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Drew McCormick for Animal Defenders International and on behalf of our Oregon supporters, in support of Senate Bill 181.

Senate Bill 181 would prevent research facilities from using public funds for medically unnecessary research classified under pain category D or E by the USDA on dogs or cats.

This bill would limit researchers from subjecting dogs and cats to certain experiments, including the following[1]: Paralyzing animals; Surgical procedures on animals without medication to alleviate the pain; Testing toxic, poisonous, and hurtful substances on animals; Starving animals of food or water; and Restraining animals for days or weeks at a time.

Every year, millions of animals suffer and die in laboratories around the world, used in experiments that cannot be trusted to translate to humans.

ANIMAL RESEARCH IS UNRELIABLE FOR HUMANS: SPECIES DIFFERENCES

During the Public Hearing for this bill, animal-research representatives claimed that research on nonhuman primates is necessary. This claim is false and the agencies that regulate medical and drug research agree.

On April 10, 2025, The U.S. Food and Drug Administration (FDA) released a plan titled *Roadmap to Reducing Animal Testing in Preclinical Safety Studies,* which explains how and why animals will be phased out of research. On the first page of the report, the FDA states: "Over 90% of drugs that appear safe and effective in animals do not go on to receive FDA approval in humans predominantly due to safety and/or efficacy issues."[2] Just because a substance or drug has a negative or positive effect on a nonhuman does not mean the same is true for humans. Each species responds differently to substances; therefore, animal tests are an unnecessary and unreliable way to predict effects in humans.

[1] Animal and Plant Health Inspection Service, *Animal Care Tech Note: Categorizing Animal Pain or Distress in Research Facility Annual Reports* https://www.aphis.usda.gov/sites/default/files/ac-tech-note-categorizing-animal-pain-or-distress.pdf (last visited May 14, 2025).

[2] U.S. Food and Drug Administration, FDA *Announces Plan to Phase Out Animal Testing Requirement for Monoclonal Antibodies and Other Drugs,* (Apr. 10, 2025) https://www.fda.gov/news-events/press-announcements/fda-announces-plan-phase-out-animal-testing-requirement-monoclonal-antibodies-and-other-drugs; *see also* U.S. Food and Drug Administration, *Roadmap to Reducing Animal Testing in Preclinical Safety Studies* https://www.fda.gov/media/186092/download?attachment (last accessed May 14, 2025).

For the same reason the National Institutes of Health released a News Release titled *NIH to prioritize human-based research technologies* to explain the following:[3]

> Some bodies of research have been inconclusive on the efficacy of translating the results of animal models to human diseases, such as Alzheimer's disease and cancer. These translational challenges to humans may be *due to differences* in anatomy, physiology, lifespan, and disease characteristics. While humans and animals may share genes, some studies have shown there could be functional *differences* between organ and body systems that may result in some translational limitations.

The FDA and NIH agree that animal testing is unreliable for human use and should be put to an end.

CUT IN FUNDING FOR ANIMAL RESEARCH

The NIH is also moving "toward reduction of funding for animal studies and an increase in funding for human-based approaches."[4]The NIH funds the National Primate Research Centers, including OSHU's Oregon National Primate Center Research Center.[5]

Oregon can better handle the animals and employees that will be displaced because of these funding cuts by proactively planning ahead instead of reacting to the inevitably negative consequences of this cut in funding. With a plan, Oregon can strategically assist these nonhuman primates and human primate employees.

ANIMAL WELFARE CONCERNS: EXPAND SENATE BILL 181 TO COVER NONHUMANPRIMATES

The FDA and NIH both concluded that research findings from experiments on animals, such as nonhuman primates, are unreliable. Not only are such experiments unreliable, but they also result in horrible suffering for the researched animals, including nonhuman primates.

However, The Oregon National Primate Center Research Center, affiliated with Oregon Health and Science University (OSHU), still conducts research on nonhuman primates.
Since 2013, the Animal and Plant Health Inspection Service has cited OSHU with 39 Non-Compliant Items (NCI), or violations of Federal Standards for animal welfare in research facilities. For years, tax dollars have funded a facility that allows profound suffering for these nonhuman primates. Oregonians have made it clear that they do not want their tax dollars funding this research

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[3] National Institutes of Health, *NIH to prioritize human-based research technologies*, (Apr. 29, 2025) https://www.nih.gov/news-events/news-releases/nih-prioritize-human-based-research-technologies.
[4] National Institutes of Health, *NIH to prioritize human-based research technologies*, (Apr. 29, 2025) https://www.nih.gov/news-events/news-releases/nih-prioritize-human-based-research-technologies; *see also* National Institutes of Health, *National Primate Research Centers Consortium* https://orip.nih.gov/division-comparative-medicine/research-resources-directory/national-primate-research-centers-consortium (Last visited May 14, 2025).
[5] National Institutes of Health, *National Primate Research Centers Consortium* https://orip.nih.gov/division-comparative-medicine/research-resources-directory/national-primate-research-centers-consortium (Last visited May 14, 2025).

that is unreliable, unnecessary, and hurtful to these sentient nonhuman primates. Below are just a few of the many examples of suffering that nonhuman primates endure at OSHU:

"On October 1, 2024 a 4-year-old female Japanese macaque held in paired housing in a catch area was observed by a technician to be lying down multiple times, but this behavior was not reported to veterinarians. On October 2, 2024, she was found deceased in the enclosure in the morning with swollen arms and stifles noted. The resulting necropsy indicated sepsis due to underlying bacterial skin infection. The failure to report unexpected signs of illness/distress such as repeatedly lying down to ensure timely delivery of veterinary medical care directly impacted the welfare of this animal." Date of Inspection March 04, 2025 (page 83).

"Two rhesus macaques were in a four-unit cage when a husbandry technician put the cage in an automatic cage washer and started the wash cycle. One macaque died and the other was euthanized doe to their injuries." Date of Alleged Violation: August 13, 2020 (page four); Focused Inspection January 25, 2021 (page 49).

"An adverse event was reported in the February 18, 2014 IACUC minutes. Two animals (30789 and 30790) suffered burns from an electric heating pad used during a procedure. Other animals that underwent the same procedure on the same day were unaffected. Both affected animals were treated by the facility veterinarians; one was allowed to heal by secondary intention, the other required more extensive treatment including surgical debridement." Routine Inspection July 29, 2014 (page 5).

"An adverse outcome was reported in early July 2013. On June 27, 2013, a total of twenty-one rhesus macaques were hospitalized and six animals died or were euthanized from a previously stable breeding group of 260 animals housed outdoors in a one-acre corral. All of the animals were injured as a result of fighting within the group. They concluded that the event was likely the result of displaced aggression triggered by construction activity - noise and vibration - on land near the corral. This new construction involved frequent heavy trucks passing around the end of the row of corrals. The affected corral was the last in that row, with the trucks passing just outside, along the exterior wall." Routine Inspection April 02, 2014 (page 1).

If we would not allow such cruel punishment on dogs and cats, then surely, we would not want the same for any sentient being, let alone our fellow primates. The suffering of nonhuman primate suffering at OHSU has been persisting for years, is not something Oregonians want their tax dollars to support, and as previously explained, is unnecessary and unreliable for human use. Therefore, this bill should be expanded to cover nonhuman primates and prevent horrible experiments on them.

ALTERNATIVES TO ANIMAL EXPERIEMENTS THAT ARE MORE RELIABLE

Experiments on animals are unreliable for human use, but fortunately, scientific innovation provides an expanding arsenal of humane and effective alternative testing methods.

New Approach Methodologies (NAMs) are cutting-edge methodologies that offer more advanced scientific tools and technologies, delivering faster, more reliable, and, crucially, more human-relevant results. Such NAMs include the following:

- **AcutoX**: This advanced, non-animal in-vitro test offers a highly accurate method for determining the toxicity of chemicals to human health. Developed by the company Emulate, Inc., AcutoX is a human-relevant alternative to animal testing for assessing acute systemic toxicity. It uses Organs-on-Chips to model the complex interactions between different human organs, such as the liver, kidney, and gut, to predict how chemicals will affect the human body. AcutoX has demonstrated an impressive accuracy rate of 93.3%. This technology not only offers a more humane approach but also provides more reliable and relevant data for assessing the safety of various substances.

- **Organs-on-a-chip:** These sophisticated 3D cell cultures utilize human cells and tissues, mimicking the intricate physiological responses of entire organs or even complex organ systems. They simulate the brain, lung, heart, and liver, offering accurate physiological responses and a more reliable means of measuring drug toxicity and predicting efficacy, as they are based on human rather than animal organs.

- **Human tissue cultures:** International cosmetic giants are growing lab-produced tissue from human skin, known as EpiSkin, to test ingredients of products before they go onto the market. Animals typically have substances applied to their shaved skin to see if they develop irritations or if the skin becomes damaged.

- **3D bioprinting:** This groundbreaking technology enables the creation of complex human tissues, including skin and hair follicles, providing highly relevant models for testing and research.

- **Advanced human brain scanning technologies:** These sophisticated tools provide accurate and detailed data about the human brain, offering a powerful alternative to invasive primate experiments and eliminating the suffering inflicted on these highly intelligent animals. These include sophisticated human brain scanning technologies which provide accurate data and avoid primate suffering in brain experiments.

CONCLUSION

Senate Bill 181 is a chance to embrace a future where science serves humanity without sacrificing our humanity.

We urge you to support Senate Bill 181. We also urge you to expand this bill to cover nonhuman primates, an outcome that most Oregonians support, as reflected in the more than 1,700 comments on this bill.

Let us choose compassion over cruelty, progress over tradition, and usher in a new era defined by scientific innovation and unwavering respect for all life.

Sincerely,
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Roadmap to Reducing Animal Testing in Preclinical Safety Studies

Executive Summary

This roadmap outlines a strategic, stepwise approach for FDA to reduce animal testing in preclinical safety studies with scientifically validated new approach methodologies (NAMs), such as organ-on-a-chip systems, computational modeling, and advanced *in vitro* assays. By partnering with federal agencies like NIH and VA through ICCVAM, FDA can accelerate the validation and adoption of these human-relevant methods, improving predictive accuracy while reducing animal use. This transition will enhance public health by streamlining drug development and ensuring safer therapies reach patients faster, while positioning FDA as a global leader in modern regulatory science and innovation.

Background

There is growing scientific recognition that animals do not provide adequate models of human health and disease.[1] Over 90% of drugs that appear safe and effective in animals do not go on to receive FDA approval in humans predominantly due to safety and/or efficacy issues (1). Animal-based data have been particularly poor predictors of drug success for multiple common diseases including cancer (2), Alzheimer's (3) and inflammatory diseases (4). Some medications which are generally recognized safe in humans, such as aspirin, may have never passed animal testing (5). Conversely, some compounds which have appeared safe in animal models have been lethal in human trials (5). These examples highlight basic physiologic differences between humans and other animal species.

Due to the limitations of animal testing as well as ethical concerns about animals testing, there has been increased focus within the scientific community on New Approach Methodologies (NAMs). NAMs encompass *in vitro* human-based systems, *in silico* modeling, and other innovative platforms that can collectively evaluate immunogenicity, toxicity, and pharmacodynamics in humans and provide an opportunity to improve the predictive relevance of preclinical drug testing while reducing or replacing animal use. NAMs also have enormous cost saving potential (6).

Recent legislative changes have signaled Congress is simultaneously open to regulatory innovation. In late 2022, Congress passed the FDA Modernization Act 2.0,[2] which explicitly authorized the use of non-animal alternatives (cell-based assays, computer models, etc.) to support an investigational new drug (IND) application and "remove[d] a requirement to use animal studies" for biosimilar biologics license application (BLA) (7). This landmark policy empowered FDA to accept NAMs in lieu of animal studies. Then in 2024, the Science Board to the FDA provided comprehensive recommendations on how the agency can spur adoption of scientifically validated NAMs.[3]

Public sentiment is also supportive of this transition with a recent survey finding that >85% of both Democratic and Republican-identifying adults felt that animal experiments should be phased out in favor of more modern methods.[4] Together, scientific advances and policy drivers create an opportune moment for the FDA to chart a roadmap to reduce animal testing while improving drug development.

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1 https://www.acd.od.nih.gov/documents/presentations/12142023_NAMs_Working_Group_Report.pdf
2 H.R.2565 - 117th Congress (2021-2022): FDA Modernization Act of 2021 | Congress.gov | Library of Congress
3 https://www.fda.gov/media/182478/download#:~:text=NAM%20Subcommittee%20Recommendations,all%20of%20FDA%20to%20use
4 https://pcrm.widen.net/s/qzfxtfh7bw/animal-testing-survey

Initial focus on monoclonal antibody testing

This program is intended to begin with monoclonal antibodies (mAb) as a promising area for reducing animal use in preclinical safety testing, and then will expand to include other biological molecules and eventually new chemical entities and medical countermeasures. Current FDA requirements for mAbs mandate GLP-compliant repeat-dose toxicity studies (often 1–6 months duration) in animals, alongside assessments of pharmacokinetics (PK) and safety pharmacology. Anti-drug antibody formation (immunogenicity) is monitored because animals often mount immune responses to human mAbs, which can alter exposure and confound toxicity interpretation. However, animal immunogenicity is not predictive of human immunogenicity due to interspecies differences in immune systems (6). In addition to inherent biological differences, stress of laboratory life and use in research can impact immune function, inflammatory responses, metabolism, and disease susceptibility and progression.[5] Moreover, some safety risks may go undetected in animals – a notable example is the mAb TGN1412, which caused a life-threatening cytokine release syndrome in human volunteers despite appearing safe in preclinical monkey studies. That tragedy highlighted the limitations of animal models for certain immune-activating mAbs and spurred efforts to develop *in vitro* assays to better predict human-specific responses (7).

Beyond scientific shortcomings and ethical issues, animal testing of mAbs poses practical challenges. The cost of drug development can vary by therapeutic class, with a market report noting the cost to develop a mAb at $650-$750 million and taking up to 9 years.[6] Typical mAb development programs typically use 144 non-human primates (NHPs).[7] In recent years, costs of NHPs have skyrocketed, up to $50,000 per NHP.[8] The time and cost of long-term animal studies slow down delivery of new therapies to patients. Indeed, a majority of drug development failures are due to lack of efficacy or unexpected safety issues that were not evident in animal tests (1), meaning that issues for humans were only realized in clinical trials or after approval. As more predictive methods are integrated into decision-making earlier, companies will not only save the direct costs of avoiding certain nonclinical animal use, but they will also be positioned to make better business decisions by making more informed go/no go decisions regarding which therapeutics to advance, which could ultimately lower drug costs.

New Approach Methodologies (NAMs)

NAMs offer the tools to assess safety, efficacy, and pharmacology of drugs and therapeutics *without* traditional animal models. NAMs include *in vitro* human-based systems such as organs-on-chips, "*in silico"*, or computer-based modeling, as well as other innovative platforms that can collectively evaluate immunogenicity, toxicity, and pharmacodynamics with high relevance to human biology. The FDA and the broader scientific community recognize NAMs as a means to obtain "faster and more accurate human risk assessments" while reducing animal use (8). Below is an overview of key NAM categories and their applicability to drug development:

In Vitro Human-Derived Systems (Organoids and Microphysiological Systems)

Advances in tissue engineering have led to organoids and microphysiological systems (MPS) (often called "organs-on-chips"). These systems use human cells to recreate miniature organ units or even interconnected multi-organ networks. Organoids are self-organizing cell cultures (e.g. liver organoids, gut organoids) that model native tissue architecture and function. Organ-on-a-chip devices go a step further by incorporating

[5] Bailey J. Does the stress of laboratory life and experimentation on animals adversely affect research data? A critical review. Altern Lab Anim. 2018;46(5):291-305. doi:10.1177/026119291804600501

[6] https://www.labmate-online.com/news/news-and-views/5/frost-sullivan/market-report-therapeutic-monoclonal-antibodies-in-europe/22346

[7] https://nc3rs.org.uk/our-portfolio/reducing-animal-use-monoclonal-antibody-development

[8] https://emulatebio.com/organ-chips-vs-nhps-cost-calculator/

microfluidic flow, mechanical forces, and multi-cell type co-cultures on a bioengineered chip, emulating the *in vivo* environment. For example, a human Liver-Chip can co-culture hepatocytes with non-parenchymal cells under perfusion, displaying liver-like metabolism and responses. These platforms maintain human-specific biology that animals lack, allowing detection of effects that only manifest in human tissue.

Notably, microphysiological systems can be as predictive (or more predictive) of human responses than animal tests (9). The drive to eliminate animal testing in cosmetics led to the first successes of this approach – e.g. *in vitro* human skin models that supplanted rabbit skin tests – and now human-based MPS devices exist for liver, heart, lung, kidney, and other organs. A recent example is a Human Liver-Chip, which was recently evaluated for its ability to predict drug-induced liver injury (DILI) and accepted into FDA's Innovative Science and Technology for Advancing New Drugs (ISTAND) pilot program. In a validation study, the Liver-Chip correctly identified 87% of hepatotoxic drugs that caused liver injury in patients (10).

In monoclonal antibody safety, organoids/MPS can evaluate target-specific and off-target effects in a controlled human microenvironment. For instance, if a mAb may cause liver injury via an immune-mediated mechanism, a Liver-Chip with integrated immune cells could detect cytokine release or hepatocyte damage. If a mAb has cardiovascular risks (e.g. binding an off-target in heart tissue), a cardiac tissue chip or human stem-cell derived cardiomyocyte assay can screen for pro-arrhythmic effects. These models also permit real-time monitoring of functional endpoints (e.g. electrophysiology, enzyme release, biomarkers) that parallel clinical safety markers. Many mAbs have immune-related effects, so human immune organoids (like lymph node or spleen organoids) and blood-on-a-chip systems with circulating immune cells can be used to test for cytokine release, T-cell activation, or other immunotoxicity. Indeed, after TGN1412, researchers developed *in vitro* cytokine release assays (CRAs) using human blood and immune cells to screen therapeutic antibodies for pro-inflammatory activity (7). Such assays, including whole-blood and peripheral blood mononuclear cell (PBMC) models, can now be employed to identify any mAb that might trigger a dangerous cytokine surge, thereby adding a crucial safety net that animal tests struggled to provide. Additionally, multi-organ "human-body-on-a-chip" setups can simulate pharmacodynamic effects systemically – for example, connecting liver and tumor tissue chips with an immune compartment to study a cancer immunotherapy mAb's on-target tumor killing and off-target organ toxicity in one human microphysiological model. By using *human* cells, these systems avoid species differences and can reveal toxicological effects that are more relevant to patients.

