

# UC DAVIS ANIMAL CARE AND USE PROGRAM - FINAL REPORT (7/6/2017)

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In conducting my review of the UC Davis animal care and use program, with specific focus on the recent U.S. Department of Agriculture (USDA) findings and subsequent investigation, my charge was to: 1) review documentation from recent event reports to determine if there are discernable patterns, and follow up as appropriate with interviews of UC Davis faculty and staff leadership of the animal care program, and/or outside professional colleagues, with the documentation to be reviewed to include Institutional Animal Care and Use Committee (IACUC) incident reports, affidavits submitted to USDA, findings of the recent Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) review, and other data as deemed appropriate; 2) based on my knowledge and expertise, compare the pattern and nature of recent incidents at UC Davis to historical experience and in relation to other institutions with respect to relative size and complexity of animal programs; 3) prepare a summary report of observations and recommendations.

During January through May of this year, I reviewed the documentation referred to above, as well as other relevant program documents and USDA findings from selected other institutions. I also met with many individuals and groups on campus, including IACUC members and staff, the Interim Attending Veterinarian, California National Primate Research Center (CNPRC) staff and administrators, campus administrators, and other individuals involved in various aspects of the animal care program, in developing this report and my recommendations.

## Overview

UC Davis has one of the largest and most diverse (in terms of species housed/use) animal research and teaching programs in the US. Although there are no statistics available to compare institutions with respect to the numbers and types of animals used for research and teaching overall, it is possible to compare institutions in terms of their USDA registered animal use (note: USDA only covers nonhuman primates, cats, dogs, guinea pigs, hamsters, farm animals used in biomedical research, and wild rodents). Based on the 2015 FY USDA reports, UC Davis makes up less than 1/10 of 1% of all USDA registered research facilities (it is 1 of approximately 1000 registered research facilities<sup>1</sup>), but has approximately 1% of all registered animal use per year<sup>2</sup>; thus, it is 10 times larger in terms of animal use than the typical USDA registered research facility. Furthermore, the campus has 4% of all registered primate use<sup>3</sup>. These statistics provide context for the section that follows about the recent USDA findings.

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<sup>1</sup> This number varies slightly from year to year

<sup>2</sup> USDA facilities reports indicate that procedures were performed on 767,622 regulated animals in FY2015 – UC Davis accounted for 9385 of those

<sup>3</sup> USDA facilities reports indicate that procedures were performed on 61,950 non-human primates in FY2015 – UC Davis accounted for 2719 of those

## USDA Inspections

I reviewed all available information about all USDA non-compliances that were included as part of the recent USDA investigation of the campus (as well as seven non-compliances that took place after the investigation concluded in June, 2016). During this time, USDA visited the campus 51 times and issued 22 reports, with no non-compliances in 6 of these reports. Of the 25 non-compliances in the remaining reports, 7 involved injury to, or death of, animals, and these will be the focus of this review. They are obviously the most serious incidents from an animal welfare perspective, and considered to be critical non-compliances by the USDA.

As background, it is important to note that USDA cites non-compliances under particular sections of the Animal Welfare Act. USDA investigations are triggered by repeated non-compliances that fall under the same section and that are deemed serious in terms of their impacts or potential impacts on the animals. The USDA investigation was triggered by the presence of two non-compliances under Section 2.38 (f)(1) (see below). UC Davis has sent USDA their written response related to the non-compliances that were part of the investigation, although at the time this report was written USDA had not yet issued their findings. The non-compliances, and the campus' findings and corrective actions as stated in the response to USDA, were (arranged by Animal Welfare Act section):

### *Section 3.72 (a) Structure of housing facilities (1 non-compliance)*

(2011) A monkey was found dead in the outdoor pens with a bungee cord around its neck.

