

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

**Petition to Amend 9 C.F.R. § 2.31(d)(1), 9 C.F.R. § 2.31(e), and 9 C.F.R. § 1.1  
to Account for State Post-Research Adoption Laws Concerning Dogs and Cats**

Submitted by:

Advancing Law for Animals  
*Petitioner and Counsel of Record*

New England Anti-Vivisection Society  
*Petitioner*

## NOTICE OF PETITION OF RULEMAKING

*Via Electronic Mail and Certified Mail/ Return Receipt Requested*

March 19, 2019

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## **CITIZEN PETITION**

### **I. Introduction**

Advancing Law for Animals (“ALA”) and New England Anti-Vivisection Society (“NEAVS”) submit this Petition to the Honorable Sonny Perdue, Secretary of United States Department of Agriculture (“USDA”), pursuant to 5 U.S.C. § 553(e) and 7 C.F.R. § 1.28. ALA and NEAVS (together, “Petitioners”) request USDA amend its regulations as follows:

- Amend 9 C.F.R. § 2.31(d)(1) to include an additional clarifying subpart, § 2.31(d)(1)(xii), which would require the Institutional Animal Care and Use Committee (“IACUC”) to determine that proposed activities or significant changes to ongoing activities involving dogs or cats, and occurring in a locality requiring post-research adoption, are compliant;
- Amend 9 C.F.R. § 2.31(e) to include an additional clarifying subpart, § 2.31(e)(6), which would require that a proposal to conduct an activity involving dogs and cats, or to make a significant change in an ongoing activity involving dogs and cats, must contain a description of compliance efforts taken or to be taken if proposed activities occur in a locality requiring post-research adoption; and
- Amend 9 C.F.R. § 1.1 to include definition of the phrase “Post-Research Adoption Law.”

Presently, nine states have enacted laws requiring post-research adoption of dogs and cats used in laboratories, where suitable. At least eight more states have introduced similar legislation. While the basic thrust of these laws remains the same, some variance exists in applicability and scope of mandate. Nonetheless, where the centralized schema regulating animals in research facilities fails to acknowledge these laws, compliance with them is frustrated. Further, where

research facilities fail to acknowledge these laws *ex ante*, when proposing activities, and instead consider compliance as an afterthought, *ex post*, compliance is frustrated.

Federal law requires that all research institutions that use animals in experiments have an IACUC. 7 U.S.C. § 2143(b); 9 C.F.R. § 2.31. Among other responsibilities, IACUCs are charged to ensure compliance with humane treatment and handling of animals in research facilities. As such, compliance with local post-research adoption laws is not only relevant, but critical to its purpose. Further, “as agents of the research facility” pursuant to 9 C.F.R. § 2.31(c), IACUCs must function to help their research facilities comply with state laws. As a result, where a research facility exists in a locality containing a post-research adoption law, compliance with that law must be considered in the proposal phase, and reported to the governing IACUC.

USDA has the authority to promulgate regulations requiring IACUCs to ensure that research facilities are compliant with local post-research adoption law. Under 7 U.S.C. § 2143(a)(1), the USDA Secretary is required to “promulgate standards to govern the humane handling, care, treatment, and transportation of animals by . . . research facilities[.]” In so doing, the Secretary is encouraged to cooperate with States or other political subdivisions. 7 U.S.C. § 2145(b) (declaring “[t]he Secretary is authorized to cooperate with the officials of the various States or political subdivisions thereof in carrying out the purposes of this chapter and of any State, local, or municipal legislation or ordinance on the same subject”).

As a result, Petitioners respectfully request USDA amend its regulations, as further detailed below.

## **II. Legal Basis for Petition**

Petitioners submit this Petition for Rulemaking pursuant to the Right to Petition Government Clause in the First Amendment to the United States Constitution; the Administrative

Procedure Act, 5 U.S.C. § 553(e); and USDA’s implementing regulations, 7 C.F.R. § 1.28. Petitioners request that the Secretary take action consistent with Congress’ statement of policy in the Animal Welfare Act, 7 U.S.C. § 2131; USDA’s obligations under the Animal Welfare Act to effectively regulate to ensure the humane treatment of animals, 7 U.S.C. § 2143(a)(1); USDA’s authority to cooperate with State, local, or municipal legislation concerning animal welfare, 7 U.S.C. § 2145(b); and principles of state sovereignty.

Petitioners are interested persons pursuant to 5 U.S.C. § 553(e). Founded in 1895, NEAVS is a non-profit organization dedicated to the welfare of animals in laboratories through public education, grassroots advocacy, and policy work. ALA is a non-profit organization dedicated to advancing the interests of animals through the legal system, including animals in laboratories.

### **III. Background**

#### **a. Nine States Require Post-Research Adoption of Dogs and Cats Where Suitable**

Nine states have passed laws relating to the adoption of dogs and cats where suitable following their use in research facilities. Minnesota passed the first of such laws, Minn. Stat. Ann. § 135A.191, which became effective on July 1, 2015. Declaration of Michael Ryan (hereinafter “Ryan Decl.”) ¶ 2, Ex. A, a true and correct copy of Minn. Stat. Ann. § 135A.191. Thereafter, Nevada passed Nev. Rev. Stat. Ann. § 574.205, effective on October 1, 2015; California passed Cal. Educ. Code § 66017.7, effective on January 1, 2016; Connecticut passed Conn. Gen. Stat. § 10a-150e, effective on June 1, 2016; New York passed N.Y. Educ. Law § 239-b, effective on September 15, 2016; Illinois passed 510 Ill. Comp. Stat. Ann. 93/10, effective on January 1, 2018; Delaware passed Del. Code Ann. tit. 16, § 3092F, effective on June 20, 2018; Maryland passed Md. Code Ann., Agric. § 15-101 (“Maryland Post-Research Adoption Law”), effective on October 1, 2018; and, most recently, Rhode Island passed 4 R.I. Gen. Laws Ann. § 4-27-2, effective on July

2, 2018. Ryan Decl. ¶ 3, Ex. B, a true and correct copy of Nev. Rev. Stat. Ann. § 574.205; *id.*, ¶ 4, Ex. C, a true and correct copy of Cal. Educ. Code § 66017.7; *id.*, ¶ 5, Ex. D, a true and correct copy of Conn. Gen. Stat. § 10a-150e; *id.*, ¶ 6, Ex. E, a true and correct copy of N.Y. Educ. Law § 239-b; *id.*, ¶ 7, Ex. F, a true and correct copy of 510 Ill. Comp. Stat. Ann. 93/10; *id.*, ¶ 8, Ex. G, a true and correct copy of Del. Code Ann. tit. 16, § 3092F; *id.*, ¶ 9, Exhibit H, a true and correct copy of Md. Code Ann., Agric. § 15-101; *id.*, ¶ 10, Ex. I, a true and correct copy of 4 R.I. Gen. Laws Ann. § 4-27-2. While many post-research adoption laws have already passed, more are pending.

**b. Post-Research Adoption Laws Governing Dogs and Cats Are Pending in at Least Eight More States**

Additional laws governing the post-research adoption of dogs and cats where suitable are pending in at least eight more states, including Indiana, Massachusetts, New Jersey, Oregon, Pennsylvania, Texas, Virginia, and Washington. H.R. 1604, 2019 Leg., 121st Sess. (Ind. 2019); S. 534, 191st Gen. Assemb., Reg. Sess. (Ma. 2019); H.R. 758, 191st Gen. Assemb., Reg. Sess. (Ma. 2019); H.R. 764, 191st Gen. Assemb., Reg. Sess. (Ma. 2019); H.R. 3274, 2018 Leg., 218th Sess. (N.J. 2018); S. 2826, 2019 Leg., 218th Sess. (N.J. 2019); S. 638, 80th Gen. Assemb., Reg. Sess. (Or. 2019); H.R. 238, 203rd Gen. Assemb., Reg. Sess. (Pa. 2019); S. 121, 2019 Leg., 86th Sess. (Tx. 2019); H.R. 146, 2019 Leg., 86th Sess. (Tx. 2019); H.R. 2590, 2019 Leg. Reg. Sess. (Va. 2019); S. 5212, 2019 Leg., 66th Sess. (Wa. 2019).