In Silico Tools and Computational Modeling

In silico approaches are another pillar of NAMs. Computational modeling, artificial intelligence (AI), and machine learning (ML) can leverage existing data to predict safety, immunogenicity, and pharmacokinetics, reducing the need for new animal experiments. Key *in silico* tools include:

- **Physiologically-Based Pharmacokinetic (PBPK) Modeling:** PBPK models are mathematical simulations of drug ADME (Absorption, Distribution, Metabolism, Excretion) using species-specific physiology. They have become integral in small-molecule drug development and are increasingly applied to biologics. FDA may review PBPK simulations to inform first-in-human dosing and to justify waiving animal studies that would normally serve that purpose. As PBPK models are refined, they can also predict how differences between patients (e.g. body weight, disease state) might affect a drug's pharmacokinetics, further enhancing safety margins.

- **ML and AI Predictive Models:** Machine learning algorithms can be trained on drug sequence features, structural motifs, and known clinical outcomes. Recently developed ML models analyze the amino acid sequence of an antibody's variable region to predict whether the mAb is likely to have high or low immunogenicity (11). Such tools can flag problematic sequences early guiding engineering to "de-risk" the product before it ever enters an animal or human. Machine learning models are also being explored to predict toxicities (like acute systemic toxicity, off-target binding, or cytokine release potential) by learning patterns from molecules that caused certain adverse events (12).

- **Quantitative Systems Pharmacology (QSP) and Modeling of Biological Pathways:** QSP models combine computational biology and pharmacology, simulating how a drug interacts with complex human biological networks. For example, a QSP model of an autoimmune disease could simulate how an antibody modulates inflammatory pathways, helping to predict efficacious dose ranges and potential toxic outcomes (such as over-suppression of the immune system). These models could reduce reliance on animal disease models by providing a *virtual human* on which to test "what-if" scenarios.
- **Bioinformatics and *In silico* Off-target Screening:** Using databases of human proteins and AI, one could screen a product's sequence for any unintended targets (such as cross-reactivity to human tissues). *In silico* tools can analyze whether the drug might bind to similar epitopes in the human proteome, highlighting potential safety concerns that would traditionally be checked via animal tissue cross-reactivity studies or broad receptor binding panels.

Overall, *in silico* NAMs may act as powerful adjuncts or replacements for animal studies by predicting human-relevant outcomes through data and modeling. They are rapid, cost-effective, and can integrate vast amounts of existing knowledge – for instance, an AI model might instantly compare a new drug to hundreds of prior ones to assess risk, something impossible with animal testing alone. Importantly, as regulators gain confidence in these tools (through retrospective validation and prospective pilot use), they could be formally adopted to reduce or replace specific animal tests.

Thresholds will need to be developed and modified for when animal testing can be reduced or eliminated. This should be continuously updated as modeling programs are augmented with more data, validated and improved.

Other Innovative Platforms

Beyond complex *in vitro* and computational *in silico* categories, a variety of innovative approaches can also contribute to a non-animal safety testing ecosystem:

- **Ex vivo Human Tissues:** Advances in organ donation and tissue preservation allow scientists to test drugs on actual human tissues. For example, donated human organ slices (liver, heart, etc.) maintained in culture can be exposed to a drug to look for localized toxic effects or immune cell infiltration. While limited in lifespan, such ex vivo systems use native human tissue architecture, complementing engineered organoids.
- **High-Throughput Cell-Based Screening:** Robotic high-content screening using panels of human cells (including induced pluripotent stem cell-derived cells from diverse genetic backgrounds) can profile the effects of a product on many cell types. This can reveal off-target cytotoxicity or functional changes in a broad, human-relevant manner, something traditionally assessed with multi-species animal testing.
- **Microdosing and Imaging in Human Volunteers:** In certain cases, microdosing studies in humans can yield early pharmacokinetic and distribution data via PET imaging. This is not a routine approach for biologics yet, but as modeling and microdose safety are established, it could provide direct human data in place of animal distribution studies, with minimal risk.
- **Refined *In Vivo* Methods (for transition):** As the field reduces reliance on animal testing, interim steps can involve refined *in vivo* methods. For instance, using humanized transgenic can reduce animal numbers and pain (these still involve animals, but fewer, or with less severe procedures).

Each NAM described addresses one or more aspects of what animal studies currently provide, often with enhanced human relevance. To minimize animal testing, it will be essential to use an integrative strategy: for example, a combination of a human organ chip for toxicity, a PBPK model for PK, and an AI immunogenicity predictor might together cover the same ground as a traditional whole-animal study, but with greater accuracy and ethical acceptability.

Implementation of reduced toxicity testing in animals at the FDA in the next 3 years

1. **Explore Pre-existing International Data:** Determine if drug toxicity data from humans already exists in countries where the compound has been approved. If international data exist, drug and biologic manufacturers will be encouraged to collect, analyze and provide these data, which the FDA will now consider in IND applications. By default, it will *not* be necessary to submit additional human data to the FDA if the product has been approved in a different country with similar regulatory standards unless the data are felt to be insufficient by FDA reviewers. If data are felt to be insufficient, FDA reviewers will outline specifically where uncertainty lies and what type of additional safety information they would like to see.

2. **Encourage sponsors to submit NAM data** in parallel with animal data to build a repository of experience. For example, communicate with manufacturers that we welcome organoid or *in silico* study results in IND/BLA packages as supportive data. Ensure companies understand that less animal testing will be required if NAM data are validated. Offer regulatory relief (e.g. fewer animal study replicates) to those who do so. Identify a few pilot cases where, based on strong rationale, an animal study is waived in favor of a NAM. For instance, if a mAb targets a human-specific receptor and the only possible animal model is a transgenic mouse, FDA could allow a sponsor to substitute a battery of human *in vitro* tests or MPS plus a PBPK model instead of the transgenic mouse study. Monitor the outcomes of those programs closely (through clinical trial phases) to verify safety was not compromised.

3. **Develop an open-access repository with a comprehensive collection of international drug toxicity data from animals and humans.** No comprehensive database containing animal and human toxicity data currently exists. Databases are either limited to countries or international collaborations focusing on publicly available toxicity testing information. One example is the Integrated Chemical Environment,[91] containing legacy animal studies in addition to curated data from the US Tox21 program, which has generated toxicity measurements of thousands of chemicals (13,14). This program has led to models integrating in vitro assays that have been found to be as reliable as animal models and in some cases superior (15), but can be substantially augmented with other private and/or international datasets. The FDA will plan to expand the Tox21 program and combine other existing international databases to create a comprehensive database to be utilized in toxicity modeling efforts. The FDA will also plan to partner with the National Toxicology Program (NTP) to expand and validate this database.

4. **Reduce the routine 6-month primate toxicology testing for mAbs** that show no concerning signals in 1-month studies plus NAM tests to three months. Notably, first-in-human enabling study, suggesting that shorter or fewer studies could suffice in most cases (15). Adopting a *data-driven paradigm* (such as a weight-of-evidence model) could allow FDA to confidently drop these extended animal studies for many mAbs.

5. **Reduction in animal toxicity testing timeframes for other drug categories:** Reduced duration of animal toxicity testing may be implemented for additional drug and biologic compounds. This will be initiated be based on all relevant prior clinic information about the compound or class of compounds and augmented by modeling in the case of low toxicity risk prediction. The FDA may implement a randomized study of new drugs evaluating costs and benefits (human, animal and economic) of 3 months of animal testing augmented with AI vs 6 months of animal testing with AI vs 3 or 6 months of animal testing alone to evaluate the benefits and costs of this initiative.

[9] Integrated Chemical Environment (ICE)

6. **Changes in toxicity testing will be tracked and quantified** on a bi-annual basis and will include, to the extent feasible:
   (1) Animal testing hours and cost by species
   (2) Toxicity testing costs per IND
   (3) Economic analysis of safety signals identified through NAMs/modeling vs through animal testing
   (4) Changes in toxicity testing costs over time
   (5) Rates of novel toxicities first identified in humans or not until post-marketing surveillance
   (6) Time from IND to full approval

In the **long-term (3-5 years)**, FDA will aim to make animal studies the *exception* rather than the norm for pre-clinical safety/toxicity testing. By this stage, validated NAMs could cover all critical areas, and FDA requirements can shift to a NAM-based default. Animal tests might only be considered if a specific scientific question cannot yet be answered by NAM (and even then, only the minimal animal use necessary, with strong justification). Ultimately, the vision is that no conventional animal testing will be required for mAb safety, and eventually all drugs/therapeutics – instead, a comprehensive integrated NAM toolbox (human cell models + computational models) will be the new standard.

Scientific and Technical Steps for FDA Adoption of NAMs

Transitioning from animal-based testing to NAMs for safety will require careful planning, robust science, and collaboration. Below is a stepwise list of specific actions the FDA is considering for validation and integration of NAMs into their regulatory process:

1. **Map Critical Endpoints and Use Cases:** FDA should begin by identifying the key safety and efficacy questions for drugs and biologics where NAMs could replace or augment animal data. These include acute toxicity, chronic toxicity and organ injury, pharmacokinetics and bio-distribution, immune responses and pharmacodynamics (target engagement and functional effects). For each area, perform a gap analysis of current methods. Prioritizing such gaps helps focus on where NAMs will have the most impact and urgency.

2. **Support Targeted Development of NAM Technologies:** FDA (through research collaborations with NIH and other venues) should invest in the development of NAM models. This could involve:

   a) Developing organotypic models for drug toxicity.

   b) Creating an open-access comprehensive database of drug and biologic toxicity data from animals and humans to improve model training data.

   c) Developing ways to study the efficacy and costs of NAMs vs more traditional models of animal testing.

   d) Developing studies to determine appropriate thresholds for reducing or eliminating animal testing based on predetermined level of likelihood and predicted severity of toxicity.

3. **Establish Validation and Qualification Pathways:** It will be critical to continuously rigorously validate NAMs to build confidence in their reliability. Possible approaches include:

   a) **Retrospective analyses:** Gather data from past (preferably well-known and well-defined) drug toxicities and determine the accuracy with which NAM (e.g. an organ chips, ML models, integrated strategies) would have predicted the human outcome. This can be compared with animal study predictiveness for a wide range of drug and biologic classes. All research projects should be preregistered and published in a timely manner.

b) **Prospective validation trials:** In collaboration with stakeholders, perform parallel testing of new drugs products in both animals and NAM systems, to directly compare accuracy, financial costs as well has harms to both humans and animals. For example, test a novel cancer therapy with organ-on-chips, computer modeling and in vivo alone or combined, and see which method/s best correlate with clinical effects both in clinical trials and in subsequent real-world data.

c) **Reproducibility and standardization:** Work through consortia (perhaps via ICCVAM, discussed below) to have multiple independent labs test the same drug product in a given NAM to ensure reproducibility. Develop standardized protocols for these methods so that results are replicable across laboratories.

d) **Benchmark against human data:** Ongoing validation studies should be implemented that assess how well NAM predictions align with human clinical trial and post-marketing findings.

e) **NAMs-based prospective post-marketing studies:** When appropriate use NAM predictions for prospective post-marketing studies of side effects.

To formalize acceptance, FDA could employ its **"Drug Development Tool" (DDT) Qualification programs** (like the ISTAND pilot) for NAMs. This provides a pathway where method developers submit qualification plans to FDA, and FDA reviews the evidence that the NAM is fit for a specific Context of Use. Once qualified, any sponsor could use that NAM in an application with confidence that FDA will accept the data. Creating clear contexts of use for NAMs is crucial; the qualification requirements will vary by intended use and defining this upfront guides the validation process (15).

4. **Develop Regulatory Guidance and Standards:** FDA will update or create guidance documents that articulate how NAMs can be used in various development programs. This might include:

a) **Guidance on replacing specific animal studies:** e.g. "If an appropriately validated microphysiological system or *in vitro* assay is used to assess XYZ toxicity, a second-species chronic toxicity study may not be required." The guidance would enumerate what data/validation is needed to justify such a replacement.

b) **Technical guidance on conduct of NAMs:** to ensure industry runs these new assays to high standards (analogous to GLP). For example, specify expectations for tissue chip stability, cell characterization, or computational model verification when used in regulatory submissions.

c) **Case examples:** Provide examples in guidance of how sponsors can incorporate NAM data alongside or in place of animal data in their IND/BLA submissions. Clear regulatory expectations will encourage sponsors to invest in NAMs.

Updating international guidelines is also important. FDA can propose revisions to ICH guidelines (e.g. ICH S6) to reflect NAM usage, ensuring global regulatory alignment so that companies do not face different rules in different regions. An ultimate vision could be an ICH guideline on New Approach Methodologies for Drugs and Biologics Safety Testing, which FDA can champion once enough evidence has been generated.

5. **Training, Communication, and Culture Change:** For this transition to succeed, FDA must ensure its reviewers and scientists are well-versed in NAM technologies and open to novel types of evidence. The Agency will commit to:

a) Provide training workshops for review staff on interpreting organ-on-chip data, understanding AI model outputs, and analyzing in vitro-in vivo extrapolation from PBPK models. Building this expertise will increase comfort and consistency in reviewing NAM-based submissions.

b) Foster a culture that recognizes the scientific merit of NAMs. Management can explicitly encourage consideration of NAM data and celebrate successful cases where a non-animal method provided a key insight or decision-enabling information, while maintaining a critical eye on potential areas of weakness where NAMs may not yet be sufficient and need further development.

c) Maintain open dialogue with industry, academia, and NGOs. For instance, hold public meetings or advisory committee discussions on NAM advances in drug and biologic development, and incorporate external expert feedback.

d) Communicate to sponsors via guidance and Q&A documents how they can engage FDA early (e.g. in pre-IND meetings) to discuss proposals for using NAMs. Clear communication will alleviate uncertainty and spur more sponsors to utilize these methods.

6. **Monitor Outcomes and Iteratively Refine**: As NAMs become integrated, FDA should establish metrics to monitor their performance in practice (e.g. correlation of NAM predictions with clinical trial safety data). Learn from any unexpected outcomes – if a safety issue arises in humans that NAMs did not predict, analyze why and determine how models might be improved. Likewise, track efficiency gains (e.g. reduction in drug development time, fewer animals used) as measures of success. This feedback loop will allow the roadmap to be adjusted and improved continually.

By executing these steps in collaboration with other federal partners, such as the NIH, the FDA will build a solid scientific foundation to reduce and, when appropriate, entirely replace animal tests with NAMs.

Interagency Coordination through ICCVAM

The FDA will collaborate with the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), which provides a ready-made platform for partnership with other federal entities like NIH and the Department of Veterans Affairs (VA). ICCVAM is a committee of 18 U.S. agencies (including FDA, NIH, DoD, EPA, VA, and others) established to "work together to develop and evaluate new, improved, and alternative test methods and strategies". Leveraging ICCVAM can accelerate progress by pooling expertise, data, and resources across government.

How FDA can partner via ICCVAM and related interagency initiatives:

- **Coordinated Validation Efforts:** Through ICCVAM, FDA can enlist multiple agencies' laboratories in multi-site validation studies of NAMs for drug and biologic safety. For example, NIH's Interagency Center for the Evaluation of Alternative Methods (NICEATM; the support organization for ICCVAM) has significant experience in method validation, and can assist in designing validation studies, statistical analyses, and independent evaluation of a new test's performance. If the FDA identifies a promising organoid model, ICCVAM could establish a working group to validate it, with participants from across the federal government and support from NICEATM. This collaborative validation not only shares the workload but also adds credibility – a method validated by multiple agencies is more likely to gain broad acceptance.

- **Funding and Research Support from NIH:** The National Institutes of Health can direct funding towards NAMs that FDA deems priority. A pertinent example is the Complement Animal Research in Experimentation (Complement-ARIE) program, which supports the development of combinatorial NAMs for critical biomedical research and regulatory questions. The NIH and FDA could also co-sponsor challenge grants or prize competitions for developing NAM solutions to specific problems (such as a computer model predicting antibody biodistribution in humans). The VA might contribute funding or clinical data for projects that have dual benefit for veteran health research and regulatory science.

- **Shared Data and Databases:** Under ICCVAM's coordination, agencies can compile shared databases of toxicology and immunogenicity that include both animal and human data from various sources. FDA's vast repository of historical IND/BLA data (de-identified/encrypted as needed) combined with NIH's research data could be a treasure trove for training AI models or doing retrospective NAM analyses. The creation of a **central database for validated NAMs,** called the Collection of Alternative Methods for Regulatory Application (CAMERA), is being led by ICCVAM and is already underway, with a beta version expected mid-2025. This will be used until a more comprehensive international database can be developed. This initiative will include an FDA-NIEHS partnership with the National Toxicology Program (NTP).

- **ICCVAM Workgroups and Outreach:** FDA can take a leadership role in ICCVAM workgroups specifically focused on safety testing of drugs and/or biologics using complex in vitro models and other NAMs. ICCVAM also hosts annual public forums and Communities of Practice webinars – FDA can use these to communicate its NAM roadmap progress and engage external stakeholders. ICCVAM's 2025 Communities of Practice webinar will discuss ongoing work in complex *in vitro* models, including NAM-based case studies.

- **Cross-Agency Training and Expertise Exchange:** FDA scientists can collaborate with NIH intramural researchers who are pioneers in organs-on-chips, with VA researchers exploring human-based models for trauma or rehabilitation or NTP researchers on testing and methods validation. Short-term staff exchanges or joint training sessions (e.g. FDA reviewers visiting a NIH tissue chip lab, and NIH scientists learning about regulatory review processes) will foster mutual understanding. This ensures the methods developed meet regulatory standards and that FDA is intimately familiar with the science behind them.

- **Public-Private Partnerships via Federal Consortia:** ICCVAM isn't limited to just government agencies; it often engages with industry, academic, and NGO stakeholders as observers or through sponsored workshops. FDA can encourage ICCVAM to organize public-private partnership forums, (initially on mAb testing and developing a more comprehensive and open access toxicity database), following models such as the IQ Consortium's Microphysiological Systems Affiliate, a collaboration among pharmaceutical companies and FDA scientists that was formed to tackle MPS evaluation for drug development.

In essence, ICCVAM provides the mechanism for a unified federal strategy. By partnering with NIH, VA, DoD and others, FDA can harness a wide pool of scientific innovation to validate NAMs faster than it could on its own. Such collaboration also presents a united front to the public and stakeholders that federal agencies are committed together to reducing animal use and advancing human-centric science.

