.32(c) - additional specifications include:
- "proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility"
- "methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility..."
- "utilization of services (e.g., National Agricultural Library, National Library of Medicine) to provide information on appropriate animal care and use, alternatives to the use of live animals in research, that could prevent unintended and unnecessary duplication of research involving animals, and regarding the intent and requirements of the Act." [USDA training specifications are more detailed than PHS Policy].

[xiv] 2.31(d)(iv)(C) - "Procedures that may cause more than momentary or slight pain or distress to the animals will...not include the use of paralytics without anesthesia."

[xv] Part 3 Subpart A 3.8 - "...research facilities must develop, document, and follow an appropriate plan to provide dogs with the opportunity for exercise. In addition, the plan must be approved by the attending veterinarian. The plan must provide written standard procedures..."

[xvi] Part 3 Subpart D 3.81 - "...research facilities must develop, document, and follow an appropriate plan for environment enhancement adequate to promote the psychological well-being of nonhuman primates."

[xvii] Part 3 Subpart A 3.6(c)(1) - "Each dog housed in a primary enclosure must be provided with a minimum amount of floor space, calculated as follows:
(length of dog in inches + 6)^2 /144 = required floor space in square feet)."

- Part 3 Subpart D 3.80 (b) - "Primary enclosures [for nonhuman primates] must meet the minimum space requirements provided in this subpart."

- In situations where the USDA regulations and the *Guide* differ with respect to space requirements, the larger of the two must be followed.

SDSU Semi-annual Facility Inspections
Inspections Conducted on October 1, 2024
Inspectors present: Attending Veterinarian, Chair, Members #19 and #30
Accompanied by: OLAC Manager, Facilities Director

LS Vivarium

Deficiency Category	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Completed
A	LS 8 – Clean Side of Autoclave		OLAC		
A	LS 17A - Housing		[redacted]		
A	LS 17B – Housing & Procedures Room		[redacted]		
A	LS 17C - Housing		[redacted]		
A	LS 17D - Housing		[redacted]		
A	LS 17E – Procedure Room		OLAC [redacted]		
A	LS 17F – Animal Food Storage		OLAC		
A	LS 17G – Hallway/Surgery Ante Room		OLAC		
A	LS 17H – Surgery Room		[redacted]	Empty Isoflurane bottle and charcoal scavenging cannister	Lab notified & removed on 10/1
A	LS 17J - Storage		OLAC		
A	LS 18A - Housing		[redacted]		
A	LS 18B – ABSL-2 Gowning/Anteroom	No animals housed	OLAC [redacted]		
A	LS 18C - Housing		[redacted]		
A	LS 18D – Quarantine		Multiple PI's		

A	LS 18N - Housing		[redacted]		
A	LS 18P – Housing		[redacted]		
A	LS 21 – ABSL-2 Gowning/Ante Room	No animals housed	OLAC		
A	LS 21 – ABSL-2 Room		[redacted]		
A	LS 21 – Autoclave		OLAC		
A	NLS 18	The IVIS will be moved into the flow core (NLS 26B), so [redacted] has to set up an SOP for bringing ABSL2 mice in and out of that facility	[redacted]	[redacted] will amend the protocol as necessary when the move is approved	

BSC Vivarium

Deficiency Category	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Completed
A	11 – Procedure or Housing		OLAC/[redacted]		
A	12 – Housing				
A	13- Equipment Room				
A	14 – Housing		[redacted]		
A	16 – Procedure Room		[redacted]		
A	17 – Housing		[redacted]		
A	20 – Cage Wash Clean Side		OLAC/EH&S		
A	21 – Cage Wash Dirty Side		OLAC		

SDSU Semi-annual Facility Inspections
Inspections Conducted on October 1, 2024
Inspectors present: Attending Veterinarian, Chair, Members #19 and #30
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Alvarado