**c. Demonstrated Need: Beltsville Animal Research Center Fails to Adopt Cats Infected with Common and Easily-Treatable Parasite**

**i. Beltsville Animal Research Center cat experimentation**

The USDA Agricultural Research Service Beltsville Agricultural Research Center is located in Beltsville, Maryland<sup>1</sup> (hereinafter, “BARC”) and has experimented on kittens and cats for decades. BARC euthanized 221 kittens over a five-year period,<sup>2</sup> and 2,988 since 1982.<sup>3</sup> BARC’s “Beltsville Area Animal Care and Use Committee (BAACUC) Animal Use Protocol Form” submitted on April 7, 2015, May 4, 2015, and May 15, 2015 (hereinafter “2015 BAACUC Protocol”) provides details into activities involving kittens and cats. Ryan Decl. ¶ 11, Ex. J, a true and correct copy of 2015 BAACUC Protocol. According to the 2015 BAACUC Protocol, the purpose of the experimentation is “to find sources of Toxoplasma infection for humans and food animals and to plan control strategies, including development of a vaccine.” *Id.*, Ex. J at p. 14, sec. C.

**ii. Beltsville Animal Research Center concedes cats are “100%” euthanized, despite infection of “no public health significance”**

The 2015 BAACUC Protocol estimated that, in a three-year period, 300 domestic cats would be used. *Id.* at p. 8, sec. V. These cats are “[t]wo month [sic] old or older” and “housed individually in cages . . .” *Id.*, Ex. J at p. 12, sec. VIII(B). In describing the “infectious agents” to

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<sup>1</sup> *Beltsville Agricultural Research Center: Beltsville, MD*, U.S. DEP’T OF AGRIC. AGRIC. RES. SERV., <https://www.ars.usda.gov/northeast-area/beltsville-md-barc/beltsville-agricultural-research-center/> (last visited Mar. 12, 2019).

<sup>2</sup> Scott Taylor, *New bill calls for USDA to stop euthanizing test kittens*, ABC7 WJLA, May 7, 2018, <https://wjla.com/features/7-on-your-side/dc-group-claims-usda-kills-hundreds-of-kittens-a-year-inside-maryland-lab> (last visited Mar. 13, 2019).

<sup>3</sup> Jessica Schladebeck, *Thousand of kittens killed in USDA research could have been treated and adopted instead, experts say*, DAILY NEWS, June 15, 2018, <https://www.nydailynews.com/news/national/ny-news-kittens-killed-usda-research-healthy-enough-adoption-20180615-story.html> (last visited Mar. 13, 2019).



be administered, BARC writes, “*Toxoplasma gondii*-*Hammondia hammondi* (it is a very close relative of *T.gondii*, and non pathogenic, ***of no public health significance***)[.]” *Id.*, Ex. J at p. 3, sec. III(F) (emphasis added). Stated otherwise, “*Hammondia hammondi* is a very close relative of *T. gondii*. It is nonpathogenic for cats and other animals. It is of **no public health significance . . .**” *Id.*, Ex. J at p. 10, sec. VI(B) (italics in original; emphasis added). The 2015 BAACUC Protocol classifies the pain and distress level to cats involved as “Category C – Minimal, transient, or no pain or distress[.]” *Id.*, Ex. J at p. 11, sec. VII(A). Further, “Cats fed *Toxoplasma*-infected tissues usually do not become sick. Most cats are euthanized 1 week after they start shedding oocysts (total period of 2 weeks from the time they are fed infected tissues).” *Id.*, Ex. J at p. 15, sec. IX(D). According to the 2015 BAACUC Protocol, cats used will “100%” not “be returned to the BARC herd/flock/colony[.]” “100%” not be “transferred to another BAACUC protocol[.]” and “100%” “will be euthanized.” *Id.*, Ex. J at p. 18, sec. XI(B)-(D).

General veterinary consensus echoes BARC’s admission that Toxoplasmosis is of no public health significance. Rather, Toxoplasmosis is common and easily-treatable with antibiotics.<sup>4</sup> According to the American Veterinary Medical Association, even handling cats with *Toxoplasma* is “unlikely to pose a risk of infection.”<sup>5</sup> Dr. Marcus Brown, a Veterinarian at the Arlington,

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<sup>4</sup> Arnold Plotnick, MS, DMV, ACVIM, *Toxoplasmosis*, MANHATTAN CAT SPECIALISTS, <https://www.manhattancats.com/article-archive/infectious-diseases/toxoplasmosis/> (last visited Mar. 6, 2019) (explaining “*Toxoplasma* occurs worldwide and infection in cats is similarly widespread”); *Toxoplasmosis in Cats*, FELINE FRIENDS, <http://www.feline-friends.org.uk/topics/toxoplasmosis-in-cats/> (last visited Mar. 6, 2019) (explaining “*Toxoplasmosis* is . . . common in nearly all warm-blooded animals” and “most cats recover from clinical toxoplasmosis when a complete [antibiotics] course is given”).

<sup>5</sup>*Toxoplasmosis*, AM. VETERINARY MED. ASS’N, <https://www.avma.org/public/PetCare/Pages/Toxoplasmosis.aspx> (last visited Mar. 12, 2019).

Virginia Nova Cat Clinic, explained one of the most challenging parts in treating the illness is diagnosing it.<sup>6</sup> But with cats used at BARC, diagnosis is not necessary.<sup>7</sup>

**iii. Beltsville Animal Research Center fails to comply with Maryland law requiring post-research adoption**

On April 24, 2018, Governor Larry Hogan signed into law Md. Code Ann., Agric. § 15-101 (“Maryland Post-Research Adoption Law”). On September 18, 2018, Petitioner NEAVS wrote to the Honorable Sonny Perdue, offering to pay all costs to rehabilitate kittens and cats at BARC, and to take possession of them to ensure adoption (“Post-Research Adoption Offer”). Ryan Decl. ¶ 12, Ex. K, a true and correct copy of Post-Research Adoption Offer. Petitioner NEAVS did not receive a response. *Id.* at ¶ 14.

On October 1, 2018, the Maryland Post-Research Adoption Law went into effect. The law applies to research facilities located within Maryland “in which dogs or cats are used for scientific research purposes[.]” *Id.* § 15-101(c). The term “research facility” includes a “higher education research facility,” a “scientific research facility,” a “medical research facility,” and a “product testing facility.” *Id.* § 15-101(a)(3)(i)-(iv).

Despite falling within the scope of the Maryland Post-Research Adoption Law, all available evidence indicates BARC has not made reasonable steps toward the adoption of any kittens or cats under its care. On September 20, 2018, USDA stated:

“[USDA Animal Research Service] is working to assemble a panel of experts to review the best available science and provide recommendations on possible alternatives to our current protocol, including adoption. We need to hear the findings of these experts before considering any proposal for such alternatives.”<sup>8</sup>

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<sup>6</sup> Jessica Schladebeck, *supra*, note 4.

<sup>7</sup> *Id.*

<sup>8</sup> Scott Taylor, *Animal advocacy group offers to adopt kittens used in USDA experiments*, ABC7 WJLA, Sept. 20, 2018, <https://wjla.com/features/7-on-your-side/usda-kitten-adoptions-new-england-anti-vivisection-society> (last visited Mar. 13, 2019).

USDA did not offer any subsequent updates.

On October 28, 2018, Petitioner NEAVS called the Surplus Property Administrator of the Maryland Department of General Services, Surplus Property Division to inquire whether the office could help facilitate the adoption of cats held at BARC as surplus government property. Ryan Decl. ¶ 16. The Maryland Department of General Services, Surplus Property Division referred NEAVS to the Property Disposal Specialist of the Government Services Administration's ("GSA") Federal Acquisition Service. Ryan Decl. ¶ 17. GSA referred NEAVS to a USDA representative, who became unresponsive. *Id.*

On November 20, 2018, NEAVS again wrote to the Honorable Sonny Perdue, United States Secretary of Agriculture (hereinafter, "Second Post-Research Adoption Offer"). Ryan Decl. ¶ 18, Ex. L, a true and correct copy of Second Post-Research Adoption Offer. The Second Post-Research Adoption Offer outlined the applicability of the Maryland Post-Research Adoption Law to BARC, reiterated the common and easily-treatable nature of Toxoplasmosis, and again offered resources to ensure the adoption of kittens and cats held at issue could occur as required under the law, without cost to the government. Ryan Decl. ¶ 19. NEAVS again did not receive a response. Ryan Decl. ¶ 20.