Recommendations and Policy Considerations

Building on the above, the FDA leadership intends to combine scientific rigor with policy actions, minimizing animal testing in preclinical safety evaluation:

- **Develop Clear Guidance and Regulatory Flexibility:** Issue new guidance (or revise existing ones like ICH S6(R1)) that explicitly allows for alternative methods. In the interim, use mechanisms like case-by-case waivers or exemptions to permit sponsors to omit animal studies if they provide adequate NAM data. For example, FDA could announce that for products meeting specific criteria, a single species study is sufficient if accompanied by an orthogonal NAM dataset addressing the same safety questions, or in other cases an exclusively NAM-based approach may be warranted. Such policy signals will encourage wider trial of NAMs in submissions.

- **Incentivize Sponsors and Promote Success Stories:** Consider incentives for companies that utilize NAMs – for instance, fast-track meeting requests and regulatory reviews, or publish case studies of successful FDA approvals that minimized animal testing. Publicize when FDA approvals were achieved with novel approaches (similar to how FDA highlights first-in-class approvals, it could highlight "first

approval with no animal testing" as a milestone) and highlight the benefits (decreased cost, higher accuracy, less harm to animals, etc). This positive reinforcement can shift industry practices. Over time, as animal testing becomes seen as optional rather than mandatory, industry will move away from the old defaults.

- **Ensure Scientific Rigor and Continuity:** While pursuing replacement, maintain a focus on scientific validity. FDA must assure that any new method is equal or superior to the animal test it replaces in protecting patients. By following modern validation principles (15), FDA can make this transition without increasing risk. In fact, by using human-relevant models, safety for patients should improve. FDA should continuously update its approach based on effects on valuable outcomes.

- **Legislative and Funding Support:** Work with lawmakers to secure funding (perhaps via FDA's budget or NIH collaborations) specifically earmarked for NAM validation and implementation. If needed, seek further legislative reinforcement – e.g. establishing deadlines after which certain animal tests cannot be required if alternatives exist (similar to how EU banned cosmetic animal testing). Although FDA has authority to use alternatives, increased support and oversight means Congress can be kept informed of progress (consistent with the proposed FDA Modernization Act 3.0).

- **Global Leadership and Harmonization:** Use FDA's influence in international regulatory forums to drive a global shift. Propose discussions at ICH for incorporating NAMs into guidelines for biologics. Collaborate with EMA, PMDA, and others on joint workshops or qualification projects (perhaps an international validation of a particular organ chip). This will help sponsors have confidence that NAM-based strategies will be accepted worldwide, not just in the US, which is critical for adoption. Work on collaborative international initiatives that are not limited to within the FDA. The ultimate vision is a global regulatory environment where animal testing for biologics is largely obsolete, replaced by a new standard toolbox of approved NAMs.

Conclusion

This scientific roadmap lays out an initial strategy for FDA to reduce and replace animal testing in preclinical safety assessment of drugs and biologics and will be refined based on feedback provided by FDA stakeholders. By combining cutting-edge *in vitro* systems, advanced *in silico* modeling, and robust validation efforts – and by working collaboratively across government and industry – the FDA can ensure that drug development becomes more ethical, more efficient, and more predictive of human outcomes. Patients will benefit from safer and faster-to-market therapies, animals will be spared from testing, and the science of drug development will enter a new era aligned with 21st-century technology. This plan aligns with congressional directives and global trends, positioning FDA as a leader in regulatory science innovation. Implementing this roadmap will demonstrate FDA's commitment to embracing scientific advancements, which are ethical, reduce costs and improve human health.

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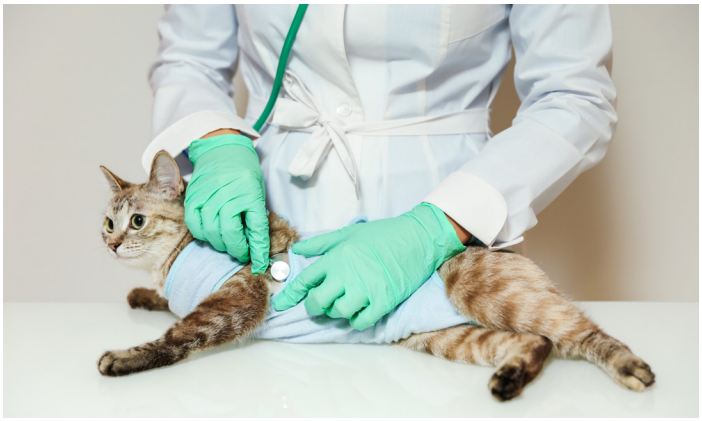
Animal Care Tech Note

Categorizing Animal Pain or Distress in Research Facility Annual Reports

The Animal Welfare Act (AWA) requires research facilities to submit an annual report that states the common names and numbers of animals used in research, testing, or experimentation. The report must also categorize these animals based on procedures involving pain, distress, and/or the use of pain-relieving drugs. Research facilities may use this tech note as a reference when assigning animals to pain and distress categories.

Animal Welfare regulations define a painful procedure as "any procedure that would reasonably be expected to cause more than slight or momentary pain or distress in a human being to which that procedure is applied, that is, pain in excess of that caused by injections or other minor procedures" (9 CFR § 1.1).



Categorizing Procedures Involving Pain and/or Distress

You should evaluate only study-related procedures when categorizing animals for reporting purposes. Veterinary care or colony management procedures performed for the health of an individual animal or the colony should not be considered. For example, treating wounds acquired in fights with other animals is not study-related and should not be considered for annual reporting.

If multiple categories may apply, you should report each animal only once in the category consistent with the greatest amount of pain or distress they experienced during that period. For this reason, animals on long-term studies that span multiple reporting periods may be reported in different categories for each period.

The table on page 2 shows the pain categories listed on the annual report and examples of procedures that apply to each category. These examples are not intended to be exhaustive. You should consider the specific animal-use activity when categorizing animals.

When anesthetics, analgesics, or sedatives are used only for restraint during procedures that do not involve more than slight or momentary pain, these animals should be placed in Category C. For example, animals that are anesthetized or sedated for collecting blood samples or for imaging procedures should be assigned to Category C.

Animals exhibiting signs of pain, or distress such as weight loss, abnormal activity level, adverse reactions to touching inoculated areas, open sores/necrotic skin lesions, abscesses, lameness, ocular pain and/or inflammation, corneal edema, and photophobia must receive appropriate and effective relief consistent with the current standard of care. Appropriate and effective relief may not necessarily require analgesics. It may also include supportive care such as ice packs, heat, soft bedding, diet alterations, and/or anti-nausea medications in addition to analgesic therapy when necessary. Animals that receive appropriate relief are listed in Category D.

You should place in Category D any animals that experience breakthrough pain after receiving appropriate anesthetic or analgesics or experience pain or distress before you detect the need for analgesics, as long as:

- The animals are appropriately monitored;
- The type, dose, and frequency of analgesics being administered are appropriate for the procedure and species; and,
- The intent is to alleviate the pain and distress as needed.

A Category D procedure may become a Category E procedure if appropriate anesthetics, analgesics, or sedatives are withheld because these agents would adversely affect the procedure, results, or interpretation of the test or research. When appropriate relief of pain or distress cannot be administered to maintain the validity of the test or research, or the nature of the activity does not allow appropriate relief, the activity must be scientifically justified in the animal activity proposal and approved by the Institutional Animal Care and Use Committee. You must report animals in this situation in Category E.

You must attach a description of the procedures producing pain and distress in Category E animals and the reasons pain-relieving drugs were not used to the annual report.

Prospective or Retrospective Reporting

You can categorize pain and distress prospectively or retrospectively. Retrospective reporting involves collecting data on individual study animals to determine the most appropriate category based on clinical signs of pain and distress the animal experienced during the reporting period. While labor intensive, this method generally produces more accurate reporting. Prospective reporting means that all animals used for a particular activity are categorized in the highest applicable pain category based on anticipated pain and distress associated with that activity. This method is less labor intensive but may result in animals being placed in a higher category than necessary.

If animals experience pain or distress during the study due to research procedures that are in a higher pain category than originally designated, you must report the animal(s) in the higher pain category. In other words, your reporting will be retrospective to indicate the pain or distress level the animal actually experienced.

For More Information

The AWA and its regulations establish the legal requirement and standards research facilities must follow. For details, see USC Title 7, Chapter 54, Sections 2131-2159 and CFR, Title 9, Chapter 1, Subchapter A, Parts 1-4.

If you have questions, contact the U.S. Department of Agriculture (USDA) Animal Care staff at (970) 494-7478 or animalcare@usda.gov.

Pain Categories

Category	Explanation	Example
B	Animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes	• Animals on breeding protocols with no research or experimental component • Animals acquired by the facility but held in quarantine or acclimation period prior to use • Euthanizing animals on a holding protocol following current professional standards • Observing animal behavior in their home enclosures without manipulation
C	Animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs	• Observing animal behavior in the lab • Positive reward training or research • Food restriction that reduces the animal's weight by no more than 15 percent of normal age-matched controls • Manipulative procedures such as weighing, injections, palpations, skin scrapings, and radiography • Administering an anesthetic, analgesic or tranquilizing drug to an animal for restraint purposes to perform a procedure that involves no pain or distress such as imaging procedures • Exposure to mild alteration in environmental conditions with appropriate acclimation
D	Animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used	• Surgical manipulations (survival or terminal) in which the animals received appropriate pre-, intra-, and post-operative anesthetics and analgesics • Using Freund's complete adjuvant if alleviation of pain/distress occurs • Tumor induction or implantation if alleviation of pain/distress occurs • Induced infections or antibody production in which animals experience pain alleviated by analgesics • Exsanguination under anesthesia
E	Animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests	• Paralysis or immobilization of a conscious animal • Any Category D procedure for which needed analgesics, tranquilizers, sedatives, or anesthetics are withheld for justifiable study purposes • Toxicological, microbiological, or infectious disease research that requires continuation after clinical signs are evident without medical care or that requires death as an endpoint • Food or water restriction which reduces the animal's weight by more than 15 percent of normal age-matched controls • Certain types of forced exercise protocols that could reasonably be expected to cause distress or exhaustion • Applying noxious stimuli that the animal cannot avoid/escape • Exposure to extreme environmental conditions • Long-term restraint (days to weeks)

APHIS-23-027 • Issued July 2023

United States Department of Agriculture
Animal and Plant Health Inspection Service

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Inspection Report

Oregon Health & Science University
3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**
Certificate: **92-R-0001**
Site: 002
OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS

Type: ROUTINE INSPECTION
Date: 02-APR-2014

2.33(b)(2)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

An adverse outcome was reported in the IACUC minutes: A female Japanese macaque was undergoing an imaging procedure under anesthesia. The procedure was necessarily conducted in a darkened room. The animal was noted to have respiratory distress and the veterinarian was notified, but the animal expired in spite of resuscitation efforts. It was found that the pop-off valve on the anesthesia machine was left closed and went unnoticed in the darkened room. This was the first of several animals scheduled to be imaged, but the remainder of the studies that day were cancelled.
Since the event and prior to resumption of study activities, the anesthesia machines have been modified so that the pop off valve cannot be left closed - it must be held closed for pressure checking the machine, and it automatically returns to the open state when the operator releases hold on the fitting.
Correct by: This non-compliance was corrected as described prior to the time of inspection.

An adverse outcome was reported in early July 2013. On June 27, 2013, a total of twenty-one rhesus macaques were hospitalized and six animals died or were euthanized from a previously stable breeding group of 260 animals housed outdoors in a one-acre corral. All of the animals were injured as a result of fighting within the group. They concluded that the event was likely the result of displaced aggression triggered by construction activity - noise and vibration - on land near the corral. This new construction involved frequent heavy trucks passing around the end of the row of corrals. The affected corral was the last in that row, with the trucks passing just outside, along the exterior wall.

The Center responded by halting construction that day and relocating the remaining 233 rhesus macaques to another outdoor corral further from the construction site. Additional enrichment was added - swimming tubs, branches, treats - as well as additional monitoring by the Behavioral Services Unit, which studied behavioral trends and compared them to readings from five noise and vibration monitors placed around the areas of construction and animal housing. They also developed housing modifications to allow for better social interaction or avoidance as needed by the animals.

Correct by: This was corrected by responding to the event, as described, prior to the time of inspection.
Additionally, the facility must develop comprehensive plans to address the impact on the animals for all future

Prepared By: GWYNN HALLBERG, D V M USDA, APHIS, Animal Care **Date:** 16-APR-2014

Title: VETERINARY MEDICAL OFFICER 5036

Received by Title: NHP RESOURCE PROJECT VETERINARIAN **Date:** 16-APR-2014

construction. These plans must include logistics for animal relocation in relation to construction activity if necessary, increased monitoring of the animals, and intervention to address any escalation of stress activity in the animals.

2.33(b)(3)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

A large percentage (>50%) of rhesus macaques in all different housing types have significant, non-pruritic hair loss. Recent response to animals with alopecia has been largely through the Behavior Sciences Unit (BSU). While studies to identify potential causes in the past have been done, there is not evidence of a comprehensive clinical diagnostic plan to determine underlying physical causes. The semi-annual physical examination of all of the non-human primates (NHPs) at the facility was adjusted recently to include alopecia scoring; once they complete a full year's data set, analysis can begin to analyze incidence by location and season to help with diagnoses.

Hair loss in NHPs is multifactorial. Physical as well as psychological components need to be considered to try and determine treatable causes. Hormonal influences are currently at their peak since it is birthing season, however animals of all ages and both genders are affected. Hair loss can be a problem in that it negatively influences the skin protection and thermoregulation abilities of the affected animals.

Correct by: May 15, 2014. The NHP Resource Veterinarian stated they will have a comprehensive colony plan in place in 30 days to diagnose and develop a therapy plan for treatable physical causes, to continue the behavioral therapy, and to implement more complex diagnostics such as food trials or other "response to therapy" modalities. The most severely affected must be evaluated and treated first.

3.75(c)(1)

HOUSING FACILITIES, GENERAL.

The bedding in the calf hutches in corral 5, and the two corrals set away from the others (Japanese macaque and a rhesus corral) is dirty. The weather has been very wet, so the bedding has quickly become soiled. High traffic areas are muddy, such as around the calf hutches, under play equipment, and at the doors to the indoor feeding area in the rhesus corral adjacent to the Japanese macaque corral. Animals must be able to avoid muddy areas. Clean bedding is necessary to ensure the animals can stay clean and dry to better thermoregulate.

The calf hutches are placed in the corrals to provide shelter in addition to the indoor feeding areas which are cleaned daily. Bedding straw is placed in the calf hutches and is changed every two weeks from October through March, and every four weeks for the remainder of the year.

Bedding changes should be done as needed rather than on a scheduled basis. Additionally, there must special attention to mud control in areas at entrances to shelters and near food and water access.

Correct by: This was corrected at the time of inspection by replacing straw bedding in the hutches and laying fresh straw over the affected traffic areas.

3.75(c)(2)

HOUSING FACILITIES, GENERAL.

There are cracks in the wall surface and areas of picked paint on walls and defects in the floor coating in four animal rooms in the colony building (1A, 2A, 3A, 4A) and in runs 5 and 8 in the Harem building. These cracks and defects make it difficult to clean and disinfect properly.

Correct by: April 25, 2014. The Colony building rooms and Harem run 8 were corrected at the time of inspection by moving the animals to other locations. Repairs will be made before any animals are placed in the rooms.The room that still contains animals,Harem run 5, is scheduled to be vacated and repaired by the correction date.

The inspection was conducted April 2-4, 2014 and was accompanied by the NHP Resource Veterinarian and personnel from the various areas. Records inspection was facilitated by IACUC office staff. Exit briefing with facility personnel on April 16, 2014.

Additional Inspectors

Mckinnie Carolyn, Supervisory Animal Care Specialist

Prepared By: GWYNN HALLBERG, D V M USDA, APHIS, Animal Care **Date:** 16-APR-2014

Title: VETERINARY MEDICAL OFFICER 5036

Received by Title: NHP RESOURCE PROJECT VETERINARIAN **Date:** 16-APR-2014

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 02-APR-14

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	002	OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS	02-APR-14

Count	Scientific Name	Common Name
000135	*Macaca fascicularis*	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000209	*Macaca fuscata*	JAPANESE MACAQUE *MALE
000125	*Macaca fuscata*	JAPANESE MACAQUE / SNOW MACAQUE
001685	*Macaca mulatta*	RHESUS MACAQUE
002590	*Macaca mulatta*	RHESUS MACAQUE *MALE
000006	*Oryctolagus cuniculus*	EUROPEAN RABBIT
000009	*Papio anubis*	OLIVE BABOON
004759	**Total**	

United States Department of Agriculture
Animal and Plant Health Inspection Service

213141735510203 Insp_id

Inspection Report

Oregon Health & Science University
3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**
Certificate: **92-R-0001**
Site: 002
OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS

Type: ROUTINE INSPECTION
Date: 29-JUL-2014

2.31(d)(1)(8)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

An adverse event was reported in the February 18, 2014 IACUC minutes. Two animals (30789 and 30790) suffered burns from an electric heating pad used during a procedure. Other animals that underwent the same procedure on the same day were unaffected. Both affected animals were treated by the facility veterinarians; one was allowed to heal by secondary intention, the other required more extensive treatment including surgical debridement. Both animals made a full recovery.

Policy at the time of the event recommended the use of circulating water heating pads or Bair Hugger® forced air heating pads for thermal support of anesthetized animals, and discouraged use of electric heating pads. The facility representatives were not sure if the Primary Investigator (PI) was trained on this issue. The IACUC was unaware of the use of electric heating pads in the animal labs because the researchers did not store them in the lab, but brought them in only when the procedures were taking place. Therefore, the items were not present during inspections of the lab.

This was corrected prior to the time of inspection by making two policy changes. First, the thermal support policy was changed so that the use of electric heating pads was not just discouraged, but banned. Second, all equipment that will be used in animal work must be made available for inspection and will be inspected by the IACUC. All personnel from all labs have been retrained according to the new policies. The facility needs to ensure all employees are trained on current policies.

The inspection was conducted on 7/29-30/2014 and was accompanied by the NHP Project Resource Veterinarian, animal area personnel, and IACUC office personnel.
The exit briefing was held on 7/30/2014 with facility veterinarians and IACUC office personnel.