Campus findings and corrective action: Bungee cords have been used to secure shade structures in the outdoor pens for 15 years, without incident. In this case, the bungee cord came loose and fell into the pen. However, the post-mortem findings were inconclusive, with no evidence that the monkey was asphyxiated by the cord. Bungee cords in all pens have now been secured with zip ties to prevent them from coming loose.

### *Section 3.87 (a)(1) Primate enclosure used for transport strong enough to contain animal (1 non-compliance)*

(2016)\* A monkey escaped from its transport box. The dart used to sedate the monkey lacerated a kidney and the monkey had to be euthanized

Campus findings and corrective action— monkeys had been transported in these boxes many times without incident; in this case, the monkey was able to bend the steel door and escape. All transport boxes have been reinforced to prevent this occurring in the future. The injury to the animal was due to an accident; the individual who sedated the monkey was extremely experienced with this procedure and had sedated many monkeys in the past without incident.

### *Section 3.80 (a) (2) (ii) Primary enclosures for primates to prevent injury (1 non-compliance)*

(2013) A juvenile monkey was caught in the squeeze cage mechanism (which is used to restrain the monkeys for procedures) and died from her injuries

Campus findings and corrective action— it is not clear how this incident occurred. Squeeze cages are the predominant type of caging used for primates, and the CNPRC has used them since the 1980s without incident. However, monkeys do sometimes learn to operate the squeeze mechanism; in the past when this was noted the mechanisms in those monkeys' cages were secured by clips to

prevent them from being moved. This particular monkey had never been seen to operate the squeeze mechanism, but it appears likely that she pulled the squeeze door forward and became trapped. Squeeze mechanisms in all cages are now locked to prevent an incident like this from occurring in the future.

*Section 2.38 (f)(1) Miscellaneous – careful animal handling (4 non-compliances)*

(2014) A lamb died during transport.

Campus findings and corrective action – The lamb was being transported with its mother to reduce stress, which is permitted under the Animal Welfare Act. Lambs had been transported in this way multiple times in the past without incident. In this case, the mother might have fallen on the lamb, causing the lamb's death, but the actual reason for the death could not be confirmed and it could have instead been due to the lamb's health condition. Regardless, lambs are now transported in a way that places them in close proximity to their mothers, with visual, olfactory and oral contact, but not direct contact that could lead to injury.

(2015) A monkey that was being restrained for the purpose of administering fluid therapy partially escaped the restraint and fractured its leg

Campus findings and corrective action – The monkey's leg was put in a cast and he fully recovered. Fluid administration is a routine procedure that has been performed more than 1000 times on primates at CNRPC without injury; animals are monitored every 15-30 minutes either live or by video while restrained. Monitoring was enhanced following this incident and staff members responsible for fluid administration were re-trained.

(2016) A monkey escaped from her cage and fractured both legs.

Campus findings and corrective action – human error, a cage divider was not properly latched. The animal technicians involved have been re-trained, and locks have been placed on the dividers to further secure them. The monkey was treated and fully recovered from her injuries.

(2016)\* Non-compatible monkeys got together because the door between their cages was not latched properly; they fought, and one monkey was severely injured and had to be euthanized; another had injuries that were treated and the monkey fully recovered.

Campus findings and corrective action – human error; the staff member was retrained on door and divider locking procedures.

\*These incidents occurred after the USDA investigation was completed

*OLAW site visit*

One of the USDA visits to UC Davis took place in conjunction with an NIH Office of Laboratory Animal Welfare (OLAW) site visit, and I also reviewed the findings from that visit. OLAW undertook this visit in 2013 as part of a mandated national review of National Primate Research Centers. Staff indicated that the review conducted during this 3-day site visit was very thorough, with four site visitors reviewing records, interviewing staff, and visiting the facilities to observe animals and procedures. The review was campus-wide, not solely focused on the CNRPC. OLAW's review was extremely positive. Their June 18, 2013 report commends numerous aspects of the program, including the institutional commitment to compliance, staff knowledge and professionalism, the high standard of management, the well-maintained physical plant, the detailed policies and documentation, and the comprehensive IACUC program. Overall they found the