**iv. Concerned Congress directs USDA to develop a post-research adoption program for cats in the Beltsville Animal Research Center.**

On February 15, 2019, President Trump signed an appropriations package into law ("FY19 Consolidated Appropriations Bill"). The Manager's statement accompanying the FY19 Consolidated Appropriations Bill states "provisions that were in both the House Report (H.Rpt. 115-706) and Senate Report (S.Rpt. 115-259) that remain unchanged by this conference

agreement, except as noted in this explanatory statement.”<sup>9</sup> The referenced Senate Report states in relevant part:

The [Senate] Committee [on Appropriations] strongly supports USDA research but is concerned about the use of cats in painful and terminal laboratory experiments at USDA’s Animal Parasitic Disease Laboratory. **The Committee appreciates USDA’s responsiveness to concerns that have been raised and directs the agency to consult scientific and veterinary experts about the feasibility of implementing alternatives to the use of cats in public health research, and to develop a program to adopt out cats no longer needed in research.** The Committee directs the Secretary to provide a report on its progress no later than 90 days after the enactment of this Act.<sup>10</sup>

(emphasis added) (hereinafter “Congressional Adoption Directive”).

The Congressional Adoption Directive reiterates that which is already required by the Maryland Post-Research Adoption Law. However, all available evidence indicates BARC has not yet taken steps toward adoption of any kittens or cats.

#### **IV. Beltsville Animal Research Center Exemplifies the Need for Further Rulemaking**

BARC is one of many research facilities in a growing number of states requiring post-research adoption of animals. Its reluctance to offer any kittens or cats for adoption is likely a consequence of poor planning. The salience of BARC’s example is that, under the current scheme, its failure will be replayed again in other research laboratories, leading to the needless death of adoptable dogs and cats—in contravention of state law. As such, a simple and sensible solution to this problem is to “front-load” the adoption planning with general research planning, rather

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<sup>9</sup> H.R. Rep. No. 116-9, Making Further Continuing Appropriations For The Department of Homeland Security for Fiscal Year 2019, and For Other Purposes, at 549 (2019).

<sup>10</sup> S. Rep. No. 115-259, at 24 (2018).

than wait until after research has concluded. The regulations proposed in this Petition are just that, in a manner consistent with the current statutory and regulatory scheme.

## **V. Action Requested**

Petitioners request three amendments: The first to 9 C.F.R. § 2.31(d), concerning IACUC review of activities involving animals; the second to 9 C.F.R. § 2.31(e), regarding proposals to conduct an activity involving animals, or to make a significant change in an ongoing activity; and the third to 9 C.F.R. § 1.1, concerning definitions. Note that 9 C.F.R. § 2.37 would extend application of proposed amended regulations to federal research facilities.

### **a. Proposed Amendment to 9 C.F.R. § 2.31(d), titled “IACUC review of activities involving animals”**

Petitioners request 9 C.F.R. § 2.31(d)(1) be amended to include an additional clarifying subpart, § 2.31(d)(1)(xii). Proposed 9 C.F.R. § 2.31(d)(1)(xii) is set forth below in bold and italicized type:

(d) IACUC review of activities involving animals.

(1) ... Further, the IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements:

[(i)-(xi)]

***(xii) are compliant with any applicable  
Post-Research Adoption Law.***

### **b. Proposed Amendment to 9 C.F.R. § 2.31(e), regarding proposals to conduct an activity involving animals, or to make a significant change in an ongoing activity**

Petitioners request 9 C.F.R. § 2.31(e) be amended to include an additional clarifying subpart, § 2.31(e)(6). Proposed 9 C.F.R. § 2.31(e)(6) is set forth below in bold and italicized type:

(e) A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following:

[(1)-(5)]

***(6) In a locality containing a Post-Research Adoption Law governing any species to be included in a proposal, a description of compliance efforts taken or to be taken.***

**c. Proposed Amendment to 9 C.F.R. § 1.1, titled “Definitions”**

Petitioners request the phrase “Post-Research Adoption Law” be added to § 1.1, titled “Definitions.” The proposed definition is as follows:

***Post-Research Adoption Law*** means any law, whether federal, state, or local, requiring adoption or reasonable steps toward adoption of specified animals in laboratories at the conclusion of their use, where suitable.

**VI. Legal Analysis**

**a. Research Facilities Must Comply with State Post-Research Adoption Laws**

Research facilities must comply with state post-research adoption laws, as such laws are not preempted by the Animal Welfare Act. *See* 7 U.S.C. § 2143(1) (stating the “Secretary shall promulgate standards to govern the humane handling, care, treatment, and transportation of animals by dealers, research facilities, and exhibitors”); *id.* § 2143(8) (stating further that “Paragraph (1) shall not prohibit any State (or a political subdivision of such State) from promulgating standards in addition to those standards promulgated by the Secretary under paragraph (1)”); *see also DeHart v. Town of Austin, Ind.*, 39 F.3d 718, 722 (7th Cir. 1994) (explaining “it is clear that the Animal Welfare Act does not evince an intent to preempt state or local regulation of animal or public welfare. Indeed, the Animal Welfare Act expressly contemplates

state and local regulation of animals”); *Hendricks Cty. Bd. of Zoning Appeals v. Barlow*, 656 N.E.2d 481, 485 (Ind. Ct. App. 1995) (“A plain reading of the [Animal Welfare] Act demonstrates that its goals are intended to be realized in part through state and local participation. Congress demonstrated no express or implied intent to preempt state or local government from regulating in the area.”); *Medlock v. Board of Trustees* (1991), Mass.App., 580 N.E.2d 387, 389, n. 3, *review denied*, 586 N.E.2d 10 (rejecting the argument that state animal welfare regulations were preempted by Animal Welfare Act); *Kerr v. Kimmell*, 740 F. Supp. 1525, 1530 (D. Kan. 1990) (explaining “plaintiff’s argument that Congress intended to totally occupy the field of animal welfare is belied by the express language of the federal statute . . . .”); *Winkler v. Colorado Dep’t of Health*, 193 Colo. 170, 176, 564 P.2d 107, 111 (1977) (finding Animal Welfare Act did not preempt state law, given “the clear expressions of Congressional intent to foster cooperation with state interests under the [Animal Welfare] Act”).<sup>11</sup>

Because the Animal Welfare Act offers no preemptive effect, applicable research facilities must comply with state post-research adoption laws.

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<sup>11</sup> Health Research Extension Act of 1985, Pub. L. No. 99-158, § 495 (1985) grants authority to the Health and Human Services secretary, acting through the National Institutes of Health (“NIH”) director, to establish guidelines and authorize the NIH director to revoke grants or contracts for failure to meet those guidelines. 42 U.S.C. § 289d(a), (d). The policy promulgated thereunder “does not affect applicable state or local laws or regulations which impose more stringent standards for the care and use of laboratory animals”). OFFICE OF LABORATORY ANIMAL WELFARE, No. 15-8013, PHS POLICY ON HUMANE CARE AND USE OF LABORATORY ANIMALS, § II (Revised 2015).

**b. USDA is Empowered to Amend its Regulations to Require that IACUCs Determine Whether Proposed Activities or Ongoing Activities Are Compliant with Post-Research Adoption Laws, Where Applicable**

USDA has the authority to promulgate regulations requiring IACUCs to ensure that research facilities are compliant with local post-research adoption law. Federal law regarding animal welfare already takes into account the existence of state law. *See, e.g.*, 7 U.S.C. § 2156(d) (declaring “the activities prohibited by such subsection shall be unlawful with respect to fighting ventures involving live birds *only if* the fight is to take place *in a State where it would be in violation of the laws thereof*”) (italics added). The USDA Secretary is required to “promulgate standards to govern the humane handling, care, treatment, and transportation of animals by . . . research facilities[.]” 7 U.S.C.A. § 2143(a)(1). With respect to animals in research facilities, the Secretary is further required to promulgate regulations “for animal care, treatment, and practices in experimental procedures to ensure that animal pain and distress are minimized . . .” 7 U.S.C.A. § 2143(a)(3)(A). Nor must the Secretary operate in isolation from States or other political subdivisions. As stated previously, the opposite is, in fact, the case, as § 2145(b) declares “[t]he Secretary is authorized to cooperate with the officials of the various States or political subdivisions thereof in carrying out the purposes of this chapter and of any State, local, or municipal legislation or ordinance on the same subject.” 7 U.S.C. § 2145(b).

Under these unambiguous statutory authorities, USDA is indisputably granted the power to promulgate the regulations requested herein.