Additional Inspectors

Cole Heather, Supervisory Animal Care Specialist

Prepared By: GWYNN HALLBERG, D V M USDA, APHIS, Animal Care **Date:** 01-AUG-2014

Title: VETERINARY MEDICAL OFFICER 5036

Received by Title: DCM NHP PROJECT RESOURCE VETERINARIAN **Date:** 01-AUG-2014

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 29-JUL-14

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	002	OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS	29-JUL-14

Count	Scientific Name	Common Name
000136	*Macaca fascicularis*	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000209	*Macaca fuscata*	JAPANESE MACAQUE *MALE
000120	*Macaca fuscata*	JAPANESE MACAQUE / SNOW MACAQUE
001738	*Macaca mulatta*	RHESUS MACAQUE
002606	*Macaca mulatta*	RHESUS MACAQUE *MALE
000009	*Papio anubis*	OLIVE BABOON
004818	**Total**	

United States Department of Agriculture
Animal and Plant Health Inspection Service

276141707310082 Insp_id

Inspection Report

Oregon Health & Science University
3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**
Certificate: **92-R-0001**
Site: 001
OREGON HEALTH & SCIENCE UNIV.

Type: ROUTINE INSPECTION
Date: 29-SEP-2014

No non-compliant items were identified during this inspection.

The facility inspection was conducted with DCM veterinarians and animal area personnel.The records review was conducted with IACUC personnel. Exit interviews conducted with representatives from their respective areas.

Prepared By: GWYNN HALLBERG, D V M USDA, APHIS, Animal Care **Date:** 03-OCT-2014

Title: VETERINARY MEDICAL OFFICER 5036

Received by Title: DIRECTOR, DCM **Date:** 03-OCT-2014

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 29-SEP-14

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	001	OREGON HEALTH & SCIENCE UNIV.	29-SEP-14

Count	Scientific Name	Common Name
000002	*Callithrix jacchus*	COMMON MARMOSET
000016	*Cavia porcellus*	DOMESTIC GUINEA PIG
000010	*Meriones unguiculatus*	MONGOLIAN GERBIL (COMMON PET / RESEARCH VARIETY)
000004	*Muscardinus avellanarius*	HAZEL DORMOUSE
000044	*Oryctolagus cuniculus*	DOMESTIC RABBIT / EUROPEAN RABBIT
000010	*Ovis aries aries*	SHEEP INCLUDING ALL DOMESTIC BREEDS
000004	*Sus scrofa domestica*	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000090	**Total**	

United States Department of Agriculture
Animal and Plant Health Inspection Service

89151954210841 Insp_id

Inspection Report

Oregon Health & Science University
3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**
Certificate: **92-R-0001**
Site: 002
OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS

Type: ROUTINE INSPECTION
Date: 24-MAR-2015

2.31(c)(7)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

A macaque was found to have necrotic lesions at three of six subcutaneous injection sites of an experimental substance. The facility 's follow-up to this incident determined that the animal received a series of six subcutaneous injections instead of a single intramuscular injection as was described in the approved protocol. An additional departure from the approved protocol was that the injection sites were not shaved. Shaving the area was to allow observation of the site post-injection.
The protocol also states that the clinical veterinary staff was to be notified when the injections were given and the IACUC was to be notified regarding the results of the study at 72 hours post-injection. A facility representative stated that the veterinary staff was not notified until 3-4 days post-injection and the IACUC was not notified until four days post-injection.
This incident resulted in injury to the animal and delay in evaluation and treatment.
The facility must ensure that from this day forward all significant changes to protocols are reviewed and approved by the IACUC prior to implementation by the Principal Investigator and research staff.

Correction date: The facility corrected the NCI prior to the time of inspection by retraining all personnel involved in the incident on the importance of following a protocol exactly, as well as on the chain of communication for working within and between departments to ensure all experimental procedures are conducted according to approved protocols.
This adverse event was self-reported to OLAW.

A high incidence of alopecia was reported on a previous inspection report. The facility's alopecia incidence was reviewed as well as supporting documentation regarding their extremely comprehensive investigation into potential causes and, therefore, remedies for the cases of alopecia at the facility.

The inspection was conducted on March 24-26, 2015, accompanied by facility representatives.

The exit briefing was conducted on March 26 with facility representatives.

Prepared By: GWYNN HALLBERG, D V M USDA, APHIS, Animal Care **Date:** 31-MAR-2015

Title: VETERINARY MEDICAL OFFICER 5036

Received by Title: FACILITY REPRESENTATIVE **Date:** 31-MAR-2015

Inspection Report

Additional Inspectors

Cole Heather, Supervisory Animal Care Specialist

Prepared By: GWYNN HALLBERG, D V M USDA, APHIS, Animal Care **Date:** 31-MAR-2015

Title: VETERINARY MEDICAL OFFICER 5036

Received by Title: FACILITY REPRESENTATIVE **Date:** 31-MAR-2015

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 24-MAR-15

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	002	OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS	24-MAR-15

Count	Scientific Name	Common Name
000132	*Macaca fascicularis*	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000206	*Macaca fuscata*	JAPANESE MACAQUE *MALE
000098	*Macaca fuscata*	JAPANESE MACAQUE / SNOW MACAQUE
001688	*Macaca mulatta*	RHESUS MACAQUE
002594	*Macaca mulatta*	RHESUS MACAQUE *MALE
000006	*Oryctolagus cuniculus*	EUROPEAN RABBIT
000006	*Papio anubis*	OLIVE BABOON
004730	**Total**	

United States Department of Agriculture
Animal and Plant Health Inspection Service

198151557460312 Insp_id

Inspection Report

Oregon Health & Science University
3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**
Certificate: **92-R-0001**
Site: 002
OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS

Type: ROUTINE INSPECTION
Date: 14-JUL-2015

No non-compliant items were identified during this inspection.

The inspection was conducted on July 14-16, 2015 by Drs. Heather Cole and Gwynn Hallberg, accompanied by the attending veterinarian, animal area personnel, and IACUC personnel. The exit interview was conducted on July 16, 2015 with facility representatives.

The researchers reported on progress of the comprehensive alopecia study.

Additional Inspectors

Cole Heather, Supervisory Animal Care Specialist

Prepared By: GWYNN HALLBERG, D V M USDA, APHIS, Animal Care **Date:** 21-JUL-2015

Title: VETERINARY MEDICAL OFFICER 5036

Received by Title: INTERIM CHIEF, DCM **Date:** 21-JUL-2015

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 14-JUL-15

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	002	OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS	14-JUL-15

Count	Scientific Name	Common Name
000128	*Macaca fascicularis*	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000203	*Macaca fuscata*	JAPANESE MACAQUE *MALE
000098	*Macaca fuscata*	JAPANESE MACAQUE / SNOW MACAQUE
001763	*Macaca mulatta*	RHESUS MACAQUE
002613	*Macaca mulatta*	RHESUS MACAQUE *MALE
000012	*Oryctolagus cuniculus*	EUROPEAN RABBIT
000009	*Papio anubis*	OLIVE BABOON
000013	*Papio hamadryas*	HAMADRYAS BABOON
004839	**Total**	

United States Department of Agriculture
Animal and Plant Health Inspection Service

261151713010480 Insp_id

Inspection Report

Oregon Health & Science University
3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**
Certificate: **92-R-0001**
Site: 001
OREGON HEALTH & SCIENCE UNIV.

Type: ROUTINE INSPECTION
Date: 15-SEP-2015

2.31(d)(1)(9)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

A room used for survival surgery on rabbits has items stored in it which are not related to the surgery, and are not readily cleanable nor sanitizable. Items include a large wooden box and a large metal cabinet holding items in drawers and on top that are simply stored there and are unrelated to the covered surgeries. These items include an open cardboard box containing water bottles and other miscellaneous items, a radio, and items related to other studies on non-covered animals.

Surgery on covered species must be conducted in dedicated facilities intended for that purpose which shall be operated and maintained under aseptic conditions. Storage of unnecessary items in the surgery room is not maintaining the room under aseptic conditions.

Correct by removing all extraneous items and maintaining the surgery room under aseptic conditions from now on.

Additionally, a sink in the animal prep area is being used as the surgeon's scrub sink. The water controls are not hands-free, the faucet is low, and there is not much clearance between the faucet and the back of the sink. It would be very difficult to assure proper surgeon hand scrub with this sink. A proper scrub sink away from the animals prep area is recommended.

The inspection was conducted on September 15-16, 2015 accompanied by facility personnel.
The exit briefing was conducted on September 16, 2015 with facility personnel.

Prepared By: GWYNN HALLBERG, D V M USDA, APHIS, Animal Care **Date:** 18-SEP-2015

Title: VETERINARY MEDICAL OFFICER 5036

Received by Title: DCM DIRECTOR **Date:** 18-SEP-2015

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 15-SEP-15

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	001	OREGON HEALTH & SCIENCE UNIV.	15-SEP-15

Count	Scientific Name	Common Name
000002	*Callithrix jacchus*	COMMON MARMOSET
000022	*Cavia porcellus*	DOMESTIC GUINEA PIG
000003	*Meriones unguiculatus*	MONGOLIAN GERBIL (COMMON PET / RESEARCH VARIETY)
000004	*Muscardinus avellanarius*	HAZEL DORMOUSE
000015	*Oryctolagus cuniculus*	DOMESTIC RABBIT / EUROPEAN RABBIT
000003	*Ovis aries aries*	SHEEP INCLUDING ALL DOMESTIC BREEDS
000006	*Sus scrofa domestica*	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000055	**Total**	

United States Department of Agriculture
Animal and Plant Health Inspection Service

Inspection Report

Oregon Health & Science University
3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**
Certificate: **92-R-0001**
Site: 002
OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS

Type: ROUTINE INSPECTION
Date: 14-JAN-2016

3.80(a)(2)(2)

PRIMARY ENCLOSURES.

The IACUC minutes dated 10/20/2015 include discussion regarding an animal that died as a result of entrapment associated with a chain securing an enrichment device. It was found that a device with an obsolete design had been used in the animal s primary enclosure. That device had enough unprotected chain length for an entrapment accident to occur. Immediate changes to the enrichment plan were to include fastener length in the maximum chain length left unprotected by a PVC sleeve, and to make the enrichment storage area accessible to only the behavioral sciences group to ensure that only approved toys and other enrichment devices are dispensed for animal use. Environmental enrichment is an important part of housing non-human primates. Design of enrichment devices must involve careful scrutiny for safety for use with these animals; they can cause harm if not carefully constructed and monitored with use to ensure they have not become unsafe.
The facility must ensure that all enrichment devices are safely constructed and maintained in order to protect the non-human primates from injury. This NCI was corrected prior to the time of inspection.

A progress report on the comprehensive alopecia study was reviewed.

The inspection was conducted by Drs. Gwynn Hallberg and Heather Cole on January 12-14, 2016 and was accompanied by facility personnel. The exit briefing was conducted on 1/14/2016 with facility personnel.

Additional Inspectors

Cole Heather, Supervisory Animal Care Specialist

Prepared By: GWYNN HALLBERG, D V M USDA, APHIS, Animal Care **Date:** 19-JAN-2016

Title: VETERINARY MEDICAL OFFICER 5036

Received by Title: CHIEF AND AV DCM **Date:** 19-JAN-2016

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 14-JAN-16

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	002	OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS	14-JAN-16

Count	Scientific Name	Common Name
000078	*Macaca fascicularis*	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000207	*Macaca fuscata*	JAPANESE MACAQUE *MALE
000109	*Macaca fuscata*	JAPANESE MACAQUE / SNOW MACAQUE
001740	*Macaca mulatta*	RHESUS MACAQUE
002619	*Macaca mulatta*	RHESUS MACAQUE *MALE
000008	*Papio anubis*	OLIVE BABOON
000014	*Papio hamadryas*	HAMADRYAS BABOON
004775	**Total**	

United States Department of Agriculture
Animal and Plant Health Inspection Service

2016082567939537 Insp_id

Inspection Report

Oregon Health & Science University
3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**
Certificate: **92-R-0001**
Site: 002
OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS

Type: FOCUSED INSPECTION
Date: 23-SEP-2016

No non-compliant items were identified during this inspection.

This inspection and exit interview were conducted with facility personnel.

Prepared By: GWYNN HALLBERG, D V M USDA, APHIS, Animal Care **Date:** 26-SEP-2016

Title: VETERINARY MEDICAL OFFICER 5036

Received by Title: ATTENDING VETERINARIAN **Date:** 26-SEP-2016

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 23-SEP-16

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	002	OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS	23-SEP-16

Count	Scientific Name	Common Name
000049	*Macaca mulatta*	RHESUS MACAQUE *MALE
000049	**Total**	

United States Department of Agriculture
Animal and Plant Health Inspection Service

2016082567945980 Insp_id

Inspection Report

Oregon Health & Science University
3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**
Certificate: **92-R-0001**
Site: 001
OREGON HEALTH & SCIENCE UNIV.

Type: ROUTINE INSPECTION
Date: 27-SEP-2016

No non-compliant items were identified during this inspection.

This inspection and exit interview were conducted with facility personnel.

Prepared By: GWYNN HALLBERG, D V M USDA, APHIS, Animal Care **Date:** 29-SEP-2016

Title: VETERINARY MEDICAL OFFICER 5036

Received by Title: DIRECTOR AND PROFESSOR **Date:** 29-SEP-2016

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 27-SEP-16

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	001	OREGON HEALTH & SCIENCE UNIV.	27-SEP-16

Count	Scientific Name	Common Name
000002	*Callithrix jacchus*	COMMON MARMOSET
000007	*Canis lupus familiaris*	DOMESTIC DOG
000061	*Cavia porcellus*	DOMESTIC GUINEA PIG
000032	*Meriones unguiculatus*	MONGOLIAN GERBIL (COMMON PET / RESEARCH VARIETY)
000005	*Mustela putorius furo*	DOMESTIC FERRET
000027	*Oryctolagus cuniculus*	DOMESTIC RABBIT / EUROPEAN RABBIT
000004	*Ovis aries aries*	SHEEP INCLUDING ALL DOMESTIC BREEDS
000007	*Sus domestica*	DOMESTIC PIG
000002	*Sus scrofa domestica*	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000147	**Total**	

United States Department of Agriculture
Animal and Plant Health Inspection Service

Inspection Report

Oregon Health & Science University
3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**
Certificate: **92-R-0001**
Site: 002
OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS

Type: ROUTINE INSPECTION
Date: 14-FEB-2017

2.31(c)(7) REPEAT

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

* A researcher self-reported to the IACUC that an off-study drug was administered to five animals. There were no ill effects to the animals. The drug's use had been included on the previously approved study, but not on the renewal. Research activities must exactly follow approved protocols for the welfare of the animals and the integrity of the science. This was corrected prior to the time of inspection by approving an amendment to the protocol.
* Two monkeys with head caps were reported by veterinary care staff to have them cleaned monthly. The margins are clean and without evidence of discharge or discoloration. The IACUC-approved protocol states that head caps are to be cleaned weekly. There is no part of the protocol addressing care when there is no activity using the posts or chambers, as is the current situation. Care of research-related implants may be different for active versus inactive status, but the difference must be addressed in the approved protocol. Correction: the IACUC is set to meet the week following the inspection, where correction will be addressed.

2.32(a) CRITICAL

PERSONNEL QUALIFICATIONS.

* Two animals were found unresponsive on first check one morning. One animal responded to treatment, the second did not and was euthanized. Review found that previously drawn-up evening insulin doses for these animals were dropped and contaminated, and so were replaced by the administering tech. TB syringes were accidentally used instead of insulin syringes, so the dose was wrong resulting in the complication.
This was corrected prior to the time of inspection by retraining the employee.

3.75(a) CRITICAL

HOUSING FACILITIES, GENERAL.

A baboon was found to have a fractured hand. It was treated and healed without complication. Upon review of the injury and the facility, it was determined that the animal had likely been injured by the heavy guillotine door. Housing facilities must be safe and secure to minimize the chance of injury. Correction was made prior to the time of inspection by modifying the doors to positively lock in the open or closed position.

Prepared By: HALLBERG GWYNN, D V M USDA, APHIS, Animal Care **Date:** 22-FEB-2017

Title: VETERINARY MEDICAL OFFICER 5036

Received by Title: CHIEF AND ATTENDING VETERINARIAN **Date:** 22-FEB-2017

Inspection Report

3.84(c)

CLEANING, SANITIZATION, HOUSEKEEPING, AND PEST CONTROL.

Catch areas of the corrals have excess cobwebs and dust above the secondary containment mesh, and the exhaust fans are excessively dusty. Room 4 in quarantine North Annex has cobwebs in the vent. Colony runs 1 and 6 have dirty air vent covers. ASA rooms have dust patterns on the ceiling around the air vents. Keeping the animal areas clean is important to the health of the animals. Accumulation of cobwebs around electrical fixtures can be a fire hazard. Correct by March 1, 2017.

This February 14-16, 2017 inspection and exit interview were conducted with facility personnel.

Additional Inspectors

Pannill Elizabeth, Veterinary Medical Officer

Prepared By: HALLBERG GWYNN, D V M USDA, APHIS, Animal Care **Date:** 22-FEB-2017

Title: VETERINARY MEDICAL OFFICER 5036

Received by Title: CHIEF AND ATTENDING VETERINARIAN **Date:** 22-FEB-2017

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 14-FEB-17

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	002	OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS	14-FEB-17

Count	Scientific Name	Common Name
000006	*Cavia porcellus*	DOMESTIC GUINEA PIG
000081	*Macaca fascicularis*	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000117	*Macaca fuscata*	JAPANESE MACAQUE *MALE
000216	*Macaca fuscata*	JAPANESE MACAQUE / SNOW MACAQUE
002646	*Macaca mulatta*	RHESUS MACAQUE
001792	*Macaca mulatta*	RHESUS MACAQUE *MALE
000005	*Oryctolagus cuniculus*	EUROPEAN RABBIT
000008	*Papio anubis*	OLIVE BABOON
000018	*Papio hamadryas*	HAMADRYAS BABOON
000006	*Saimiri boliviensis*	BLACK-CAPPED SQUIRREL MONKEY
004895	**Total**	

United States Department of Agriculture
Animal and Plant Health Inspection Service

2016082568869036 Insp_id

Inspection Report

Oregon Health & Science University
3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**
Certificate: **92-R-0001**
Site: 001
OREGON HEALTH & SCIENCE UNIV.

Type: ROUTINE INSPECTION
Date: 25-SEP-2017

No non-compliant items were identified during this inspection, which was conducted on 9/25-26/2017.

This inspection and exit interview were conducted with facility personnel.