animals that they examined to be “healthy, in good condition, and being cared for by experienced personnel throughout the program.” They also identified six “areas which would benefit from additional attention in order to enhance the overall program.” These areas were: 1) reassessing one aspect of rodent euthanasia; 2) reassessing endpoint determination and monitoring of animals used in tumor models; 3) continuing social housing and enrichment efforts for all species; 4) developing a documentation system to verify observation of anesthetized primates; 5) implementing twice-daily observations of all outside primate enclosures; 6) ensuring adequate heat and shade provision in outdoor primate enclosures. The campus satisfactorily addressed all of these issues in a letter to OLAW on September 30, 2013 and in the campus’ subsequent annual report to OLAW.

### *AAALAC History and 2017 AAALAC Site Visit*

AAALAC International is a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs.<sup>4</sup> UC Davis initially received AAALAC accreditation in 1966. This accreditation was initially limited to the School of Veterinary Medicine, but was extended to the whole campus in 1975, making UC Davis the first campus-wide AAALAC accredited Land Grant University in the US. Currently, less than half (47%) of the Land Grant universities in the US have campus-wide AAALAC accreditation.

AAALAC conducts site visits for accreditation review and renewal every three years, and UC Davis received Continued Full Accreditation in the first three triennial site visits after initial accreditation. Thereafter, however, the campus underwent a lengthy period during which it failed (with one exception) to achieve Continued Full Accreditation after the site visit. From 1985 to 2008, most (5/8) site visits resulted in Probationary accreditation.

As background, AAALAC identifies two types of findings during site visits. Suggestions for Improvement are suggestions to improve the program but which do not need to be addressed in order for the institution to maintain Full Accreditation. Mandatory items, on the other hand, do have to be satisfactorily addressed in order for the institution to achieve or maintain Full Accreditation. AAALAC defines Mandatory items as those that have “potential to adversely affect the health, well-being or safety of animals or humans.” There are several categories of “less-than-full” accreditation (<https://www.aaalac.org/accreditation/categories.cfm>), but the most serious of these is Probation, which means that Mandatory items have been identified by the site visitors that cannot be corrected quickly (in less than about 2 months).

Full records were not available for most of the campus’ site visits, but summaries from other documents, as well as discussions with individuals on campus, indicate that among the most persistent issues preventing Full Accreditation were: 1) facilities deficiencies; 2) lack of oversight/authority of the Attending Veterinarian (AV) for the entire campus program; 3) inadequate occupational health and safety program; 4) inadequate IACUC oversight with respect to animal procedure areas (i.e. laboratories) and lack of post-approval monitoring to ensure that investigators were following their approved animal protocols. Underlying these issues was the

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<sup>4</sup> <https://www.aaalac.org/about/index.cfm>

size and decentralization of the campus animal care program, which created barriers to coordinated oversight and provision of animal care and veterinary care.

In response, the campus undertook major efforts to address several of the core issues that led to these findings. These included: 1) the construction or renovation of some animal facilities/support areas; 2) moving the “centralized” animal facility (now called the Teaching and Research Animal Care Services, TRACS) from the School of Veterinary Medicine to campus administration (Safety Services) and appointing the AV as TRACS director; 3) improving consistency of the veterinary care program/veterinary oversight via a number of different mechanisms (e.g. reporting systems, campus-wide standard operating procedures, establishing and/or subsidizing more centralized veterinary care provision [for example for rodent health surveillance]; 4) increasing the size of the IACUC staff and hiring a dedicated IACUC Administrator, which allowed for the implementation of a post-approval monitoring program, laboratory inspections, and hands-on training programs for investigators; 5) increasing administrative communication/interaction about the program (e.g. via the Leadership and Communications teams).