**c. IACUCs are Well-Positioned to Assess Compliance, and Must Indeed Aide in Compliance, with Post-Research Adoption Laws**

IACUCs are well-positioned to assess compliance with state post-research adoption laws, whether such laws apply to state- or federally-funded research facilities. Notably, all research facilities must have an IACUC. 7 U.S.C. § 2143(b); 9 C.F.R. § 2.31; 9 C.F.R. § 2.37. Compliance



with post-research adoption law falls squarely within the purview of the IACUCs. The IACUC must review and approve all experimentation “to minimize pain and distress to animals.” 7 U.S.C. § 2143(b)(3). Among other specified tasks, an IACUC must determine that proposed activities or significant changes to ongoing activities provide for the humane care and handling of animals. 9 C.F.R. § 2.31(d). Additionally, members of the IACUC “shall represent society’s concerns regarding the welfare of animal subjects used at such facility.” 7 U.S.C.A. § 2143(b)(1). Relevant here, society *is* concerned with euthanasia of dogs and cats following their use in research facilities—resulting in post-research adoption laws in nine states, and pending post-research adoption laws in many more. This concern is further echoed in the Congressional Adoption Directive, ratified in the FY19 Consolidated Appropriations Bill, as described *supra* at sec. III.c.iv.

Finally, USDA regulations make clear IACUCs function “as an agent of the research facility.” 9 C.F.R. § 2.31(c). Consequently, because both federal and state research facilities are already obligated to comply with state post-research adoption laws, discussed *supra* at sec. VI.a., their IACUCs must also comply as the agents of these facilities. The regulations proposed by this Petition facilitate this compliance.

**d. The Proposed Regulations Are Consistent with Existing Law, As Well As the Congressional Directive to Adopt Cats at the Conclusion of Use in Beltsville Animal Research Center**

Proposed regulations are consistent with existing law and policy. Research facilities “transporting, selling, or otherwise disposing of any live dog or cat to another person” are already required to “make and maintain records or forms which fully and correctly disclose,” among other items, “[t]he date of transportation, sale, euthanasia, or other disposition of the animal[.]” 9 C.F.R. § 2.35(c)(2). The Guide for the Care and Use of Laboratory Animals also includes in its list of “topics [that] should be considered in the preparation of the protocol by the researcher and its review by the

IACUC” the “method of euthanasia or disposition of animals, including planning for care of long-lived species after study completion[.]”<sup>12</sup>

Proposed regulations are also consistent with acts of Congress. In its Congressional Statement of Policy accompanying the Animal Welfare Act, Congress declared regulation of animals as provided is necessary “to insure that animals intended for use in research facilities . . . are provided humane care and treatment[.]” 7 U.S.C. § 2131(1). The necessity of providing animals used in research facilities with humane care and treatment is echoed in the Congressional Adoption Directive, discussed *supra* at sec. III.c.iv. Since an IACUC functions “as an agent of the research facility,” this Congressional Adoption Directive should apply to IACUCs as well. *See* 9 C.F.R. § 2.31(c). As a result, Petitioners’ proposed regulations are consistent with the Animal Welfare Act’s Congressional Statement of Policy, the letter and spirit of the Animal Welfare Act itself, as well as the Congressional Adoption Directive.

## **VII. Conclusion**

Based on the foregoing, Petitioners respectfully request USDA amend 9 C.F.R. § 2.31(d)(1), 9 C.F.R. § 2.31(e), and 9 C.F.R. § 1.1 to account for state post-research adoption laws concerning dogs and cats.

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<sup>12</sup> NATIONAL RESEARCH COUNCIL, GUIDE FOR THE CARE AND USE OF LABORATORY ANIMALS 25-26 (8th ed. 2011). “The Guide is an internationally accepted primary reference on animal care and use, and its use is required in the United States by the Public Health Service Policy.” *Id.* at xiii.

Respectfully submitted,

A handwritten signature in blue ink, appearing to be 'VShakib', written in a cursive style.

Vanessa Shakib (Cal. Bar No. 287339)

Ryan Gordon (Cal. Bar No. 278414)

**Advancing Law for Animals**

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*Petitioner and Counsel of Record*

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**UNITED STATES DEPARTMENT OF AGRICULTURE**

Petition to Amend 9 C.F.R. § 2.31(d)(1), 9  
C.F.R. § 2.31(e), and 9 C.F.R. § 1.1 to  
Account for State Post-Research Adoption  
Laws Concerning Dogs and Cats

Declaration of Michael Ryan in Support  
of Petition for Rulemaking

I, Michael Ryan, declare as follows:

1. I am Director of Policy and Government Affairs at the New England Anti-Vivisection Society (“NEAVS”). NEAVS, along with Advancing Law for Animals (collectively, “Petitioners”), submitted the Petition to Amend 9 C.F.R. § 2.31(d)(1), 9 C.F.R. § 2.31(e), and 9 C.F.R. § 1.1 to Account for State Post-Research Adoption Laws Concerning Dogs and Cats (“Petition for Rulemaking”). I respectfully submit this declaration in support of the Petitioners’ Petition for Rulemaking. I have personal knowledge of the facts set forth in this declaration.

2. Attached as Exhibit A is a true and correct copy of Minn. Stat. Ann. § 135A.191.
3. Attached as Exhibit B is a true and correct copy of Nev. Rev. Stat. Ann. § 574.205.
4. Attached as Exhibit C is a true and correct copy of Cal. Educ. Code § 66017.7.
5. Attached as Exhibit D is a true and correct copy of Conn. Gen. Stat. § 10a-150e.
6. Attached as Exhibit E is a true and correct copy of N.Y. Educ. Law § 239-b.
7. Attached as Exhibit F is a true and correct copy of 510 Ill. Comp. Stat. Ann. 93/10.
8. Attached as Exhibit G is a true and correct copy of Del. Code Ann. tit. 16, § 3092F.
9. Attached as Exhibit H is a true and correct copy of Md. Code Ann., Agric. § 15-101.
10. Attached as Exhibit I is a true and correct copy of 4 R.I. Gen. Laws Ann. § 4-27-2.

11. Upon information and belief, attached as Exhibit J is a true and correct copy of “BARC’s Beltsville Area Animal Care and Use Committee (BAACUC) Animal Use Protocol Form” submitted on April 7, 2015, May 4, 2015, and May 15, 2015 by United States Department of Agriculture Agricultural Research Service Beltsville Agricultural Research Center (“BARC”).

12. On September 18, 2018, the Executive Director of NEAVS, Nathan Herschler, on behalf of Petitioner NEAVS, wrote to the Honorable Sonny Perdue, United States Secretary of Agriculture (“Post-Research Adoption Offer”). Attached as Exhibit K is a true and correct copy of the Post-Research Adoption Offer. I submitted the Post-Research Adoption Offer through electronic mail on behalf of Mr. Herschler.

13. The Post-Research Adoption Offer includes an offer to pay all costs to rehabilitate kittens and cats at BARC, and to take possession of them to ensure adoption.

14. To my knowledge, Petitioner NEAVS has not received a response to the Post-Research Adoption Offer.

15. On October 1, 2018, Minn. Stat. Ann. § 135A.191 went into effect.

16. On October 28, 2018, I, on behalf of Petitioner NEAVS, called the Surplus Property Administrator of the Maryland Department of General Services, Surplus Property Division to inquire whether the office could help facilitate the adoption of cats held at BARC as surplus government property.

17. The Maryland Department of General Services, Surplus Property Division referred me to the Property Disposal Specialist of the Government Services Administration’s (“GSA”) Federal Acquisition Service. GSA referred NEAVS to a USDA representative, who became unresponsive.

18. On November 20, 2018, I, on behalf of Petitioner NEAVS, wrote to the Honorable Sonny Perdue, United States Secretary of Agriculture (“Second Post-Research Adoption Offer”). Attached as Exhibit L is a true and correct copy of the Second Post-Research Adoption Offer. I submitted the Second Post-Research Adoption Offer through electronic mail.

19. The Second Post-Research Adoption Offer outlined the applicability of Minn. Stat. Ann. § 135A.191 to BARC; reiterated the common and easily-treatable nature of Toxoplasmosis; and offered resources to ensure the adoption of kittens and cats held at BARC could occur as required under the law, without cost to the government.

20. To my knowledge, Petitioner NEAVS has not received a response to the Second Post-Research Adoption Offer.

I declare under penalty of perjury under the laws of the District of Columbia and of the United States that the foregoing is true and correct. Executed this 19th day of March, 2019 in the District of Columbia.

A handwritten signature in black ink, appearing to read 'Michael Ryan' in a stylized, cursive script.