Prepared By: HALLBERG GWYNN, D V M USDA, APHIS, Animal Care **Date:** 27-SEP-2017

Title: VETERINARY MEDICAL OFFICER 5036

Received by Title: DIRECTOR, DCM **Date:** 27-SEP-2017

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 25-SEP-17

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	001	OREGON HEALTH & SCIENCE UNIV.	25-SEP-17

Count	Scientific Name	Common Name
000071	*Cavia porcellus*	DOMESTIC GUINEA PIG
000061	*Meriones unguiculatus*	MONGOLIAN GERBIL (COMMON PET / RESEARCH VARIETY)
000007	*Mustela putorius furo*	DOMESTIC FERRET
000014	*Oryctolagus cuniculus*	DOMESTIC RABBIT / EUROPEAN RABBIT
000008	*Sus scrofa domestica*	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000161	**Total**	

United States Department of Agriculture
Animal and Plant Health Inspection Service

2016082569072176 Insp_id

Inspection Report

Oregon Health & Science University
3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**
Certificate: **92-R-0001**
Site: 002
OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS

Type: ROUTINE INSPECTION
Date: 05-FEB-2018

2.31(d)(1)(x)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

A NHP was erroneously assigned to a second study involving a major operative procedure. The animal had been flagged in the research animal information system as surgically restricted, but the flag was overlooked. The animal underwent a C-section in one study, and an embryo transfer procedure in the other. The animal has recovered completely and without complications.

This non-compliance was corrected before the time of inspection by retraining the involved personnel to confirm the status of the animal prior to use. They also created a second line of protection by building a flagging system into the surgical records system. The surgery group will now also be alerted if a surgically-restricted animal appears on the surgical schedule.

2.38(f)(1) CRITICAL

MISCELLANEOUS.

A NHP being transferred between enclosures for a procedure injured his tail. The tail was caught in a gap between the enclosures. The degloving injury was treated by amputation. The animal recovered without complications.
The gap between the cages resulted from a malfunctioning mechanism that connects the cages for transfers. The problem was not apparent to handling personnel on visual inspection.
This noncompliant item was corrected prior to the time of inspection by improving the line of communication from the animal care staff to the facility maintenance staff and training both groups in the new procedures to expedite reporting and repair of facilities and equipment.

During a group release from a catch area following processing, a juvenile animal was able to get, unnoticed, behind the wall-hung cages where he became entrapped and died.
This non-compliant item was corrected prior to inspection. Unable to determine exactly how the animal got into the position where he was found, the facilty's corrective measures were comprehensive. New procedures include assigning a safety observer to ensure that all animals released continue out into the corral, and ensuring that cages from which animals have been removed are closed. Final checks must then be conducted to ensure all animals have been removed from the cages and transfer systems in the catch area.

Prepared By: HALLBERG GWYNN, D V M USDA, APHIS, Animal Care **Date:** 05-MAR-2018

Title: VETERINARY MEDICAL OFFICER 5036

Received by Title: ATTENDING VETERINARIAN **Date:** 05-MAR-2018

United States Department of Agriculture
Animal and Plant Health Inspection Service

Inspection Report

This inspection and exit interview were conducted on 2/5/2018 through 2/8/2018 with facility and IACUC personnel.

Additional Inspectors

Schnell Michael, Veterinary Medical Officer

Prepared By: HALLBERG GWYNN, D V M USDA, APHIS, Animal Care **Date:** 05-MAR-2018

Title: VETERINARY MEDICAL OFFICER 5036

Received by Title: ATTENDING VETERINARIAN **Date:** 05-MAR-2018

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 05-FEB-18

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	002	OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS	05-FEB-18

Count	Scientific Name	Common Name
000002	*Cavia porcellus*	DOMESTIC GUINEA PIG
000078	*Macaca fascicularis*	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000341	*Macaca fuscata*	JAPANESE MACAQUE / SNOW MACAQUE
004589	*Macaca mulatta*	RHESUS MACAQUE
000014	*Papio anubis*	OLIVE BABOON
000004	*Papio hamadryas*	HAMADRYAS BABOON
000004	*Saimiri boliviensis*	BLACK-CAPPED SQUIRREL MONKEY
005032	**Total**	

United States Department of Agriculture
Animal and Plant Health Inspection Service

Inspection Report

Oregon Health & Science University
3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**
Certificate: **92-R-0001**
Site: 001
OREGON HEALTH & SCIENCE UNIV.

Type: ROUTINE INSPECTION
Date: 19-JUL-2018

2.32(c)(3) CRITICAL

PERSONNEL QUALIFICATIONS.

A PI self-reported to the Department of Comparative Medicine (DCM) the deaths of two GPs post-procedure. The PI requested DCM veterinary review. The DVM veterinarian determined the anesthetic monitoring was inadequate. Training and instruction of personnel in the proper use of anesthetics must be provided to minimize risk of adverse events.

This was corrected prior to the time of inspection. The DCM evaluated the procedures and made recommendations for improvement which were successfully implemented.

3.28(a) CRITICAL

PRIMARY ENCLOSURES.

An adverse event was reported in the July 2017 IACUC minutes. A 4 month old guinea pig injured its leg in the perforated floor of newly-purchased bedding-free caging. It was thought to have gotten its foot caught in a corner hole, which was slightly larger than the other holes in the flooring. The animal failed to respond to treatment and was euthanized. Bedding-free flooring must allow waste to drop through, but protect feet and legs from injury. This was corrected quickly after the incident, prior to the time of inspection. The study was concluded shortly after this incident without further cases. The cage floors have since been replaced with solid-bottom flooring with bedding.

Another incident was reported in the October 2017 IACUC minutes. A guinea pig was injured when its leg got trapped in a damaged igloo. The animal was euthanized when it did not respond to treatment. Husbandry staff had not removed the damaged item as per policy. Items in the enclosure must be replaced when damaged to protect from injury. This was corrected prior to the time of inspection by retraining the staff on evaluating enrichment items for safety.

3.83

WATERING.

Prepared By: HALLBERG GWYNN, D V M USDA, APHIS, Animal Care **Date:** 26-JUL-2018

Title: VETERINARY MEDICAL OFFICER 5036

Received by Title: DIRECTOR, ANIMAL CARE AND USE PROGRAM **Date:** 26-JUL-2018

The female marmosets were found without water on a Saturday morning. It was determined that when they were returned to their home enclosure the previous afternoon, the IACUC-approved protocol for providing water was not followed, and they were without water overnight. They were given water; the animals displayed no ill effects.
Animals must be given water as required by the IACUC-approved research protocol to ensure their health and comfort.
This was corrected immediately by giving the animals water as per protocol. The situation was reviewed by the IACUC prior to the time of inspection; laboratory staff was counseled regarding ensuring the protocol is strictly followed.

3.130

WATERING.

A surgery was postponed due to a miscommunication in a lab that resulted in a ferret going without water for approximately 24 hours. The Department of Comparative Medicine (DCM) veterinarian was notified; the ferret recovered fully with no ill effects.
Water must be provided as often as necessary to ensure the health and comfort of the animal. This animal is under an IACUC-approved protocol describing how and when water is to be provided, but the miscommunication resulted in deviation from the protocol's requirements.
This was corrected prior to the time of inspection. The lab personnel reviewed and revised their communication procedures to minimize the possibility of recurrence.

This inspection and exit interview were conducted on 7/17-19/2018 with facility personnel. A follow-up communication was conducted by telephone on 7/26/2018.

Prepared By: HALLBERG GWYNN, D V M USDA, APHIS, Animal Care **Date:** 26-JUL-2018

Title: VETERINARY MEDICAL OFFICER 5036

Received by Title: DIRECTOR, ANIMAL CARE AND USE PROGRAM **Date:** 26-JUL-2018

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 19-JUL-18

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	001	OREGON HEALTH & SCIENCE UNIV.	19-JUL-18

Count	Scientific Name	Common Name
000004	*Callithrix jacchus*	COMMON MARMOSET
000049	*Cavia porcellus*	DOMESTIC GUINEA PIG
000075	*Meriones unguiculatus*	MONGOLIAN GERBIL (COMMON PET / RESEARCH VARIETY)
000005	*Mustela putorius furo*	DOMESTIC FERRET
000008	*Oryctolagus cuniculus*	DOMESTIC RABBIT / EUROPEAN RABBIT
000002	*Sus scrofa domestica*	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000143	**Total**	

United States Department of Agriculture
Animal and Plant Health Inspection Service

2016082569239077 Insp_id

Inspection Report

Oregon Health & Science University
3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**
Certificate: **92-R-0001**
Site: 002
OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS

Type: ROUTINE INSPECTION
Date: 06-AUG-2018

2.33(b)(5)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

On February 16, 2018, a nonhuman primate that had received a non-major surgical procedure was not administered buprenorphine or cefazolin the morning after surgery. The protocol approved by the Institutional Animal Care and Use Committee included these treatments as part of their description of procedures. During the routine post-surgical assessment, a certified veterinary technician (CVT) indicated a pain score of 0 (no pain). The NHP received all other treatments, including pre-operative and other post-operative medications.

The corrective and preventative actions taken by the facility included using an additional cross-check reference to the medication sheets. Additional assistance to the technicians in charge of administering these medications is being provided on days with high numbers of injections to be performed. Additionally the use of a sustained-release formulation administered peri-procedurally, which would decrease the number of injections for a NHP, has been instituted.

Adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures are necessary for adequate care of the animals.

Corrected prior to this inspection.

3.80(a)(2)(ii) **CRITICAL**

PRIMARY ENCLOSURES.

The facility reported that on May 6, 2018, facility personnel found a young non-human primate (NHP) that was constrained by PVC pipes of a resting perch. The (NHP) was freed and taken immediately for evaluation by a veterinary technician. A veterinarian assessed and initiated treatment a few minutes after presentation to the veterinary technician. The NHP responded to initial treatment but later developed neurological signs. The NHP was euthanized based upon the follow-up veterinary evaluation. The necropsy and histopathology revealed signs that appeared consistent with the entrapment and subsequent events.

The facility installed a device to decrease the side-to-side movement of the PVC pipes of the perch. Their

Prepared By: SCHNELL MICHAEL, D V M USDA, APHIS, Animal Care **Date:** 09-AUG-2018

Title: VETERINARY MEDICAL OFFICER 6100

Received by Title: CHIEF AND ATTENDING VETERINARIAN **Date:** 09-AUG-2018

evaluation of other perches did not reveal any similarly affected. All other perches were evaluated to assess stability, the potential for entrapment, ease of sanitization as well as to identify and prioritize possible refinements of the perches. They have instituted a policy of daily checking of perches for damage, wear or instability.

Primary enclosures must be designed and constructed of suitable materials so that they are structurally sound for the species of nonhuman primates contained in them. Primary enclosures must be constructed and maintained so that they protect the nonhuman primates from injury

Corrected prior to this inspection.

This inspection and exit briefing were conducted with facility representatives.

Additional Inspectors

Forbes Diane, Veterinary Medical Officer

Prepared By: SCHNELL MICHAEL, D V M USDA, APHIS, Animal Care **Date:** 09-AUG-2018

Title: VETERINARY MEDICAL OFFICER 6100

Received by Title: CHIEF AND ATTENDING VETERINARIAN **Date:** 09-AUG-2018

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 06-AUG-18

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	002	OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS	06-AUG-18

Count	Scientific Name	Common Name
000018	*Cavia porcellus*	DOMESTIC GUINEA PIG
000094	*Macaca fascicularis*	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000339	*Macaca fuscata*	JAPANESE MACAQUE / SNOW MACAQUE
004759	*Macaca mulatta*	RHESUS MACAQUE
000013	*Papio anubis*	OLIVE BABOON
000002	*Papio hamadryas*	HAMADRYAS BABOON
000004	*Saimiri boliviensis*	BLACK-CAPPED SQUIRREL MONKEY
005229	**Total**	

United States Department of Agriculture
Animal and Plant Health Inspection Service

Inspection Report

Oregon Health & Science University
3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**
Certificate: **92-R-0001**
Site: 002
OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS

Type: ROUTINE INSPECTION
Date: 11-MAR-2019

No non-compliant items were identified during this inspection.

This inspection was conducted on March 11-13, 2019 and the exit interview was conducted on March 14, 2019 with personnel from various facility areas.

Additional Inspectors

Schnell Michael, Veterinary Medical Officer

Prepared By: HALLBERG GWYNN, D V M USDA, APHIS, Animal Care **Date:** 13-MAR-2019

Title: VETERINARY MEDICAL OFFICER 5036

Received by Title: ATTENDING VETERINARIAN **Date:** 14-MAR-2019

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 11-MAR-19

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	002	OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS	11-MAR-19

Count	Scientific Name	Common Name
000006	*Cavia porcellus*	DOMESTIC GUINEA PIG
000108	*Macaca fascicularis*	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000352	*Macaca fuscata*	JAPANESE MACAQUE / SNOW MACAQUE
004532	*Macaca mulatta*	RHESUS MACAQUE
000007	*Papio anubis*	OLIVE BABOON
000014	*Papio hamadryas*	HAMADRYAS BABOON
000004	*Saimiri boliviensis*	BLACK-CAPPED SQUIRREL MONKEY
005023	**Total**	

United States Department of Agriculture
Animal and Plant Health Inspection Service

Inspection Report

Oregon Health & Science University
3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**
Certificate: **92-R-0001**
Site: 001
OREGON HEALTH & SCIENCE UNIV.

Type: ROUTINE INSPECTION
Date: 03-JUN-2019

2.32

PERSONNEL QUALIFICATIONS.

A lab group was found on April 2, 2019 to be conducting a surgery with poor sterile technique. Department of Comparative Medicine (DCM) veterinarians and technicians in attendance stepped in to ensure the welfare of the ferret. This pilot surgery ran into unexpected anatomical complications, and the animal was euthanized under anesthesia. The materials and methods for this euthanasia were not on the approved protocol.
The lab's training records were not current prior to the incident – copies provided were back-filled with training information and dates after the deficiencies in the lab were noted in April. The IACUC did not have personnel qualification information available at the time the protocol was approved.
The mitigation plan included a training covering scrubbing and gowning on 5/21/19. Two of the people in that training under the lab's protocol number are not listed as personnel on the approved protocol. It is unclear if they have participated in procedures.
The IACUC must evaluate qualifications of all personnel on the protocol, and ensure all personnel are listed on the protocol, as part of the approval process.
Correct by ensuring all aspects of Section 2.32 are met prior to approving protocols from this point forward.

2.33(b)(2) DIRECT

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

In the same lab, there were containers of dressing supplies used for ferret cap care on the bench. The containers appeared dirty, and had large areas of corrosion on the lids and under the lid. The containers held gauze for cleaning and non-stick pads for dressing the caps.
Corroded metal cannot be adequately cleaned, disinfected, or sterilized. Their use is not appropriate for procedures requiring clean or sterile technique because they can harbor pathogens which may result in infection.
Correct by using containers able to be properly cleaned and disinfected or sterilized from this point forward.

2.33(b)(3) DIRECT

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

At the time of inspection, the same lab had a ferret (#100951) in a restraint for training and cap care. The ferret had

Prepared By: HALLBERG GWYNN, D V M USDA, APHIS, Animal Care **Date:** 11-JUN-2019

Title: VETERINARY MEDICAL OFFICER 5036

Received by Title: DIRECTOR, ANIMAL CARE AND USE PROGRAM **Date:** 11-JUN-2019

a strong foul odor, and the cap margins were moist with crusty exudate. A second ferret (#270877B) in a holding cage was rubbing its head cap on the fabric of a hammock. Review of the protocol revealed that rubbing or itching of the surgery site will trigger notification to the DCM. Neither animal had been reported to the AV in the DCM. Both animals were immediately examined by DCM veterinarians and a treatment plan was initiated.
Correct by ensuring that, from this point forward, all animal use personnel are aware of the daily observation requirements in this section, and that they know that they must immediately report problems to the Attending Veterinarian.

This inspection and exit interview were conducted on June 3, 4, and 6, 2019 with facility personnel.

Prepared By: HALLBERG GWYNN, D V M USDA, APHIS, Animal Care **Date:** 11-JUN-2019

Title: VETERINARY MEDICAL OFFICER 5036

Received by Title: DIRECTOR, ANIMAL CARE AND USE PROGRAM **Date:** 11-JUN-2019

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 03-JUN-19

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	001	OREGON HEALTH & SCIENCE UNIV.	03-JUN-19

Count	Scientific Name	Common Name
000004	*Callithrix jacchus*	COMMON MARMOSET
000031	*Cavia porcellus*	DOMESTIC GUINEA PIG
000028	*Meriones unguiculatus*	MONGOLIAN GERBIL (COMMON PET / RESEARCH VARIETY)
000003	*Mustela putorius furo*	DOMESTIC FERRET
000016	*Oryctolagus cuniculus*	DOMESTIC RABBIT / EUROPEAN RABBIT
000016	*Sus scrofa domestica*	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000019	*Urocitellus parryii*	ARCTIC GROUND SQUIRREL / ARCTIC SOUSLIK
000117	**Total**	

United States Department of Agriculture
Animal and Plant Health Inspection Service

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Inspection Report

Oregon Health & Science University
3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**
Certificate: **92-R-0001**
Site: 001
OREGON HEALTH & SCIENCE UNIV.

Type: FOCUSED INSPECTION
Date: 08-JUL-2019

No non-compliant items were identified during this inspection.

This inspection and exit interview were conducted with facility personnel.

Prepared By: HALLBERG GWYNN, D V M USDA, APHIS, Animal Care **Date:** 09-JUL-2019

Title: VETERINARY MEDICAL OFFICER 5036

Received by Title: ATTENDING VETERINARIAN **Date:** 09-JUL-2019

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 08-JUL-19

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	001	OREGON HEALTH & SCIENCE UNIV.	08-JUL-19

Count	Scientific Name	Common Name
000004	*Callithrix jacchus*	COMMON MARMOSET
000005	*Mustela putorius furo*	DOMESTIC FERRET
000009	**Total**	

United States Department of Agriculture
Animal and Plant Health Inspection Service

Inspection Report

Oregon Health & Science University
3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**
Certificate: **92-R-0001**
Site: 002
OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS

Type: ROUTINE INSPECTION
Date: 10-SEP-2019

No non-compliant items were identified during this inspection.

This inspection and exit interview were conducted with facility personnel on September 10-12, 2019.