Deficiency Category	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Completed
A	2		[redacted]		
A	6 – Testing Room		Not in use		
A	8 – Survival Surgery / Procedure Room		[redacted]		
A	9 – Storage/Liquid Nitrogen		[redacted]		
A	10 – Entry Area		OLAC		
A	11 - Housing		Not in use		
A	12 – Testing Room		Not in use		
A	13 – Testing Room		[redacted]		
A	15 – Housing		[redacted]	LCP Procedure cages - please be sure to make a note on cages or in a logbook in the room when Buprenorphine is administered.	Lab notified 10/1
A	16 – Survival Surgery / Procedure Room		[redacted]		
A	16- Hallway Outside of Room		[redacted]	Multiple containers of chemical waste left in hallway	Lab notified 10/1 – Pickup scheduled for 10/11

				pending pickup. PI requested EHS pickup, waiting on response	
A	17 – Cage Setup/Storage		OLAC		
A	18 – Testing Room		[redacted]		
A	19 – Wet Lab		[redacted]	Liquid in fume hood is not biohazardous. The stickers should be removed. The animals are not exposed to biohazards as part of the approved research at ABSL1. This is chemical waste and should be labeled as containing water and nicotine.	PI notified 10/1
A	20 – Procedure/Testing Room		Not in use/Storage		
A	20 – Hallway Outside of Room		OLAC/Facilities		
A	24 – Surgery/Procedure Room		[redacted]		
A	25 – Bedding Closet		OLAC		
A	26 – Testing Room		[redacted]/EH&S		

A	29 – Testing Room		[redacted]		
A	31 – Testing Room		[redacted]		
A	32 – Testing Room		[redacted]		
A	33 – Testing Room		[redacted]		
A	34 – Testing Room		[redacted]		
A	35 – Testing Room		[redacted]		
A	36 – Testing Room		[redacted]		
A	37 – Testing Room		[redacted]	Bin of rodent diet with no information on it.	Lab notified 10/4
A	38 – Testing Room		[redacted]		
A	39 – Housing		[redacted]		
A	42 – Hallway Outside Room		College of Sciences		
A	46 – Cagewash		OLAC/EH&S		
A	48 – Testing Room		[redacted]/Facilities		
A	49 – Feed and Bedding Storage		OLAC		

Laboratories

Deficiency Category	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Completed
A	NLS-224		[redacted]		
A	NLS-228		[redacted]		
A	BSC-426/427		[redacted]	Expired Xylazine on shelf	Lab contacted 10/1

SDSU Semi-annual Facility Inspections
Inspections Conducted on October 1, 2024
Inspectors present: Attending Veterinarian, Chair, Members #19 and #30
Accompanied by: OLAC Manager, Facilities Director

CMIL

Inspection date 09/25/24

Deficiency Category	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Completed
A	CMIL	Suggested posting Vet contact info. Recommended Dr. Hovel collaborates with IACUC to develop a Standard of Care SOP for animals at CMIL	[redacted]	[redacted] provided with Veterinarian contact information	10/2/24

Zebra Housing

Deficiency Category	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Completed
A	BSC 12	No fish currently housed	[redacted]		
A	BSC 13	No fish currently housed	[redacted]		

Controlled Substances

Deficiency Category	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Completed
All facilities were in excellent condition and the IACUC would like to commend the OLAC staff for their attention to detail and quality care of all the research animals and facilities. Thank you as well to all who participated in the inspection.					
A	Alvarado Vivarium	No concerns, inventory reconciled	[redacted]		
A	Alvarado Vivarium	No inventory at this time	[redacted]		
A	NLS 426	No concerns, inventory reconciled	[redacted]		
A	NLS 407	No inventory at this time	[redacted]		
A	BSC 2200	No concerns, inventory reconciled	[redacted]		

A	BSC2201	No inventory at this time	[redacted]		
A	TBD	No inventory at this time			
A	BSC 4105	No inventory at this time			
A	TBD	No inventory at this time			
A	TBD	No inventory at this time			

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)
SEMI-ANNUAL FACILITY AND PROGRAM REPORTS APPROVAL

Date of Inspections: October 1, 2024

IACUC Member Number	Name	Signature of Approval	Signature of Disapproval*	Minority View*
3	[redacted]	[redacted]		
16	[redacted]	[redacted]		
17	[redacted]	[redacted]		
18	[redacted]	[redacted]		
19	[redacted]	[redacted]		
20	[redacted]	[redacted]		
21	[redacted]	[redacted]		
26	[redacted]	[redacted]		
30	[redacted]	[redacted]		
Chair	[redacted]	[redacted]		
Attending Veterinarian	[redacted]	[redacted]		

Your signature verifies your approval and indicates you have no objections to the reports.

*Disapproval indicates you do not agree with all or some of the findings and the Minority View includes your objections. Include your member number and your minority view or any comments below.