Michael Ryan  
Director of Policy and Government Affairs  
New England Anti-Vivisection Society  
333 Washington Street, Suite 850  
Boston, Massachusetts 02108  
[mryan@neavs.org](mailto:mryan@neavs.org)

# Exhibit A



Minnesota Statutes Annotated  
Postsecondary Education (Ch. 135A-137)  
Chapter 135A. Public Postsecondary Education  
Miscellaneous

M.S.A. § 135A.191

135A.191. Research dogs and cats

Effective: July 1, 2015

[Currentness](#)

(a) A higher education research facility that receives public money or a facility that provides research in collaboration with a higher education facility that confines dogs or cats for science, education, or research purposes and plans on euthanizing a dog or cat for other than science, education, or research purposes must first offer the dog or cat to an animal rescue organization. A facility that is required to offer dogs or cats to an animal rescue organization under this section may enter into an agreement with the animal rescue organization to protect the facility. A facility that provides a dog or cat to a rescue organization under this section is immune from any civil liability that otherwise might result from its actions, provided that the facility is acting in good faith.

(b) For the purposes of this section, “animal rescue organization” means any nonprofit organization incorporated for the purpose of rescuing animals in need and finding permanent, adoptive homes for the animals.

**Credits**

[Laws 2014, c. 312, art. 13, § 47](#). Amended by [Laws 2015, c. 69, art. 3, § 19](#).

M. S. A. § 135A.191, MN ST § 135A.191

Current with legislation through the end of the 2018 Regular Session.

# Exhibit B

West's Nevada Revised Statutes Annotated  
Title 50. Animals (Chapters 561-577)  
Chapter 574. Cruelty to Animals: Prevention and Penalties  
Adoption of Dogs and Cats at Research Facilities

N.R.S. 574.205

574.205. Requirement to offer dog or cat for adoption before euthanization; immunity from civil liability

Effective: October 1, 2015

[Currentness](#)

1. A research facility that intends to euthanize a dog or cat for any purpose other than scientific, medical or educational research shall, before euthanizing the dog or cat, offer the dog or cat for adoption if the dog or cat is appropriate for adoption. A research facility may offer the dog or cat for adoption through a program of the research facility or enter into a collaborative agreement with an animal shelter that performs the work of an animal rescue organization or an animal rescue organization for the purpose of carrying out the provisions of this subsection. Any such animal shelter or animal rescue organization must be domiciled in Nevada and exempt from taxation pursuant to [26 U.S.C. § 501\(c\)\(3\)](#).

2. A research facility and any officer, director, employee or agent of the research facility is immune from civil liability for any act or omission relating to the adoption of a dog or cat pursuant to subsection 1.

3. As used in this section:

(a) "Animal rescue organization" means a nonprofit organization established for the purpose of rescuing animals in need and finding permanent, adoptive homes for such animals.

(b) "Research facility" means an organization that is engaged in:

(1) Animal research for the purpose of testing the performance, safety or quality of a product; or

(2) Scientific research for scientific, medical or educational purposes.

**Credits**

Added by [Laws 2015, c. 323, § 1, eff. Oct. 1, 2015](#).

N. R. S. 574.205, NV ST 574.205

Current through Ch. 2 of the 80th Regular Session (2019) of the Nevada Legislature subject to change from the reviser of the Legislative Bureau.

# Exhibit C

West's Annotated California Codes  
Education Code (Refs & Annos)  
Title 3. Postsecondary Education (Refs & Annos)  
Division 5. General Provisions (Refs & Annos)  
Part 40. Donahoe Higher Education Act (Refs & Annos)  
Chapter 2. General Provisions (Refs & Annos)  
Article 3. General Provisions (Refs & Annos)

West's Ann.Cal.Educ.Code § 66017.7

§ 66017.7. Animals used for diagnostic purposes or medical  
research; adoption after completion of testing or research

Effective: January 1, 2016

[Currentness](#)

(a) A public postsecondary educational institution or independent institution of higher education, or employee or student thereof, that confines dogs or cats for the purposes set forth in [Section 1650 of the Health and Safety Code](#), if the institution assesses the health of an animal and determines, after the completion of any testing or research, that the animal is suitable for adoption, the animal's destruction is not required, and the animal is no longer needed, and if the institution's existing procedures for adopting the animal do not result in an adoption, shall offer the dogs or cats to an animal adoption organization or animal rescue organization for adoption prior to euthanizing those animals. A public postsecondary educational institution or independent institution of higher education that is required to offer dogs or cats to an animal adoption organization or animal rescue organization under this section may enter into an agreement with an animal adoption organization or animal rescue organization for the implementation of this section.

(b) For purposes of this section, the following definitions shall apply:

(1) "Animal adoption organization" or "animal rescue organization" means a not-for-profit entity that is exempt from taxation pursuant to [Section 501\(c\)\(3\) of the Internal Revenue Code](#) established for purposes of rescuing animals in need and finding permanent, adoptive homes for those animals and that maintain records pursuant to [Section 32003 of the Food and Agriculture Code](#).

(2) "Independent institution of higher education" means a nonpublic educational institution as defined in [subdivision \(b\) of Section 66010](#).

(3) "Public postsecondary educational institution" means any campus of the University of California, the California State University, or the California Community Colleges.

(c) This section does not apply to animals within the meaning of [Section 17006 of the Food and Agricultural Code](#).

#### Credits

(Added by [Stats.2015, c. 551 \(A.B.147\)](#), § 1, eff. Jan. 1, 2016.)

Footnotes

<sup>1</sup> Internal Revenue Code sections are in Title 26 of the U.S.C.A.  
West's Ann. Cal. Educ. Code § 66017.7, CA EDUC § 66017.7  
Current with urgency legislation through Ch. 2 of 2019 Reg.Sess

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# Exhibit D

Connecticut General Statutes Annotated  
Title 10a. State System of Higher Education (Refs & Annos)  
Chapter 185B. Constituent Units  
Part V. Miscellaneous (Refs & Annos)

C.G.S.A. § 10a-150e

§ 10a-150e. Offering for adoption of cat or dog used for conducting research or testing

Effective: June 1, 2016

[Currentness](#)

(a) For purposes of this section, “animal adoption or animal rescue organization” means any collaboration of individuals or any nonprofit organization that is exempt from taxation pursuant to [Section 501\(c\)\(3\) of the Internal Revenue Code of 1986](#), or any subsequent corresponding internal revenue code of the United States, as amended from time to time, that has, as part of such collaboration's or organization's purposes, the sale or placement of animals that were removed from animal shelters, municipal dog pounds or an individual's home.

(b) Each constituent unit of the state system of higher education, each public institution of higher education and each independent institution of higher education shall offer for adoption by an animal adoption or animal rescue organization any cat or dog that such constituent unit or institution of higher education possesses for the purpose of conducting research or testing provided such offer occurs after the completion of any such research or testing, such research or testing does not require the destruction of such cat or dog and such animal is no longer needed by such constituent unit or institution of higher education. Any constituent unit of higher education or institution of higher education that is required to offer a cat or dog for adoption pursuant to this section may enter into an agreement with an animal adoption or animal rescue organization for the purpose of complying with the provisions of this section.

**Credits**

(2015, P.A. 15-201, § 1; 2016, P.A. 16-89, § 6, eff. June 1, 2016.)

**Footnotes**

<sup>1</sup> [26 U.S.C.A. § 501.](#)

C. G. S. A. § 10a-150e, CT ST § 10a-150e

The statutes and Constitution are current through General Statutes of Connecticut, Revision of 1958, Revised to January 1, 2019.



# Exhibit E

McKinney's Consolidated Laws of New York Annotated  
Education Law (Refs & Annos)  
Chapter 16. Of the Consolidated Laws (Refs & Annos)  
Title I. General Provisions  
Article 5. University of the State of New York (Refs & Annos)  
Part I. General Organization (Refs & Annos)

McKinney's Education Law § 239-b

§ 239-b. Research dogs and cats

Effective: September 15, 2016

[Currentness](#)

1. A higher education research facility that receives public money, including tax-exempt status, or a facility that provides research in collaboration with a higher education facility shall after the completion of any testing or research involving a dog or cat, assess the health of the dog or cat and determine whether it is suitable for adoption. Such facility shall thereafter make reasonable efforts to offer for adoption the dog or cat determined to be suitable for adoption, either through private placement or through an animal rescue and shelter organization, a duly incorporated society for the prevention of cruelty to animals, a duly incorporated humane society, or a duly incorporated animal protective association that operates physical animal sheltering facilities and offers household pets to the public for adoption by way of an established adoption program, prior to euthanizing such dog or cat. Nothing in this section shall create a duty upon such an organization, association or society to accept a dog or cat offered by a higher education research facility for adoption.
2. A facility that is required to offer dogs or cats for adoption under this section may enter into an agreement with an animal rescue and shelter organization, a duly incorporated society for the prevention of cruelty to animals, a duly incorporated humane society, or a duly incorporated animal protective association that operates physical animal sheltering facilities and offers household pets to the public for adoption by way of an established adoption program.
3. The attending or institutional veterinarian at a facility that is required to offer dogs or cats for adoption under this section shall have the authority to assess the health of an animal and determine whether an animal is suitable for adoption.