Additional Inspectors

Sismour Naomi, Veterinary Medical Officer

Prepared By: HALLBERG GWYNN, D V M USDA, APHIS, Animal Care **Date:** 12-SEP-2019

Title: VETERINARY MEDICAL OFFICER 5036

Received by Title: ATTENDING VETERINARIAN **Date:** 12-SEP-2019

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 10-SEP-19

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	002	OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS	10-SEP-19

Count	Scientific Name	Common Name
000014	*Cavia porcellus*	DOMESTIC GUINEA PIG
000094	*Macaca fascicularis*	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000355	*Macaca fuscata*	JAPANESE MACAQUE / SNOW MACAQUE
004834	*Macaca mulatta*	RHESUS MACAQUE
000006	*Papio anubis*	OLIVE BABOON
000014	*Papio hamadryas*	HAMADRYAS BABOON
000004	*Saimiri boliviensis*	BLACK-CAPPED SQUIRREL MONKEY
005321	**Total**	

United States Department of Agriculture
Animal and Plant Health Inspection Service

2016082569707799 Insp_id

Inspection Report

Oregon Health & Science University
3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**
Certificate: **92-R-0001**
Site: 001
OREGON HEALTH & SCIENCE UNIV.

Type: ROUTINE INSPECTION
Date: 21-JAN-2020

2.32(c)(1)(iv) REPEAT

PERSONNEL QUALIFICATIONS.

At the time of inspection, a ferret was undergoing a survival procedure involving an open craniotomy chamber exposing the brain cavity (major operative procedure). The procedure involved placing study devices inside the chamber. The placement of the sterile field for instruments and supplies was in a location where it could be easily contaminated, unobserved by the person doing the procedure. During the observation, the sterile field was on an instrument table in a corner of the very small room outfitted as an acoustic chamber. As the person manipulated the electrode and fiber optic cables, the sterile field was at times behind him, allowing his lab coat to breach sterility of the field.
Aseptic technique requires that sterile fields be maintained the entire time a body cavity is open. Failure to do so may result in infection, harming the animal and interfering with the research.
From this point forward, ensure that all sterile fields remain sterile for the duration of any procedure involving an open body cavity.

2.33(b)(3) CRITICAL REPEAT

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

An incident occurred recently when an employee needed to leave before completing care for one room of prairie voles. Another employee completed the work in that room for the day. The next day, four animals in that room were found dead and another was moribund and euthanized. The facility determined that cage change and water bottle replacement for a section of the animal area was missed during the change of employees. Due to the lack of that day's observation for these animals, their water ran out, resulting in dehydration and death.
All animals must be observed daily to assess their health and any needs they may have.
Corrected prior to the time of inspection by revising the communication and transition procedure for a staff change during the workday.

2.36(b)(3)

ANNUAL REPORT.

Prepared By: HALLBERG GWYNN, D V M USDA, APHIS, Animal Care **Date:** 27-JAN-2020

Title: VETERINARY MEDICAL OFFICER 5036

Received by Title: DIRECTOR, DEPARTMENT OF COMPARATIVE MEDICINE **Date:** 27-JAN-2020

United States Department of Agriculture
Animal and Plant Health Inspection Service

Inspection Report

The IACUC approved exceptions to the requirement for a dedicated surgery area for non-rodent animals for protocols IP01561 and IP00211. These exceptions were not reported on the 2019 annual report.
All granted exceptions not specifically allowed in the regulations must be reported on the annual report.
Correct within 30 days by submitting an amended report to USDA.

This inspection was conducted on January 21-23, 2020 with facility personnel, and the exit interview was conducted with the IACUC Director on January 23, 2020.

Prepared By: HALLBERG GWYNN, D V M USDA, APHIS, Animal Care **Date:** 27-JAN-2020

Title: VETERINARY MEDICAL OFFICER 5036

Received by Title: DIRECTOR, DEPARTMENT OF COMPARATIVE MEDICINE **Date:** 27-JAN-2020

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 21-JAN-20

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	001	OREGON HEALTH & SCIENCE UNIV.	21-JAN-20

Count	Scientific Name	Common Name
000003	*Callithrix jacchus*	COMMON MARMOSET
000019	*Cavia porcellus*	DOMESTIC GUINEA PIG
000031	*Meriones unguiculatus*	MONGOLIAN GERBIL (COMMON PET / RESEARCH VARIETY)
000332	*Microtus ochrogaster*	PRAIRIE VOLE
000003	*Mustela putorius furo*	DOMESTIC FERRET
000006	*Oryctolagus cuniculus*	DOMESTIC RABBIT / EUROPEAN RABBIT
000008	*Ovis aries aries*	SHEEP INCLUDING ALL DOMESTIC BREEDS
000012	*Sus scrofa domestica*	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000414	**Total**	

Inspection Report

OREGON HEALTH & SCIENCE UNIVERSITY
3181 S W SAM JACKSON PARK RD., #L335
PORTLAND, OR 97239

Customer ID: **1046**
Certificate: **92-R-0001**
Site: 002
OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS

Type: FOCUSED INSPECTION
Date: 25-JAN-2021

3.80(a)(1)

Primary enclosures.

On October 26, 2020 a pair of male rhesus macaques were able to shake their paired-cage enclosure enough to knock one of the enclosures partly off the mount, creating a gap between the units. This allowed both animals to escape into the secondary enclosure, a secured animal room. The escaped animals were not injured, but five still-caged macaques housed in the same room sustained injuries – bites, lacerations, abrasions – requiring veterinary care. All have since healed without evidence of long-term impact to their welfare.

All enclosures must be structurally sound to contain the animals. While the enclosures were brand new and an upgrade from the enclosures they replaced, the large male macaques exposed a design flaw. This NCI has since been corrected by adding a bounce-limiting stabilizing bar that keeps the enclosures securely on their mounts.

3.85 **Critical**

Employees.

A January 31, 2020 incident was reported where a juvenile macaque was found trapped under a stainless-steel trough drain cover. The husbandry technician had not properly secured the drain cover after cleaning and sanitizing. The animal was returned to his social group after a few weeks of fully successful treatments for his injury.

Prepared By: GWYNN HALLBERG
USDA, APHIS, Animal Care
Date: 02-FEB-2021

Title: VETERINARY MEDICAL OFFICER

Received by Title: IACUC Representative
Date: 02-FEB-2021

Inspection Report

An August 13, 2020 incident was reported where two rhesus macaques were present in a four-unit cage when a husbandry technician put it into an automatic cage washer and started the wash cycle. The husbandry technician had mistakenly pulled the clean rack of cages holding the two monkeys from the housing room to put into the cage washer. Upon the technician's return to the housing room, the mistake was realized. The washer was immediately shut down and the cage unit removed. Veterinarians were immediately called to provide medical care, however the injuries to both animals were fatal.

A root cause analysis conducted after each of these incidents determined insufficient training and/or supervision resulted in both accidents. The NCIs were corrected prior to inspection by upgrading policies and procedures to prevent such occurrences in the future.

This inspection and exit interview were conducted with representatives from the IACUC and with veterinary staff.

Additional Inspectors:

NAOMI SISMOUR, VETERINARY MEDICAL OFFICER

Prepared By: GWYNN HALLBERG
USDA, APHIS, Animal Care
Date: 02-FEB-2021

Title: VETERINARY MEDICAL OFFICER

Received by Title: IACUC Representative
Date: 02-FEB-2021

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 25-Jan-2021

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	002	OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS	25-JAN-2021

Count	Scientific Name	Common Name
000000	NONE	NONE
000000	Total	

Inspection Report

OREGON HEALTH & SCIENCE UNIVERSITY
3181 S W SAM JACKSON PARK RD., #L335
PORTLAND, OR 97239

Customer ID: **1046**
Certificate: **92-R-0001**
Site: 001
OREGON HEALTH & SCIENCE UNIV.

Type: FOCUSED INSPECTION
Date: 15-DEC-2020

2.33(b)(3) **Critical** **Repeat**

Attending veterinarian and adequate veterinary care.

Male marmoset (841-550-025 “Hood”) was euthanized 11/11/2020 due to intracranial abscess. This was the second marmoset that was euthanized due to this problem in 2020. After the female marmoset died in January, the Department of Comparative Medicine (DCM) veterinarians worked closely with the group to improve training and technique. However, the male was noted to have scarring and abnormal bone thickness at the craniotomy site on 10/5; DCM was not contacted to examine it until 10/9. Treatment for infection was started on 10/15 after culture results were positive for infection.

Prompt reporting of veterinary problems is necessary to ensure proper diagnosis so treatment can be implemented in a timely manner.

This inspection and exit interview were conducted with IACUC and Department of Comparative Medicine personnel.

Prepared By: GWYNN HALLBERG
USDA, APHIS, Animal Care
Date: 23-DEC-2020

Title: VETERINARY MEDICAL OFFICER

Received by Title: IACUC Representative
Date: 23-DEC-2020

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 15-Dec-2020

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	001	OREGON HEALTH & SCIENCE UNIV.	15-DEC-2020

Count	Scientific Name	Common Name
000000	NONE	NONE
000000	Total	

United States Department of Agriculture
Animal and Plant Health Inspection Service

GHALLBERG
2016090000579959 Insp_id

Inspection Report

OREGON HEALTH & SCIENCE UNIVERSITY
3181 S W SAM JACKSON PARK RD., #L335
PORTLAND, OR 97239

Customer ID: **1046**
Certificate: **92-R-0001**
Site: 001
OREGON HEALTH & SCIENCE UNIV.

Type: FOCUSED INSPECTION
Date: 13-APR-2021

No non-compliant items were identified during this inspection.

This inspection and exit interview were conducted with IACUC personnel.

Prepared By: GWYNN HALLBERG
USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL OFFICER
Date: 16-APR-2021

Received by Title: IACUC Representative
Date: 16-APR-2021

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 13-Apr-2021

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	001	OREGON HEALTH & SCIENCE UNIV.	13-APR-2021

Count	Scientific Name	Common Name
000000	NONE	NONE
000000	Total	

United States Department of Agriculture
Animal and Plant Health Inspection Service

GHALLBERG
2016090000618456 Insp_id

Inspection Report

OREGON HEALTH & SCIENCE UNIVERSITY
3181 S W SAM JACKSON PARK RD., #L335
PORTLAND, OR 97239

Customer ID: **1046**
Certificate: **92-R-0001**
Site: 002
OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS

Type: ROUTINE INSPECTION
Date: 24-MAY-2021

No non-compliant items were identified during this inspection.

This inspection and exit interview were conducted with facility personnel.

Additional Inspectors:

NAOMI SISMOUR, VETERINARY MEDICAL OFFICER

Prepared By: GWYNN HALLBERG
USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL OFFICER
Date: 28-MAY-2021

Received by Title: IACUC Representative
Date: 28-MAY-2021

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 24-May-2021

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	002	OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS	24-MAY-2021

Count	Scientific Name	Common Name
000061	*Macaca fascicularis*	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000367	*Macaca fuscata*	JAPANESE MACAQUE / SNOW MACAQUE
004299	*Macaca mulatta*	RHESUS MACAQUE
000016	*Papio hamadryas*	HAMADRYAS BABOON
000006	*Papio anubis*	OLIVE BABOON
000004	*Saimiri sciureus*	COMMON SQUIRREL MONKEY
004753	**Total**	

United States Department of Agriculture
Animal and Plant Health Inspection Service

GHALLBERG
2016090000647512 Insp_id

Inspection Report

OREGON HEALTH & SCIENCE UNIVERSITY
3181 S W SAM JACKSON PARK RD., #L335
PORTLAND, OR 97239

Customer ID: **1046**
Certificate: **92-R-0001**
Site: 001
OREGON HEALTH & SCIENCE UNIV.

Type: ROUTINE INSPECTION
Date: 30-JUN-2021

No non-compliant items were identified during this inspection.

This inspection and exit interview were conducted with facility personnel.

Prepared By: GWYNN HALLBERG
USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL OFFICER
Date: 02-JUL-2021

Received by Title: IACUC Representative
Date: 02-JUL-2021

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 30-Jun-2021

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	001	OREGON HEALTH & SCIENCE UNIV.	30-JUN-2021

Count	Scientific Name	Common Name
000240	*Microtus ochrogaster*	PRAIRIE VOLE
000012	*Cavia porcellus*	DOMESTIC GUINEA PIG
000002	*Callithrix jacchus*	COMMON MARMOSET
000004	*Sus scrofa domestica*	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000042	*Meriones unguiculatus*	MONGOLIAN GERBIL (COMMON PET / RESEARCH VARIETY)
000002	*Mustela putorius furo*	DOMESTIC FERRET
000302	**Total**	

Inspection Report

Oregon Health & Science University
3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**
Certificate: **92-R-0001**
Site: 001
OREGON HEALTH & SCIENCE UNIV.

Type: ROUTINE INSPECTION
Date: 06-DEC-2021

3.129(a) **Critical**

Feeding.

An incident occurred that involved five adult Mongolian gerbils and resulted in the death of one of the animals on October 4, 2021. The animals were assigned to a study and undergoing regulated access to their daily ration to encourage them to conduct behavioral tests for food rewards. A verbal request for services by a laboratory staff member to the husbandry supervisor was not communicated to the husbandry technician responsible for feeding in the room. Consequently, five animals were not given their daily ration on October 2, 2021. The problem was identified on October 3, 2021 and the animals were immediately provided food. In addition, the veterinarian was notified and conducted a physical exam.

According to the facility, four of the five gerbils were bright and alert. One animal, however, presented as lethargic and was administered fluids by the veterinarian. The animal's condition improved and all five animals consumed their rations provided on October 3rd. On October 4th, when the veterinarian rechecked the gerbils, the same animal was again lethargic. Thermal and nutritional support were administered, but the animal died shortly after on October 4, 2021.

Animals must be given food as required to ensure their health and comfort. These animals were under an IACUC-approved protocol describing how food was to be provided and the amount of the daily ration to be given to each animal.

Prepared By: DIANE FORBES
USDA, APHIS, Animal Care
Date: 13-DEC-2021

Title: VETERINARY MEDICAL OFFICER

Received by Title: Facility Representative
Date: 13-DEC-2021

Inspection Report

The miscommunication resulted in a deviation from the protocol's requirements. The facility has enacted a corrective action plan. Correct from this time forward.

This inspection and exit interview were conducted with the facility representatives.

Prepared By: DIANE FORBES
USDA, APHIS, Animal Care

Date: 13-DEC-2021

Title: VETERINARY MEDICAL OFFICER

Received by Title: Facility Representative

Date: 13-DEC-2021

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 06-Dec-2021

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	001	OREGON HEALTH & SCIENCE UNIV.	06-DEC-2021

Count	Scientific Name	Common Name
000187	*Microtus ochrogaster*	PRAIRIE VOLE
000005	*Cavia porcellus*	DOMESTIC GUINEA PIG
000004	*Sus scrofa domestica*	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000028	*Meriones unguiculatus*	MONGOLIAN GERBIL (COMMON PET / RESEARCH VARIETY)
000002	*Mustela putorius furo*	DOMESTIC FERRET
000008	*Ovis aries aries*	SHEEP INCLUDING ALL DOMESTIC BREEDS
000234	**Total**	

Inspection Report

Oregon Health & Science University
3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**
Certificate: **92-R-0001**
Site: 002
OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS

Type: ROUTINE INSPECTION
Date: 08-FEB-2022

3.80(a)(1) **Critical**

Primary enclosures.

On October 15, 2021, two male rhesus macaques in adjacent cages were injured when a pin in the separating slide mechanism failed. This allowed the slide to open, and the macaques had direct access to each other. The macaques fought and injured each other, requiring veterinary care. They were treated for lacerations and abrasions. One macaque fully recovered in seven days. The other required clinical treatment for an additional week and is still receiving physical therapy with good results. Full recovery is expected.

All enclosures must be structurally sound to contain the animals and protect them from injury.

This was corrected prior to the time of inspection by immediately removing the affected cage from service. The point of structural failure was identified. Correction was made. All the joints like the one where the pin failed were welded on all cages known to have this mechanism to prevent similar failure. The manufacturer was contacted to find out if other onsite caging purchased from them might have the same mechanism that would also need to be addressed.

This inspection and exit interview were conducted with facility personnel.

Prepared By: GWYNN HALLBERG
USDA, APHIS, Animal Care
Date: 11-FEB-2022

Title: VETERINARY MEDICAL OFFICER

Received by Title: IACUC Representative
Date: 11-FEB-2022

Inspection Report

Additional Inspectors:

NAOMI SISMOUR, VETERINARY MEDICAL OFFICER

Prepared By: GWYNN HALLBERG
USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER

Date: 11-FEB-2022

Received by Title: IACUC Representative

Date: 11-FEB-2022

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 08-Feb-2022

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	002	OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS	08-FEB-2022

Count	Scientific Name	Common Name
000056	*Macaca fascicularis*	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000333	*Macaca fuscata*	JAPANESE MACAQUE / SNOW MACAQUE
004282	*Macaca mulatta*	RHESUS MACAQUE
000013	*Papio hamadryas*	HAMADRYAS BABOON
000005	*Papio anubis*	OLIVE BABOON
000004	*Saimiri sciureus*	COMMON SQUIRREL MONKEY
004693	**Total**	

United States Department of Agriculture
Animal and Plant Health Inspection Service

GHALLBERG
INS-0000824105

Inspection Report

Oregon Health & Science University

3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**

Certificate: **92-R-0001**

Site: 002
OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS

Type: ROUTINE INSPECTION

Date: 17-OCT-2022

No non-compliant items were identified during this inspection.

This inspection and exit interview were conducted with facility personnel.

Additional Inspectors:

SCOTT WELCH, VETERINARY MEDICAL OFFICER

Prepared By: GWYNN HALLBERG
USDA, APHIS, Animal Care

Date: 19-OCT-2022

Title: VETERINARY MEDICAL OFFICER

Received by Title: IACUC Representative

Date: 19-OCT-2022

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 17-Oct-2022

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	002	OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS	17-OCT-2022

Count	Scientific Name	Common Name
000051	*Macaca fascicularis*	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000343	*Macaca fuscata*	JAPANESE MACAQUE / SNOW MACAQUE
004266	*Macaca mulatta*	RHESUS MACAQUE
000007	*Papio hamadryas*	HAMADRYAS BABOON
000008	*Papio anubis*	OLIVE BABOON
000004	*Saimiri sciureus*	COMMON SQUIRREL MONKEY
004679	**Total**	

United States Department of Agriculture
Animal and Plant Health Inspection Service

DFORBES
INS-0000874365

Inspection Report

Oregon Health and Science University

3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**

Certificate: **92-R-0001**

Site: 001
OREGON HEALTH & SCIENCE UNIV.

Type: ROUTINE INSPECTION

Date: 13-JUN-2023

No non-compliant items identified during this inspection.