The campus has achieved Continued Full Accreditation during the last three site visits, including the visit that was conducted in October 2016, meaning that no Mandatory items were identified by AAALAC during any of these visits. The UC Davis AAALAC review takes five days for 8 site visitors. It is comprehensive, involving record review, interviews with staff, faculty, administrators and students, and inspections of all animal facilities on campus, as well as selected laboratory and study areas.

It is important to note that, as a private non-profit organization, AAALAC does not make information about individual institutions (e.g. size, animal census, current accreditation status, deficiencies found) publicly available, although accredited institutions can choose to be listed as such on the AAALAC website. It is therefore impossible to directly compare UC Davis to other institutions of comparable size and complexity. However, AAALAC does periodically provide summary statistics. The most recent are for the 700 site visits that AAALAC conducted from 2011-2013 ([https://www.aaalac.org/education/2014\\_Conference.cfm](https://www.aaalac.org/education/2014_Conference.cfm)). These site visits resulted in 4815 total findings, with 12% of those Mandatory items. Of the Mandatory items, the most common were related to occupational health and safety of personnel, IACUC oversight, and institutional/physical plant issues, followed by animal environment (mainly behavioral and social management of animals) and veterinary care issues. Again, none of these items were noted as Mandatory issues by AAALAC during the last three site visits to UC Davis.

### *Campus inspections*

The UC Davis IACUC conducts routine inspections of animal housing areas and laboratories and study areas where procedures are performed on animals. In addition, the IACUC conducts post-approval monitoring of at least 10% of recently approved protocols annually (some randomly selected, some specifically selected for additional scrutiny because they are considered to be higher-risk or “for cause”). As mentioned above, IACUC oversight was intensified in the last

decade in response both to AAALAC findings and evolving standards and practices within the animal research community.

The summary statistics in the UC Davis IACUC Annual Reports I reviewed indicate that deficiencies overall have decreased during this period of increased monitoring. The number of deficiencies identified in the animal facilities decreased from 2 to 1 per inspection from 2008 to 2016, while deficiencies in laboratories and study areas decreased from 0.8 to 0.1 during that same period. Deficiencies found during post-approval monitoring have not decreased (staying at about 0.8), but this is perhaps not surprising given that these inspections are mainly directed towards protocols that have already been identified by the IACUC as posing higher risk or because of already-identified issues. I reviewed the detailed findings in the last three years of semi-annual inspections, and the vast majority of the deficiencies found in the animal facilities, laboratory and study areas, and during post-approval monitoring, were minor (that is, they posed no risk to animals or humans). During those three years there were a total of 27 significant (posing a risk to animals or humans) deficiencies, 3 in the animal facilities and 4 in the laboratory/study areas and 20 found during the post-approval monitoring process. Prompt corrective actions were taken for all of these deficiencies.

### *Conclusions*

Based on the documents I reviewed and the interviews I conducted, I can determine no consistent patterns to the critical non-compliances found by USDA during the inspections between 2011 and March 2017. All but one of the non-compliances that resulted in animal injury or death involved non-human primates, but non-human primates make up nearly 40% of registered animal use on campus. Several non-compliances were due to human error/accident, although there was variability in terms of the types of incidents and the individuals involved, suggesting that there is not a systematic problem with lack of training or oversight either at the CNRPC or across campus. Indeed, I found that the CNRPC had detailed Standard Operating Procedures (SOPs) in place that covered topics relevant to these non-compliances (e.g. cage locking procedures, restraint during fluid administration, primate transport, sedation via darting) prior to them occurring, as well as well-documented staff training on all of these SOPs.

Some of the non-compliances in the USDA reports were due to accidents that it would have been very difficult to foresee based on successful past experience with those same procedures. However, given that most of the critical non-compliances did involve primates, I reviewed the 2014-2016 USDA inspection reports the other National Primate Research Centers (and where relevant the universities with which they are affiliated). The specific incidents that led to animal death or injury at UC Davis seem similar in nature to those seen at these other institutions, for example involving human error or accidents during the performance of procedures, monkeys escaping from enclosures, and animals becoming injured as a result of being caught in enclosure structures.