**Credits**

(Added [L.2016, c. 240, § 2, eff. Sept. 15, 2016.](#))

McKinney's Education Law § 239-b, NY EDUC § 239-b  
Current through L.2019, chapters 1 to 19.

# Exhibit F

West's Smith-Hurd Illinois Compiled Statutes Annotated  
Chapter 510. Animals  
Act 93. Research Dogs and Cats Adoption Act

510 ILCS 93/10

93/10. Research dog and cat adoption

Effective: January 1, 2018

[Currentness](#)

§ 10. Research dog and cat adoption.

(a) A research facility, after the completion of any research involving a dog or cat, shall assess the health of the dog or cat and determine whether it is suitable for adoption.

(b) A research facility shall thereafter make reasonable efforts to offer for adoption a dog or cat determined to be suitable for adoption, either through private placement or through an animal adoption organization.

(c) A research facility that provides a dog or cat to an animal adoption organization under its research facility adoption policy is immune from any civil liability resulting from the research facility's actions as described in this Section, except for willful or wanton misconduct.

(d) Nothing in this Section shall create a duty upon an animal adoption organization to accept a dog or cat offered for adoption by a research facility.

(e) An attending veterinarian shall have the authority to assess the health of the dog or cat and determine whether the dog or cat is suitable for adoption.

(f) A research facility that owns dogs or cats for scientific, educational, or research purposes shall have a research facility adoption policy. The research facility adoption policy shall be made available on the research facility's website.

**Credits**

[P.A. 100-323, § 10, eff. Jan. 1, 2018.](#)

510 I.L.C.S. 93/10, IL ST CH 510 § 93/10

Current through P.A. 100-1180 of the 2018 Reg. Sess., and P.A. 101-1 of the 2019 Reg. Sess.

# Exhibit G

West's Delaware Code Annotated  
Title 16. Health and Safety  
Part II. Regulatory Provisions Concerning Public Health  
Chapter 30F. Animal Welfare (Refs & Annos)  
Subchapter VI. Research Animal Retirement Act

16 Del.C. § 3092F

§ 3092F. Adoption of cats and dogs used in research, education, or testing

Effective: June 20, 2018

[Currentness](#)

(a) When a research facility that confines and uses dogs and cats for research, education, testing, or other scientific purposes no longer needs a cat or dog that does not pose a health or safety risk to the public, the research facility shall do 1 of the following:

(1) Offer the cat or dog to an animal rescue organization or animal shelter for adoption.

(2) Offer the cat or dog for adoption through a private placement.

(b) A research facility must enter into an agreement with an animal rescue organization or animal shelter for the implementation of this section.

**Credits**

Added by [81 Laws 2018, ch. 272, § 1, eff. June 20, 2018](#).

16 Del.C. § 3092F, DE ST TI 16 § 3092F

Current through 82 Laws 2019, ch. 4. Revisions to 2019 Acts by the Delaware Code Revisors were unavailable at the time of publication.

# Exhibit H

West's Annotated Code of Maryland

Agriculture

Title 15. Research Facilities that Use Dogs or Cats (Refs & Annos)

MD Code, Agriculture, § 15-101

§ 15-101. Adoptions of dogs or cats used in research facilities

Effective: October 1, 2018

[Currentness](#)

**Definitions**

(a)(1) In this section the following words have the meanings indicated.

(2) “Animal rescue organization” includes:

(i) A nonprofit organization incorporated for the purpose of rescuing animals in need and finding permanent adoptive homes for the animals; and

(ii) A government-operated animal control unit that provides animals for adoption.

(3) “Research facility” includes:

(i) A higher education research facility;

(ii) A scientific research facility;

(iii) A medical research facility; and

(iv) A product testing facility.

(4) “Scientific research purposes” includes:

(i) Investigation;

(ii) Experimentation;

(iii) Instruction; and



(iv) Testing.

#### **Application of section**

(b) This section applies to a dog or cat that, in the determination of an attending veterinarian, is suitable for adoption.

#### **Adoption**

(c) A research facility located in the State in which dogs or cats are used for scientific research purposes shall take reasonable steps to provide for the adoption of a dog or cat that, in the determination of the research facility, is no longer needed for scientific research purposes by:

- (1) Establishing a private placement process to provide for the adoption of a dog or cat;
- (2) Establishing a list of animal rescue organizations that are approved by the research facility and are willing to take a dog or cat from the research facility; and
- (3) Offering the dog or cat to the animal rescue organizations identified in the list established under item (2) of this subsection if the research facility is unable to place the dog or cat through its private placement process.

#### **Collaborative agreements**

(d) A research facility may enter into a collaborative agreement with an animal rescue organization for the purpose of carrying out the provisions of this section.

#### **Credits**

Added by [Acts 2018, c. 236, § 1, eff. Oct. 1, 2018](#).

MD Code, Agriculture, § 15-101, MD AGRIC § 15-101

Current through all legislation from the 2018 Regular Session of the General Assembly

# Exhibit I

West's General Laws of Rhode Island Annotated  
Title 4. Animals and Animal Husbandry  
Chapter 27. Retirement of Research Dogs and Cats

Gen.Laws 1956, § 4-27-2

§ 4-27-2. Research dogs and cats--Retirement

Effective: July 2, 2018

[Currentness](#)

(a) A higher education research facility that receives public money, including tax-exempt status, or a facility that provides research in collaboration with a higher education facility shall, after the completion of any testing or research involving a dog or cat, assess the health of the dog or cat and determine whether it is suitable for adoption. The facility shall thereafter make reasonable efforts to offer for adoption the dog or cat determined to be suitable for adoption, either through private placement or through an animal rescue and shelter organization; a duly incorporated society for the prevention of cruelty to animals; a duly incorporated humane society; or a duly incorporated animal protective association that operates physical animal sheltering facilities and offers household pets to the public for adoption by way of an established adoption program. These efforts shall be made prior to euthanizing the dog or cat. Nothing in this section shall create a duty upon an organization, association, or society to accept a dog or cat offered by a higher education research facility for adoption.

(b) A facility that is required to offer dogs or cats for adoption under this section may enter into an agreement with an animal rescue and shelter organization; a duly incorporated society for the prevention of cruelty to animals; a duly incorporated humane society; or a duly incorporated animal protective association that operates physical animal sheltering facilities and offers household pets to the public for adoption by way of an established adoption program.

(c) The attending or institutional veterinarian at a facility that is required to offer dogs or cats for adoption under this section shall have the authority to assess the health of an animal and determine whether an animal is suitable for adoption.

**Credits**

[P.L. 2018, ch. 147, § 1](#), eff. July 2, 2018; [P.L. 2018, ch. 283, § 1](#), eff. July 2, 2018.

Gen. Laws, 1956, § 4-27-2, RI ST § 4-27-2

The statutes and Constitution are current through Ch. 353 of the January 2018 session.

# Exhibit J

**Beltsville Area Animal Care and Use Committee (BAACUC)**  
**Animal Use Protocol Form**

**I. General Information**

Date Submitted: 4-7-2015, 5-4-2015, 5-15-2015

A. Protocol Title: **Toxoplasmosis in cats**B. Principal Investigator: **Jitender P. Dubey**

C. Institute/Laboratory/Address:

**USDA,ARS,BARC, Animal Parasitic Diseases laboratory, 1001, Beltsville,  
MD 20705**

D. Telephone Number: **301-504-8128**Fax Number: **301-504-9222**Email: **jitender.dubey@ars.usda.gov**E. CRIS Number: **1265-32000-090-00D**

**CRIS Title: Integrated Approach to the Detection and Control of Foodborne Parasites and  
the Impact on Food Safety**

F. Is this protocol associated with the submission of an extramural grant proposal?

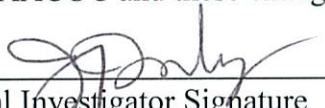
Yes ☒

If yes, please indicate the grant funding agency (*e.g.*, CSREES-NRI, DOD, DOE, NIH, CDC, NSF, VA, *etc.*): **NIH, EPA, NIFA**

\*\*\*Please note that for grant proposals covered by PHS Policy, PHS requires verification of approval by the BAACUC of those components within the proposal related to the care and use of animals. Therefore, a copy of the grant proposal should be forwarded to the BA Animal Care Program Manager for comparison with the BAACUC-approved protocol.