This inspection and exit interview were conducted with the facility representatives.

Prepared By: DIANE FORBES
USDA, APHIS, Animal Care

Date: 14-JUN-2023

Title: VETERINARY MEDICAL OFFICER

Received by Title: IACUC Representative

Date: 14-JUN-2023

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 13-Jun-2023

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	001	OREGON HEALTH & SCIENCE UNIV.	13-JUN-2023

Count	Scientific Name	Common Name
000012	*Cavia porcellus*	DOMESTIC GUINEA PIG
000005	*Sus scrofa domestica*	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000008	*Meriones unguiculatus*	MONGOLIAN GERBIL (COMMON PET / RESEARCH VARIETY)
000002	*Mustela putorius furo*	DOMESTIC FERRET
000003	*Ovis aries aries*	SHEEP INCLUDING ALL DOMESTIC BREEDS
000030	**Total**	

United States Department of Agriculture
Animal and Plant Health Inspection Service

DFORBES
INS-0000881177

Inspection Report

Oregon Health and Science University
3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**
Certificate: **92-R-0001**
Site: 002
OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS

Type: FOCUSED INSPECTION
Date: 19-JUL-2023

2.38(f)(1) **Critical**

Miscellaneous.

A 2-day-old male rhesus macaque sustained an accidental injury and was euthanized on 4 May 2023. According to the research facility, the infant macaque was injured by a sliding door as technicians were attempting to capture the mother and baby. Technicians were trying to direct the pair into a transfer box which was holding up the sliding door; however, the female macaque charged the box, the door fell, and the infant was injured. The animal was immediately transported to the veterinary hospital where it was diagnosed with an untreatable spinal/shoulder injury and was euthanized.

Handling of all animals shall be done as expeditiously and carefully as possible in a manner that does not cause trauma, behavioral stress, physical harm, or unnecessary discomfort.

Corrected prior to the inspection.

This inspection and exit interview were conducted with the facility representatives.

Additional Inspectors:

ANN GOPLEN, VETERINARY MEDICAL OFFICER

Ashley Alger

Prepared By: DIANE FORBES
USDA, APHIS, Animal Care
Date: 28-JUL-2023

Title: VETERINARY MEDICAL OFFICER

Received by Title: IACUC Representative
Date: 28-JUL-2023

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 19-Jul-2023

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	002	OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS	19-JUL-2023

Count	Scientific Name	Common Name
000000	NONE	NONE
000000	Total	

United States Department of Agriculture
Animal and Plant Health Inspection Service

DFORBES
INS-0000896382

Inspection Report

Oregon Health and Science University

3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**

Certificate: **92-R-0001**

Site: 002
OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS

Type: FOCUSED INSPECTION

Date: 27-SEP-2023

No non-compliant items identified during this inspection.

This inspection and exit interview were conducted with the facility representatives.

Prepared By: DIANE FORBES
USDA, APHIS, Animal Care

Date: 29-SEP-2023

Title: VETERINARY MEDICAL OFFICER

Received by Title: IACUC Representative

Date: 29-SEP-2023

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 27-Sep-2023

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	002	OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS	27-SEP-2023

Count	Scientific Name	Common Name
000000	NONE	NONE
000000	Total	

United States Department of Agriculture
Animal and Plant Health Inspection Service

DFORBES
INS-0000912235

Inspection Report

Oregon Health and Science University

3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**

Certificate: **92-R-0001**

Site: 002
OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS

Type: ROUTINE INSPECTION

Date: 11-DEC-2023

No non-compliant items identified during this inspection.

This inspection and exit interview were conducted with the facility representatives.

Additional Inspectors:

Eduardo Vivas, VETERINARY MEDICAL OFFICER

Prepared By: DIANE FORBES
USDA, APHIS, Animal Care

Date: 13-DEC-2023

Title: VETERINARY MEDICAL OFFICER

Received by Title: IACUC Representative

Date: 13-DEC-2023

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 11-Dec-2023

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	002	OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS	11-DEC-2023

Count	Scientific Name	Common Name
000063	*Macaca fascicularis*	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000355	*Macaca fuscata*	JAPANESE MACAQUE / SNOW MACAQUE
004359	*Macaca mulatta*	RHESUS MACAQUE
000012	*Papio hamadryas*	HAMADRYAS BABOON
000008	*Papio anubis*	OLIVE BABOON
000004	*Saimiri sciureus*	COMMON SQUIRREL MONKEY
004801	**Total**	

United States Department of Agriculture
Animal and Plant Health Inspection Service

DFORBES
INS-0001004477

Inspection Report

Oregon Health and Science University

3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**

Certificate: **92-R-0001**

Site: 002
OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS

Type: FOCUSED INSPECTION

Date: 14-MAY-2024

No non-compliant items identified during this inspection.

This inspection and exit interview were conducted with the facility representatives.

Prepared By: DIANE FORBES
USDA, APHIS, Animal Care

Date: 15-MAY-2024

Title: VETERINARY MEDICAL OFFICER

Received by Title: IACUC Representative

Date: 15-MAY-2024

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 14-May-2024

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	002	OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS	14-MAY-2024

Count	Scientific Name	Common Name
000000	NONE	NONE
000000	Total	

United States Department of Agriculture
Animal and Plant Health Inspection Service

DFORBES
INS-0001005610

Inspection Report

Oregon Health and Science University

3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**

Certificate: **92-R-0001**

Site: 001
OREGON HEALTH & SCIENCE UNIV.

Type: ROUTINE INSPECTION

Date: 15-MAY-2024

No non-compliant items identified during this inspection.

This inspection and exit interview were conducted with the facility representatives.

Prepared By: DIANE FORBES
USDA, APHIS, Animal Care

Date: 16-MAY-2024

Title: VETERINARY MEDICAL OFFICER

Received by Title: IACUC Representative

Date: 16-MAY-2024

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 15-May-2024

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	001	OREGON HEALTH & SCIENCE UNIV.	15-MAY-2024

Count	Scientific Name	Common Name
000007	*Sus scrofa domestica*	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000036	*Meriones unguiculatus*	MONGOLIAN GERBIL (COMMON PET / RESEARCH VARIETY)
000009	*Mustela putorius furo*	DOMESTIC FERRET
000052	**Total**	

United States Department of Agriculture
Animal and Plant Health Inspection Service

DFORBES
INS-0001228646

Inspection Report

Oregon Health and Science University

3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**

Certificate: **92-R-0001**

Site: 002
OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS

Type: ROUTINE INSPECTION

Date: 15-OCT-2024

2.38(f)(1)

Miscellaneous.

On July 12, 2024, an 8-year-old male rhesus macaque was injured following an unintended interaction with another adult macaque that escaped during a cage transfer. The animal was treated for a laceration on the palm of the left hand. Handling of nonhuman primates shall be done as carefully as possible in a manner that does not cause trauma, behavioral stress, physical harm, or unnecessary discomfort. The research facility must ensure that all animals are protected from harm and distress.
Corrected prior to inspection on October 15, 2024

3.80(a)(2)(iv)

Primary enclosures.

On January 28, 2024, an 18-year-old male rhesus macaque sustained lacerations to the head and base of the right ear when a mesh slide was pushed out, which then allowed unintended direct contact with a single male macaque in an adjoining enclosure. One of the primates was able to push the mesh slide between the enclosures, allowing unwanted contact between the macaques causing distress and injury in this animal. Primary enclosures must be constructed and maintained so that they keep other unwanted animals from entering the enclosure or having physical contact with the nonhuman primates. The research facility must ensure the enclosures protect the animals from injury and distress.
Corrected prior to inspection on October 15, 2024

This inspection and exit interview were conducted with facility representatives.

Additional Inspectors:

Darren Rausch, VETERINARY MEDICAL OFFICER

Prepared By: DIANE FORBES
USDA, APHIS, Animal Care

Date: 23-JAN-2025

Title: VETERINARY MEDICAL OFFICER

Received by Title: Facility Representative

Date: 23-JAN-2025

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 15-Oct-2024

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	002	OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS	15-OCT-2024

Count	Scientific Name	Common Name
000053	*Macaca fascicularis*	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000358	*Macaca fuscata*	JAPANESE MACAQUE / SNOW MACAQUE
004270	*Macaca mulatta*	RHESUS MACAQUE
000011	*Papio hamadryas*	HAMADRYAS BABOON
000007	*Papio anubis*	OLIVE BABOON
000004	*Saimiri sciureus*	COMMON SQUIRREL MONKEY
004703	**Total**	

Inspection Report

Oregon Health and Science University

3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**

Certificate: **92-R-0001**

Site: 001
OREGON HEALTH & SCIENCE UNIV.

Type: ROUTINE INSPECTION

Date: 07-NOV-2024

2.32(c)(1)(iii) **Critical**

Personnel qualifications.

On June 24, 2024, the facility self-reported an incident where, during anesthesia on a young adult ferret ("438073F"), the pop-off valve was inadvertently closed resulting in the death of the ferret. At inspection the anesthesia monitoring form for "438073F " was reviewed and confirmed the pop-off valve was accidentally closed. The problem was recognized, corrected, and immediate resuscitation attempts were unsuccessful. Necropsy results identified a ruptured airway and subsequent lung collapse. In response to this event, the facility has updated anesthesia machines and provided retraining on team roles to prevent reoccurrence.
Adherence to established procedural role delineation and oversight, including anesthesia, is essential to ensure animal health and well-being. It is the responsibility of the research facility to provide training and instruction to ensure personnel involved in animal care, treatment, and use understand their role and are qualified to perform their duties. Previously corrected before inspection 07NOV2024.

This inspection and exit interview were conducted with facility representatives.

Prepared By: DARREN RAUSCH
USDA, APHIS, Animal Care

Date: 10-JAN-2025

Title: VETERINARY MEDICAL OFFICER

Received by Title: Facility Representative

Date: 10-JAN-2025

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 07-Nov-2024

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	001	OREGON HEALTH & SCIENCE UNIV.	07-NOV-2024

Count	Scientific Name	Common Name
000023	*Meriones unguiculatus*	MONGOLIAN GERBIL
000005	*Mustela putorius furo*	DOMESTIC FERRET
000002	*Cavia porcellus*	DOMESTIC GUINEA PIG
000005	*Ovis aries aries*	SHEEP INCLUDING ALL DOMESTIC BREEDS
000035	**Total**	

Inspection Report

Oregon Health and Science University

3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**

Certificate: **92-R-0001**

Site: 002
OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS

Type: ROUTINE INSPECTION

Date: 04-MAR-2025

2.33(b)(3) **Critical**

Attending veterinarian and adequate veterinary care.

On October 1, 2024 a 4 year old female Japanese macaque held in paired housing in a catch area was observed by a technician to be lying down multiple times, but this behavior was not reported to veterinarians. On 2 October, 2024, she was found deceased in the enclosure in the morning with swollen arms and stifles noted. The resulting necropsy indicated sepsis due to underlying bacterial skin infection. The failure to report unexpected signs of illness/distress such as repeatedly lying down to ensure timely delivery of veterinary medical care directly impacted the welfare of this animal. While the facility conducted daily observations of all animals to assess their health and well-being, in this case there was a failure of direct and frequent communication to ensure that timely and accurate information on problems of animal health, behavior and well-being are conveyed to the attending veterinarian.

Corrected prior to inspection on 4 March, 2025

3.75(c)(2)

Housing facilities, general.

Surfaces of the non-human primate housing facilities require maintenance, and animals in the enclosures have access to these surfaces. They include:
• Catch #1 has a section of rusted metal pipe along the base of this indoor group enclosure. Irregularly shaped holes with sharp jagged edges are observed through the metal sheathing covering an animal access door in the same enclosure.
• Catch #3 has chipping paint along the base of the wall exposing concrete rendering this area difficult to effectively clean and sanitize.

Specifically in the Rhesus Macaque Shelter housing area, there are:
• Cracking and chipped off paint and marine board exposing concrete observed in units 5, 9, 13, 14, 19, 20, 21, 22, 23, 24, and 25. Rust on metal surfaces in unit 6 under the licks-it on metal drain cover and metal flashing of unit 12 cannot be readily cleaned and sanitized.
• In several shelter units there are sections of marine board covering walls which have either deep grooved irregular surfaces, frayed jagged edges, or missing rivets leaving open holes making these areas impossible to effectively sanitize and protect the animals from potential injury.

Prepared By: KATHARINE FRANK
USDA, APHIS, Animal Care

Date: 14-MAR-2025

Title: VETERINARY MEDICAL OFFICER

Received by Title: Facility Representative

Date: 14-MAR-2025

Inspection Report

Surfaces in non-human primate housing facilities require regular maintenance to keep them in good repair, to allow them to be readily cleaned and sanitized and to protect the animals from injury. All surfaces of non-human primate housing facilities must be maintained on a regular basis. Surfaces that cannot be readily cleaned and sanitized must be replaced when worn or soiled.

Correct by 15 August 2025.

3.75(e)

Housing facilities, general.

In several nonhuman primate kitchen areas, there were substances such as bleach, glass/stainless steel cleaner and other cleaning or sanitizing agents stored openly. Supplies of food must be stored in a manner that protects the supplies from contamination. Substances that are toxic to the nonhuman primates but that are required for normal husbandry practices must not be stored in food storage and preparation areas, but may be stored in cabinets in animal areas.

Corrected during inspection.

3.80(b)(1)

Primary enclosures.

During inspection, the facility was in the middle of processing the field corral of Japanese macaques and brought them into sheltered catch facilities (2/8) on Monday and the animals were maintained in those enclosures until released as a group on Friday. Facilities in Catch 8 include a variety of wall mounted enclosures, with a mix of 4.5, 5.7 and 6 feet of floor space per enclosure. Inspectors noticed that several animals appeared to be too large for the enclosures they were housed in based on the handwritten weights on masking tape on the front of the enclosure. In Catch 8, thirty eight enclosures housing Japanese macaques did not meet space requirements for the weights of the animals housed therein, based on facility data collected during processing and the cage sizes. Additional animals fell under exemptions for pregnancy or obesity (BCS >4), but 38/169 of the animals in catch 8 were housed in enclosures not meeting minimum space requirements for approximately 96 hours. Each Japanese macaque must have at a minimum the floorspace correlated to their weight according to table (b)(1): 3-10 Kgs requires 4.3 feet of floorspace, 10-15 kgs requires 6.0 feet of floorspace and 15-25 kgs requires 8.0 feet of floorspace. A majority of the group was released on Friday, and any individuals held into the next week were held in enclosures meeting their minimum space requirements.

Current situation was corrected by the end of inspection on 7 March 2025, future roundups should provide minimum space requirements for all Japanese macaques.

This inspection and exit interview were conducted with the veterinary staff.

Prepared By: KATHARINE FRANK
USDA, APHIS, Animal Care
Date: 14-MAR-2025

Title: VETERINARY MEDICAL OFFICER

Received by Title: Facility Representative
Date: 14-MAR-2025

Inspection Report

Additional Inspectors:

Darren Rausch, VETERINARY MEDICAL OFFICER

Prepared By: KATHARINE FRANK
USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER

Date: 14-MAR-2025

Received by Title: Facility Representative

Date: 14-MAR-2025

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046
Inspection Date: 04-Mar-2025

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1046	92-R-0001	002	OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS	04-MAR-2025

Count	Scientific Name	Common Name
000048	*Macaca fascicularis*	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000349	*Macaca fuscata*	JAPANESE MACAQUE / SNOW MACAQUE
004162	*Macaca mulatta*	RHESUS MACAQUE
000008	*Papio hamadryas*	HAMADRYAS BABOON
000006	*Papio anubis*	OLIVE BABOON
000003	*Saimiri sciureus*	COMMON SQUIRREL MONKEY
004576	**Total**	

Oregon Health & Science University
3181 SW Sam Jackson Park RD, #L335
Portland, OR 97239

CITATION AND NOTIFICATION OF PENALTY

We believe that you violated the Animal Welfare Act (7 U.S.C. § 2131 et seq.) (AWA), as described below.

Date of Alleged Violation: February 5, 2018 (Site 002)

9 C.F.R. § 2.38(f)(1) Handling.
Handling of all animals shall be done as expeditiously and carefully as possible in a manner that does not cause trauma, overheating, excessive cooling, behavioral stress, physical harm, or unnecessary discomfort.

Oregon Health & Science University (OHSU) personnel failed to handle animals as expeditiously and carefully as possible in a manner that does not cause trauma, overheating, excessive cooling, behavioral stress, physical harm, or unnecessary discomfort.

A nonhuman primate being transferred between enclosures had its tail caught in a gap between the enclosures. The degloving injury to the animal's tail was treated by amputation.

During a group release, a juvenile animal was able to move behind the wall-hung cages where the animal became entrapped and died.

Date of Alleged Violation: May 6, 2018 (Site 002)

9 C.F.R. § 3.80(a)(2)(ii) Primary enclosures. General requirements.
(2) Primary enclosures must be constructed and maintained so that they:
(ii) Protect the nonhuman primates from injury;

OHSU failed to construct and maintain enclosures to protect nonhuman primates from injury.

A young nonhuman primate was found constrained by the PVC pipes of a resting perch. OHSU personnel freed the animal and immediately sought treatment by the veterinarian. The nonhuman primate responded to initial treatment, but later developed neurological symptoms. The animal was euthanized after a follow-up veterinary evaluation.

Date of Alleged Violation: July 19, 2018 (Site 001)

9 C.F.R. § 2.32(c)(3) Personnel qualifications.
(c) Training and instruction of personnel must include guidance in at least the following areas:
Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility;

OHSU failed to train and instruct personnel in the proper use of anesthetics, analgesics, and tranquilizers.

A primary investigator performed inadequate post-procedure anesthetic monitoring for two guinea pigs. Both guinea pigs died.

Date of Alleged Violation: June 3, 2019 (Site 001)

9 C.F.R. § 2.33(b)(2) Attending Veterinarian and adequate veterinary care.
(b) Each research facility shall establish and maintain programs of adequate veterinary care that include:
(2) The use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care;

OSHU failed to use appropriate methods to prevent, control, diagnose, and treat diseases and injuries.

APHIS officials observed containers of dressing supplies used for ferret cap care on a bench. The containers that held gauze for cleaning and non-stick pads for dressing the caps were dirty, with large areas of corrosion and unable to be cleaned and disinfected.