It is important to note that all of the non-compliances discussed above in the USDA reports were actually first identified by UC Davis, not by USDA. These were then self-reported by UC Davis either to OLAW (which requires such reporting for serious incidents involving federally supported research, and which informs USDA of these reports if they involve regulated species) and/or to USDA directly (although USDA does not require such self-reporting). Based on my experience evaluating programs for animal care nationally and internationally, the responses of UCD to these animal injuries and deaths were consistent with best practices in the animal research community and indicate that the campus has a robust oversight program for dealing with these types of occurrences. Specifically: 1) all animal injuries or deaths were reported either to the IACUC administrator (who then reported them to the Attending Veterinarian) and/or to the Attending Veterinarian within 24 hours after they were discovered; 2) a full investigation of each incident was undertaken in coordination with the IACUC and/or veterinary staff; 3) corrective actions were taken and documented with a goal of preventing recurrences.

The positive results of the OLAW review, as well as the last three AAALAC site visits, also indicate that the campus has a robust animal care program. These reviews were much more extensive than the one I was able to undertake, involving multiple site visitors with varying types of expertise performing a comprehensive review of records and research protocols, interviewing staff across campus, and visiting the animal facilities and support areas. Given the campus' AAALAC history, size, and level of decentralization, AAALAC's lack of any mandatory findings during the last three site visits reflects very positively on the campus' animal care program.

Regardless, I believe that there are some areas of risk within the UC Davis program, and these form the basis for my recommendations.

## **Recommendations**

### **Recommendation 1: Develop a long-term plan for construction/renovation of animal facilities and procedure/support areas, based on projected research and teaching needs**

There have been a number of recent reports discussing issues of concern related to the animal facilities and support areas at UC Davis, all highlighting that there are older facilities in use that are difficult to maintain in satisfactory condition and not ideally configured. A particular concern from these reports, and which I also heard articulated many times during my discussions on campus, is the lack of co-localization of animal housing space with procedure (e.g. laboratory) and support (e.g. cage wash) space in various locations on the campus. The resulting need to transport animals (or cages) poses a risk to both animals and humans, in terms of the potential both for injury and disease transmission. Related to this issue, the campus has not undertaken a systematic review of projected needs for animal housing/procedure/support space in terms of its future animal research and teaching portfolio (e.g., are there projected changes in the pattern or scope of animal use, and therefore facilities needs, related to predicted changes in extramural funding or student enrollments?). Such a review would be timely, given that the animal care program is moving administratively to the Office of the Vice Chancellor for Research.

Recommendation 2: Review processes and procedures for USDA regulated species.

Given the decentralized nature of the UC Davis animal care program, aspects of housing and care for regulated species may be made at the department or college level rather than centrally. This could lead to different standards across campus and potentially to risks for future non-compliance with USDA. I therefore recommend that the IACUC be charged with evaluating policies and procedures for regulated species on campus, with a view towards determining appropriate standards and best practices with respect to issues such as staff training/qualifications and requirements for housing and procedure/support space (e.g. configuration, quality, maintenance, oversight) campus-wide.

Recommendation 3: Commence recruitment of Attending Veterinarian

The campus has had an Interim AV since last year, with recruitment of a permanent AV put on hold because of the administrative reorganization of the animal care program and potential recruitment of a Director. With the scope of the Director position now being reconsidered and that hire thus delayed, I recommend that the campus begin recruitment of a permanent Attending Veterinarian as soon as possible. The AV plays a key role in regulatory compliance for USDA (and interfacing with AAALAC). While an Interim AV can certainly successfully perform the functions required, it will be important to have a permanent AV in place to help during the process of administrative reorganization and planning for future needs (Recommendation 1), with the responsibilities of that position well-defined to ensure that the campus animal care program continues to have adequate and coordinated programmatic oversight.