No ☐**II. Principal Investigator and Research Leader Assurances**

The information contained herein is accurate to the best of my knowledge. Procedures involving animals will be carried out humanely and will minimize discomfort, distress and pain. Any changes to the approved protocol will be submitted in the form of an amendment to the BAACUC and these changes will only be implemented after approval is granted.

  
 \_\_\_\_\_  
 Principal Investigator Signature

Date: 5/19/2015

  
 \_\_\_\_\_  
 \* Supervisor Signature

Date: 5/20/15

\* If the Principal Investigator (PI) submitting the protocol is a SY then your Research Leaders' signature is required.

\* If the Principal Investigator (PI) submitting the protocol is a Research Leader than the Institute Directors' signature is required.

**III. Required Pre-Submission Consultations and Approvals**

The Principal Investigator certifies that all appropriate consultations have been held and approvals obtained **prior** to protocol submission.

- A. Research Support Services (RSS) has been contacted to ensure that the number of animals requested, as well as adequate housing and staffing, are available. If multiple RSS units will be involved, contact information should be provided for each unit.

Yes ☒

Name of RSS Contact Person/Unit Supervisor: (b) (6)

Phone number of RSS Contact Person/Unit Supervisor: **504-8080**

Date of RSS Consultation: **4-4-2015**

No ☐

- B. The study will use animals obtained from a commercial vendor or outside source.

Yes ☒

For animals **NOT** obtained via centralized ordering through the Animal Care Program Manager, a veterinarian must be consulted about the health status of the animals and whether or not specific biosecurity procedures must be implemented prior to protocol submission.

Name of Veterinarian: **Dr. Craig Storozuk**

Phone Number of Veterinarian: **504-5624**

Date of Consultation: **4-4-2015**

No ☐

- C. The protocol will involve euthanasia.

Yes ☒

If yes, a veterinarian must be consulted about the methods of euthanasia.

Name of Veterinarian: **Dr. Storozuk**

Phone Number of Veterinarian: **504-5624**

Date of Veterinarian Consultation: **4-4-2015**

No ☐

- D. The protocol will involve a procedure(s) that has the potential to cause more than momentary pain or distress (Category D or E).

Yes ☐

If yes, a veterinarian must be consulted about the procedure(s).

Name of Veterinarian: **Dr. Storozuk**

Phone Number of Veterinarian: **504-5624**

Date of Veterinarian Consultation: **4-4-2015**

No ☒

E. Controlled substances (e.g., barbiturates) will be used in this animal study.

Yes ☐

Name of Controlled Substance(s):

Name of Licensee:

License #:

License Expiration Date:

No ☒

F. Infectious agents and/or hazardous chemicals, the latter as defined by the EPA Resource Conservation and Recovery Act (RCRA), will be used in this animal study.

Yes ☒

BA SOHES Approval Date: 4-10-2015

Name of Infectious Agent(s): *Toxoplasma gondii-Hammondia hammondi*

*(it is a very close relative of T.gondii, and non pathogenic, of no public health significance)*

Name of Chemical(s):

No ☐

G. Recombinant DNA will be used in conjunction with animals in this animal study.

Yes ☐

BA Institutional Biosafety Committee (IBC) most recent approval/review Date:

Recombinant DNA Project #:

No ☒

H. Radioisotopes will be used in conjunction with animals in this protocol.

Yes ☐

RSC #:

Approval Date:

No ☒

I. Has the PI's supervisor been notified of the submission of this protocol?  
(\*Note: The PI's supervisor needs to be cc'd on the submission of the original version of the protocol. The final approved version of the protocol requires the supervisor's signature in Section II).

Yes ☒

No ☐

J. If applicable, please list any other consultations or approvals that are not covered in the sections above, which are pertinent to the research proposed in this protocol (e.g., BA Ecology Committee approval, a collaborating institution IACUC approval, etc.):

K. **ALL** personnel listed in Section IV (except RSS personnel performing routine animal care) have completed and passed the mandatory "Working with the BAACUC" online training module. **NOTE: This requirement will NOT be implemented until after November 1, 2009.**

Yes ☒

No ☐



**IV. Personnel**

(List all personnel involved with this protocol; check all duties that apply to each person listed; briefly describe the **specific** qualifications and experience that each person has for the duties/procedures that they will be performing on the species indicated in Section V.)

Note: If RSS will be only performing routine animal care ("duty A"), then please indicate "RSS" and the appropriate supervisor's name in the "Name" section and "varying levels" after certifications and qualifications. If an individual member(s) of RSS will be involved in duties other than routine animal care, they must be listed individually by name and their specific certifications and qualifications described.

**EXAMPLE OF PERSONNEL FOR DEMONSTRATIVE PURPOSES ONLY**

Name: Joe Smith

Duties: A ☐, B ☒, C ☐, D ☐, E ☐, F ☐, G ☒, H ☒

Degree and/or relevant certifications: Ph.D. in Animal Science; AALAS LAT certified

Title: Research Biologist

Qualifications: Four years of experience collecting blood samples from mice and rats. Two years of experience performing invasive surgical procedures on rodents. Three years of experience euthanizing rodents with carbon dioxide.

Duties:

A. Routine animal care

B. Perform surgery

C. Assist in surgery

D. Administer drugs

E. Catheterize

F. Induce and monitor anesthesia

G. Sacrifice

H. Special care, including injections, bleedings, etc.

Name: J.P.Dubey

Duties: A ☐, B ☐, C ☐, D ☐, E ☐, F ☐, G ☒, H ☐

Degree and/or relevant certifications: B.V.Sc., P.H.D.

Title: Microbiologist

Qualifications: Dr. Dubey has 40 years of experience in handling cats, inducing minor anesthesia, drawing blood samples from peripheral veins or heart, and sacrificing cats

I certify that I have read and understand the protocol, and that I either have or will develop the necessary skills/expertise to perform my assigned duties so as to ensure the humane treatment of animals and to minimize animal discomfort. Further, I certify that I am aware of the Employee Animal Exposure Surveillance Program (EAESP) (<http://staffonly.ba.ars.usda.gov/animal-care/health.html>) or that I am covered by a similar program in force at another institution.

\*\*Signature: \_\_\_\_\_

Name: (b) (6)

Duties: A ☐, B ☐, C ☐, D ☐, E ☐, F ☐, G ☒, H ☐

Degree and/or relevant certifications: D.V.M.

Title: Visiting scientist

Qualifications: (b) (6) has 1 year experience of anesthesia, drawing blood samples from peripheral veins or heart, and sacrificing cats-she learnt as part of her DVM training.

I certify that I have read and understand the protocol, and that I either have or will develop the

necessary skills/expertise to perform my assigned duties so as to ensure the humane treatment of animals and to minimize animal discomfort. Further, I certify that I am aware of the Employee Animal Exposure Surveillance Program (EAESP) (<http://staffonly.ba.ars.usda.gov/animal-care/health.html>) or that I am covered by a similar program in force at another institution.

(b) (6)  
 \*\*Signature: \_\_\_\_\_

Name: (b) (6)  
 Duties: A ☐, B ☒, C ☐, D ☐, E ☐, F ☐, G ☒, H ☒  
 Degree and/or relevant certifications: Ph.D.  
 Title: Visiting Scientist

Qualifications: Two years experience of anesthesia, drawing blood samples from peripheral veins or heart, and sacrificing cats. Has obtained training in inserting microchips in cats.

(b) (6)  
 \*\*Signature: \_\_\_\_\_

Name: RSS  
 Duties: A ☒, B ☐, C ☐, D ☐, E ☐, F ☐, G ☐, H ☐  
 Degree and/or relevant certifications: **Varying degrees of formal education and AALAS certification, depending on the individual.**  
 Title: Animal care taker  
 Qualifications: **These individuals have varying levels of experience in the routine husbandry and care of laboratory animals and will not perform technical procedures without BAACUC approval and only with proper training and supervision.**

I certify that I have read and understand the protocol, and that I either have or will develop the necessary skills/expertise to perform my assigned duties so as to ensure the humane treatment of animals and to minimize animal discomfort. Further, I certify that I am aware of the Employee Animal Exposure Surveillance Program (EAESP) (<http://staffonly.ba.ars.usda.gov/animal-care/health.html>) or that I am covered by a similar program in force at another institution.