Date of Alleged Violation: June 3, 2019 (Site 001)

9 C.F.R. § 2.33(b)(3) Attending veterinarian and adequate veterinary care.
(b) Each research facility shall establish and maintain programs of adequate veterinary care that include:
(3) Daily observation of all animals to assess their health and well-being; Provided, however, that daily observation of animals may be accomplished by someone other than the Attending Veterinarian; and provided, further, that a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the Attending Veterinarian;

OSHU failed to conduct daily observations of animals and provide timely communication of problems with animal health, behavior, and well-being to the Attending Veterinarian.

APHIS officials observed two ferrets assigned to protocol IPO1561 with symptoms that had not been reported to the Attending

Veterinarian. One ferret (#100951) had a strong, foul odor and crusty exudate around the cap margins. A second ferret (#270877B) was observed rubbing its head cap, a symptom that should have triggered the protocol requirement to notify the Department of Comparative Medicine (DCM). Neither the Attending Veterinarian nor DCM veterinarians were notified about either ferret. After notifying the veterinarians, both ferrets immediately received an examination and treatment was initiated.

Date of Alleged Violation: December 21, 2019 (Site 001)

9 C.F.R. § 2.33(b)(3) Attending veterinarian and adequate veterinary care.
(b) Each research facility shall establish and maintain programs of adequate veterinary care that include:
(3) Daily observation of all animals to assess their health and well-being; Provided, however, That daily observation of animals may be accomplished by someone other than the attending veterinarian; and Provided, further, That a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian;

OSHU failed to conduct daily observations of animals to assess their health and well-being.

OSHU personnel failed to complete cage change and water bottle replacement for a section of prairie voles. The following day four prairie voles were found deceased. A fifth prairie vole was found moribund and was later euthanized. Due to the lack of that day's observation of those animals, their water ran out, resulting in dehydration and death.

Date of Alleged Violation: January 21, 2020 (Site 001)

9 C.F.R. § 2.32(c)(1)(iv) Personnel qualifications.
(c) Training and instruction of personnel must include guidance in at least the following areas:
(1) Humane methods of animal maintenance and experimentation, including:
(iv) Aseptic surgical methods and procedures;

OSHU failed to train and instruct personnel in proper aseptic surgical methods and procedures.

At the time of inspection, a ferret was undergoing a major operative procedure. APHIS officials observed OSHU personnel breach sterility by neglecting to maintain sterile fields for the duration of the procedure. During the procedure, the lab coat of the OSHU personnel breached the sterile field by touching the sterile

instruments located on a table behind him while the animal's body cavity remained open.

Date of Alleged Violation: January 31, 2020 (Site 002)

9 C.F.R. § 3.85 Employees.
Every person subject to the Animal Welfare regulations (9 CFR parts 1, 2, and 3) maintaining nonhuman primates must have enough employees to carry out the level of husbandry practices and care required in this subpart. The employees who provide husbandry practices and care, or handle nonhuman primates, must be trained and supervised by an individual who has the knowledge, background, and experience in proper husbandry and care of nonhuman primates to supervise others. The employer must be certain that the supervisor can perform to these standards.

OSHU failed to train and supervise an employee performing husbandry practices and care or handling of nonhuman primates.

A juvenile macaque was found trapped under a stainless steel trough drain cover that was not properly secured after cleaning and sanitizing.

Date of Alleged Violation: August 13, 2020 (Site 002)

9 C.F.R. § 3.85 Employees.
Every person subject to the Animal Welfare regulations (9 CFR parts 1, 2, and 3) maintaining nonhuman primates must have enough employees to carry out the level of husbandry practices and care required in this subpart. The employees who provide husbandry practices and care, or handle nonhuman primates, must be trained and supervised by an individual who has the knowledge, background, and experience in proper husbandry and care of nonhuman primates to supervise others. The employer must be certain that the supervisor can perform to these standards.

OSHU failed to train and supervise an employee that performed husbandry practices and care or handling of nonhuman primates.

Two rhesus macaques were in a four-unit cage when a husbandry technician put the cage into an automatic cage washer and started the wash cycle. One macaque died and the other was euthanized due to their injuries.

Date of Alleged Violation: October 5, 2020 (Site 001)

9 C.F.R. § 2.33(b)(3) Attending veterinarian and adequate veterinary care.
(b) Each research facility shall establish and maintain programs of adequate veterinary care that include:
(3) Daily observation of all animals to assess their health and well-being;

Provided, however, That daily observation of animals may be accomplished by someone other than the attending veterinarian; and Provided, further, That a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian;

OSHU failed to provide timely communication of problems with animal health, behavior, and well-being to the veterinarian.

A male marmoset ("Hood", No. 841-5550-025) was euthanized on November 11, 2020. On October 5, 2020, personnel noted that the animal had scarring and abnormal bone thickness at its craniotomy site, but did not request that a veterinarian examine the animal until October 9, 2020. On October 15, 2020, after culture results showed an infection, the animal began receiving treatment. Due to delayed medical treatment, the animal was euthanized due to intracranial abscess.

In January 2020, a female marmoset was euthanized due to the same complications following craniotomy surgery.

Date of Alleged Violation: October 2, 2021 (Site 001)

9 C.F.R. § 3.129(a) Feeding.
(a) The food shall be wholesome, palatable, and free from contamination and of sufficient quantity and nutritive value to maintain all animals in good health. The diet shall be prepared with consideration for the age, species, condition, size, and type of the animal. Animals shall be fed at least once a day except as dictated by hibernation, veterinary treatment, normal fasts, or other professionally accepted practices.

OSHU failed to feed gerbils at least once a day except as dictated by hibernation, veterinary treatment, normal fasts, or other professionally accepted practices.

On October 2, 2021, five Mongolian gerbils were not given their daily ration. The next day, OSHU personnel identified the issue and notified the veterinarian. Despite feeding and treatment by the veterinarian, one of the five gerbils died on October 4, 2021.

Date of Alleged Violation: October 15, 2021 (Site 002)

9 C.F.R. § 3.80(a)(1) Primary enclosures.
Primary enclosures for nonhuman primates must meet the following minimum requirements:
(a) General requirements.
(1) Primary enclosures must be designed and constructed of suitable materials

so that they are structurally sound for the species of nonhuman primates contained in them. They must be kept in good repair.

OSHU failed to ensure that enclosures were constructed of suitable materials, maintained in good repair, and structurally sound for the species of nonhuman primates contained in them.

The pin in the slide mechanism of adjacent cages of two male rhesus macaques failed. The animals had direct access to each other, fought and injured each other. The animals were treated for lacerations and abrasions.

The penalty for the alleged violation(s) described above is $37,900.

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE	**CASE NUMBER:** OR240001
	ALLEGED VIOLATOR: Oregon Health and Science University
	ADDRESS (*City, State, ZIP Code*)**:** Portland, OR 97239

OFFICIAL WARNING
NOTICE OF ALLEGED VIOLATION

The U.S. Department of Agriculture has evidence that on or about the date(s) listed below, you or your organization committed the following alleged violation(s) of Federal laws:

Date of Alleged Violation: July 19, 2023

9 C.F.R. § 2.38(f)(1) Miscellaneous.

Handling.

Handling of all animals shall be done as expeditiously and carefully as possible in a manner that does not cause trauma, overheating, excessive cooling, behavioral stress, physical harm, or unnecessary discomfort.

The Animal and Plant Health Inspection Service (APHIS) published federal regulations to ensure the welfare of animals and help prevent the spread of animal and plant pests and diseases. Since violations of the regulations can have serious and costly impacts that are detrimental to the public interest, APHIS is providing you with an Official Warning for the alleged violation(s) described above. This Official Warning is not to be construed as a final agency action, or as an adjudicated finding of a violation. If APHIS obtains evidence of any future violation of these federal regulations, APHIS may pursue civil penalties, criminal prosecution, or other sanctions for this alleged violation(s) and for any future violation(s). If you have any questions concerning this Official Warning or alleged violation(s), please contact the APHIS official listed in this notice.

APHIS OFFICIAL (*Name)*:	**OFFICE ADDRESS:**	
Dr. Roxanne Mullaney, D.V.M.	4700 River Road, Unit 84 Riverdale, MD 20737	
APHIS OFFICIAL (*Title)*:	**DATE ISSUED:**	**TELEPHONE NUMBER:**
Deputy Administrator, APHIS, Animal Care	October 12, 2023	(970) 494-7478

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE	**CASE NUMBER:** OR250003
	ALLEGED VIOLATOR: Oregon Health and Science University
	ADDRESS (*City, State, ZIP Code*)**:** Portland, OR 97239

OFFICIAL WARNING
NOTICE OF ALLEGED VIOLATION

The U.S. Department of Agriculture has evidence that on or about the date(s) listed below, you or your organization committed the following alleged violation(s) of Federal laws:

Date of Alleged Violation: November 7, 2024

9 C.F.R. § 2.32(c)(1)(iii) Personnel qualifications.

Training and instruction of personnel must include guidance in at least the following areas:

Humane methods of animal maintenance and experimentation, including:

Proper pre-procedural and post-procedural care of animals.

Date of Alleged Violation: March 4, 2025

9 C.F.R. § 2.33(b)(3) Attending veterinarian and adequate veterinary care.

Each research facility shall establish and maintain programs of adequate veterinary care that includes:

Daily observation of all animals to assess their health and well-being; Provided, however, That daily observation of animals may be accomplished by someone other than the attending veterinarian; and Provided, further, That a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian.

The Animal and Plant Health Inspection Service (APHIS) published federal regulations to ensure the welfare of animals and help prevent the spread of animal and plant pests and diseases. Since violations of the regulations can have serious and costly impacts that are detrimental to the public interest, APHIS is providing you with an Official Warning for the alleged violation(s) described above. This Official Warning is not to be construed as a final agency action, or as an adjudicated finding of a violation. If APHIS obtains evidence of any future violation of these federal regulations, APHIS may pursue sanctions, which may include criminal prosecution, for this alleged violation(s) and for any future violation(s). If you have any questions concerning this Official Warning or alleged violation(s), please contact the APHIS official listed in this notice.

APHIS OFFICIAL (*Name)*:	**OFFICE ADDRESS:**	
Sarah Helming	4700 River Road, Unit 84 Riverdale, MD 20737	
APHIS OFFICIAL (*Title)*:	**DATE ISSUED:**	**TELEPHONE NUMBER:**
Deputy Administrator, APHIS, Animal Care	April 17, 2025	(970) 494-7478

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year: 2023

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

REGISTRATION NUMBER: 92-R-0001

Customer Number: 1046

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include ZIP Code)*

Oregon Health and Science University
3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239
Telephone: 5034941085

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY*(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	**B.** Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes	**C.** Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	**D.** Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	**E.** Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	**F.** TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4 Dogs	0	0	6	0	6
5 Cats	0	0	0	0	0
6 Guinea Pigs	0	0	69	0	69
7 Hamsters	0	0	0	0	0
8 Rabbits	0	0	1	0	1
9 Non-Human Primates	4117	416	870	0	1286
10 Sheep	0	0	59	0	59
11 Pigs	0	0	84	0	84
12 Other Animals	0	0	70	0	70
Prairie vole	0	0	36	0	36
Mongolian gerbil	0	0	10	0	10
Domestic Ferret	0	0	24	0	24

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.)) I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

Date Signed
14-Dec-2023

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year: 2021

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

REGISTRATION NUMBER: 92-R-0001

Customer Number: 1046

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include ZIP Code)*

Oregon Health & Science University
3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239
Telephone: 5034941085

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY*(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	**B.** Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes	**C.** Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	**D.** Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	**E.** Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	**F.** TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4 Dogs	0	0	9	0	9
5 Cats	0	0	0	0	0
6 Guinea Pigs	0	0	22	0	22
7 Hamsters	0	0	0	0	0
8 Rabbits	0	0	2	0	2
9 Non-Human Primates	4278	400	982	0	1382
10 Sheep	0	0	136	0	136
11 Pigs	0	0	154	0	154
12 Other Animals	0	0	121	0	121
Domestic Ferret	0	0	24	0	24
Prairie vole	0	0	97	0	97

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.)) I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

Date Signed
28-Oct-2021

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year: 2020

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

REGISTRATION NUMBER: 92-R-0001

Customer Number: 1046

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include ZIP Code)*

OREGON HEALTH & SCIENCE UNIVERSITY
3181 S W SAM JACKSON PARK RD., #L335
PORTLAND, OR 97239
Telephone: 5034941085

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY*(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	**B.** Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes	**C.** Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	**D.** Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	**E.** Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	**F.** TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4 Dogs	0	0	15	0	15
5 Cats	0	0	0	0	0
6 Guinea Pigs	0	0	119	0	119
7 Hamsters	0	0	0	0	0
8 Rabbits	0	0	6	0	6
9 Non-Human Primates	4439	787	894	0	1681
10 Sheep	0	0	131	0	131
11 Pigs	0	0	145	0	145
12 Other Animals	0	0	145	0	145
Domestic Ferret	0	0	29	0	29
Mongolian gerbil	0	0	22	0	22
Vole	0	0	94	0	94

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.)) I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

Date Signed
06-Nov-2020

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year: 2019

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

REGISTRATION NUMBER: 92-R-0001

Customer Number: 1046

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include ZIP Code)*

OREGON HEALTH & SCIENCE UNIVERSITY
3181 S W SAM JACKSON PARK RD., #L335
PORTLAND, OR 97239
Telephone: 5034941085

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY*(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	**B.** Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes	**C.** Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	**D.** Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	**E.** Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	**F.** TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4 Dogs	0	0	0	0	0
5 Cats	0	0	0	0	0
6 Guinea Pigs	8	0	219	0	219
7 Hamsters	0	0	0	0	0
8 Rabbits	0	0	19	0	19
9 Non-Human Primates	4225	1325	885	0	2210
10 Sheep	0	0	34	0	34
11 Pigs	0	0	203	0	203
12 Other Animals	0	0	348	0	348
Domestic Ferret	0	0	2	0	2
Gerbil	0	0	6	0	6
Prairie vole	0	0	319	0	319
Ground Squirrels	0	0	21	0	21

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.)) I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

Date Signed
27-Nov-2019

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year: 2018

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

REGISTRATION NUMBER: 92-R-0001

Customer Number: 1046

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include ZIP Code)*

OREGON HEALTH & SCIENCE UNIVERSITY
3181 S W SAM JACKSON PARK RD., #L335
PORTLAND, OR 97239
Telephone: 5034941085

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY*(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	**B.** Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes	**C.** Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	**D.** Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	**E.** Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	**F.** TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
Pigs	0	0	228	0	228
Dogs	0	0	10	0	10
Guinea Pigs	12	0	348	0	348
Rabbits	0	0	60	0	60
Non-Human Primates	1357	3629	1281	0	4910
Sheep	0	0	96	0	96
Ferrets	0	0	4	0	4
GERBILS	0	0	42	0	42

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.)) I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

Date Signed

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2017

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
92-R-0001

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

OREGON HEALTH & SCIENCE UNIVERSITY
3181 S W SAM JACKSON PARK RD., #L335

PORTLAND, OR 97239

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

[redacted]

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	2	0	2
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	280	0	280
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	64	0	64
9. Non-human Primates	437	4400	1138	0	5538
10. Sheep	0	0	87	0	87
11. Pigs	0	0	347	0	347
12. Other Farm Animals					
13. Other Animals	0	0	103	0	103

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

[redacted]

DATE SIGNED
31-JAN-2018

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2017

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
92-R-0001

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

OREGON HEALTH & SCIENCE UNIVERSITY
3181 S W SAM JACKSON PARK RD., #L335

PORTLAND, OR 97239

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
FERRETS	0	0	3	0	3
GERBILS	0	0	100	0	100

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

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4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(*Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.)*)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

[redacted]

DATE SIGNED
31-JAN-2018

APHIS FORM 7023A
AUG 2013

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2016

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
92-R-0001

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

OREGON HEALTH & SCIENCE UNIVERSITY
3181 S W SAM JACKSON PARK RD., #L335

PORTLAND, OR 97239

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

[redacted]

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	32	0	32
5. Cats	0	0	2	0	2
6. Guinea Pigs	4	0	345	0	345
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	188	0	188
9. Non-human Primates	2792	30	2093	0	2123
10. Sheep	0	0	105	0	105
11. Pigs	0	0	131	0	131
12. Other Farm Animals					
13. Other Animals	0	0	24	0	24

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

[redacted]

DATE SIGNED
13-FEB-2017

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2016

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
92-R-0001

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

OREGON HEALTH & SCIENCE UNIVERSITY
3181 S W SAM JACKSON PARK RD., #L335

PORTLAND, OR 97239

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
FERRET	0	0	7	0	7
GERBIL	0	0	17	0	17

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(*Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.)*)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

[redacted]

DATE SIGNED
13-FEB-2017

APHIS FORM 7023A
AUG 2013

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2015

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
92-R-0001

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

OREGON HEALTH & SCIENCE UNIVERSITY
3181 S W SAM JACKSON PARK RD., #L335

PORTLAND, OR 97239

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

[redacted]

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	20	0	20
5. Cats	0	2	0	0	2
6. Guinea Pigs	0	0	277	0	277
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	260	0	260
9. Non-human Primates	2111	11	2337	0	2348
10. Sheep	0	0	132	0	132
11. Pigs	0	0	52	0	52
12. Other Farm Animals					
13. Other Animals	0	0	50	0	50

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(*Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.)*)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

[redacted]

DATE SIGNED
30-DEC-2015

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2015

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
92-R-0001

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

OREGON HEALTH & SCIENCE UNIVERSITY
3181 S W SAM JACKSON PARK RD., #L335

PORTLAND, OR 97239

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
FERRETS	0	0	11	0	11
GERBILS	0	0	39	0	39

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(*Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.)*)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

[redacted]

DATE SIGNED
30-DEC-2015

APHIS FORM 7023A
AUG 2013

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2014

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
92-R-0001

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

OREGON HEALTH & SCIENCE UNIVERSITY
3181 S W SAM JACKSON PARK RD., #L335

PORTLAND, OR 97239

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

[redacted]

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	29	0	29
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	201	0	201
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	296	0	296
9. Non-human Primates	2633	140	2143	0	2283
10. Sheep	0	0	114	0	114
11. Pigs	0	0	116	0	116
12. Other Farm Animals					
13. Other Animals	0	0	41	0	41

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

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4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

[redacted]

DATE SIGNED
25-FEB-2015

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2014

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
92-R-0001

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

OREGON HEALTH & SCIENCE UNIVERSITY
3181 S W SAM JACKSON PARK RD., #L335

PORTLAND, OR 97239

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
FERRETS	0	0	6	0	6
GERBILS	0	0	35	0	35

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(*Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.)*)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

[redacted]

DATE SIGNED
25-FEB-2015

APHIS FORM 7023A
AUG 2013