\*\*Signature: \_\_\_\_\_

**\*\*Signatures from the personnel listed above should be obtained after the protocol has received verbal "final" approval from the BAACUC and prior to submitting a hardcopy to the Animal Care Compliance Office.**

#### Principal Investigator Certification

Please check the appropriate box below:

- ☒ I certify that **all** of the individuals listed above have the appropriate expertise and/or training to perform the techniques associated with their assigned duties.
- ☐ I certify that **one or more** of the individuals listed above require further experience and/or training to enable them to perform their assigned duties.

Please indicate the individuals that require further training, who will supervise their training, and how they will be trained:

PI Initial: JPahy

**V. Animals to Be Used in This Protocol****A. Description of animals to be used.**Species: **Feline**Sex: **male & female**Breed/Strain: **Domestic short hair, mixed**Age: **2 months to 6 years**Weight: **500 grams or more**

B. Estimated number of animals.      Year 1: **100**  
    Year 2: **100**  
    Year 3: **100**  
    Total: **300**

In the past 3 years the PI has used only cats from BARC facility, except replacement breeder male.

**C. Source of animals.**

Purchased:    Yes    ☒                      No                      ☒

Vendor: **Liberty lab**City/State: **Kimballton, Iowa**

Vendor:

City/State:

Vendor:

City/State:

BARC herd or flock: Yes    ☒                      No                      ☐

Unit: APU ☐, Beef ☐, BHNRC ☐, Dairy ☐, Poultry ☐, Swine ☐

**D. Location of animal housing and research.**

BARC: Yes ☒                      No                      ☐

Unit: APU ☒, Beef ☐, BHNRC ☐, Dairy ☐, Poultry ☐, Swine ☐

Building/Room number: **(b) (6)**

Non-BARC location: Yes ☐                      No ☐

If yes, please provide the address of this location:

If yes, will the animals be covered by a different IACUC protocol while at the non-BARC location? Yes ☐                      No ☐

If yes, please provide the name and contact information of the IACUC chair or the collaborating scientist who will secure IACUC approval at that location.

Contact name:

Title of Contact:

Phone number:

E. Cage or pen type/size/bedding material/number of animals per unit (if appropriate):  
**individual cages 22.50" w X 30"d X 30.25" h--The cats are housed individually in individual cages only for a period of 1-3 weeks during the time of fecal collection. in building (b) (6). Enrichment will be provided for animals housed in individual cages.**

F. Is a quarantine/acclimation period required: Yes ☐ No X ☐

If Yes, please specify time period and location:

G. Will this protocol involve the transportation of animals (other than delivery by a commercial vendor)? Yes ☐ No X ☐

If Yes, will transportation be performed in accordance with either the *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Training* or the *Guide for the Care and Use of Laboratory Animals*?

Yes ☐

No X ☐; if no, why not?

Description of Animal Transport (locations of origin and destination; type of vehicle and caging used for transport; whether the vehicle is climate controlled; approximate length of time of transport; whether a non-skid surface will be used; etc):



## VI. Consideration of Alternatives to Animal Use

- A. How will the proposed use of animals improve the health of people or animals, and/or advance the interests of the agricultural, veterinary, or medical community? (In general, a compelling potential for benefit is needed to warrant the use of animals.)

**Currently, there is no vaccine for prevention of toxoplasmosis in humans or livestock. The proposed research using cats will assist in developing a vaccine to prevent needless suffering caused by this parasite in humans or animals.**

- B. Rationale for Use of Animals - Provide a brief narrative statement stating why it is necessary to use animals for this study and your determination that alternatives to their use do not exist:

**Toxoplasma oocysts can not be produced in cell culture or any other animal species. Cats are also needed to detect parasites in tissues of farm animals, because they are the most sensitive animal to use for the bioassay.**

***Hammondia hammondi* is very close relative of *T. gondii*. It is nonpathogenic for cats and other animals. It is of no public health significance, but it is managed just like *Toxoplasma*. Oocysts of this parasite are planned to be used by collaborator (NIH grant, Univ. of Pittsburg) to study its genetic make up for possible use for immunoprophylaxis.**

- C. Appropriateness of the Animal Species - Provide a brief narrative statement as to the appropriateness of the species being used **and** why a lower phylogenetic species would not be an acceptable substitute:

**This work cannot be performed in any other species because *Toxoplasma* oocysts are produced only in cat and oocysts are needed to study efficacy of the vaccine and to develop protocols to reduce environmental contamination due to this parasite..**

- D. Appropriateness of the Number of Animals to be Used - Provide a brief narrative statement as to why it is necessary to use this number of animals. A statistical justification is required when appropriate. Where the number of animals required is dictated by other than statistical considerations (such as the amount of tissue needed, period of viability, etc.) justify the number of animals requested on this basis:

**The total number of cats used per year is variable and depends on the tissues received from cooperators and the number of *Toxoplasma* strains detected. In addition, *T. gondii* strains of different genetic characteristics are revived periodically, first in mice and then cycled through cats. The number of cats proposed to be used is an estimate based on work in previous years.**

## **VII. Consideration of Alternatives to Pain and Distress**

### **A. Classification of Pain and Distress**

Check the appropriate category and indicate the approximate number of animals in each category. The sum of all categories should equal the number of animals indicated in Section V.

- ☒ Category C - Minimal, transient, or no pain or distress:  
☐ Category D - Pain or distress relieved by appropriate measures \*\*\*:  
☐ Category E - Unrelieved pain or distress \*\*\*:

\*\*\* FOR ANIMALS INDICATED IN CATEGORY D and E, A WRITTEN SCIENTIFIC JUSTIFICATION IS REQUIRED TO EXPLAIN WHY THE APPROPRIATE USE OF ANESTHETICS, ANALGESICS, SEDATIVES OR TRANQUILIZERS ARE CONTRAINDICATED IN THIS PROTOCOL. ATTACH AS SEPARATE SHEET(S).

### **B. Principal Investigator Certification**

FOR ALL CATEGORY D AND E PROPOSALS, I certify that I have reviewed the pertinent scientific literature and the sources and/or databases noted below and have found no valid alternative to any procedures described herein which may cause more than momentary pain or distress to animals whether it is relieved or not. Further, I certify that the proposed research in this protocol is not an unwarranted duplication of previously conducted research. (Please attach a copy of the literature review.)

Date search performed:

Databases searched (more than 1 database must be searched):

Keywords used in search:

Time period covered by search:

Results of search:

Were any applicable alternatives for the reduction, refinement, and/or replacement of animals to be used in your proposed research identified?

Yes ☐ No ☐

Does your proposed research represent an unnecessary duplication of previously conducted research? Yes ☐ No ☐

PI Initial: 

\*Note: The Animal Welfare Information Center (AWIC) is available for conducting searches for alternative or duplicative use of animals. The purpose of the alternative search is to address the 3'Rs of Alternatives: Reduction, Refinement and Replacement of animal models. Their contact information is listed below:

**The Animal Welfare Information Center, ARS, NAL**  
**10301 Baltimore Avenue, 5<sup>th</sup> Floor Beltsville, MD 20705-2351**  
**Phone: (301) 504-6212 | FAX: (301) 504-7125 | E-mail: [awic@nal.usda.gov](mailto:awic@nal.usda.gov)**  
**Internet: [www.nal.usda.gov/awic](http://www.nal.usda.gov/awic)**

## VIII. Description of Experiment(s) in this AUP

- A. State the scientific goals and hypothesis to be tested: **One of the goals of the project is to survey farm animals and retail meat stores for the presence of viable Toxoplasma so that control measures can be devised to reduce microbial contamination in meat. Through the use of cats as biological detectors, we hypothesize that Toxoplasma will be detected in commercial retail meats and the isolates will be genetically defined. Hammondia infected mice or cats are treated like Toxoplasma—exact same procedures are used for both organisms.**
- B. Procedures [Explain **ALL** animal manipulations in all of the proposed procedures and specific animal care requirements for each procedure. Attach extra page(s) if needed as well as any referenced SOP's. Use flow sheet or outline style whenever possible with details of each animal procedure described in the sequence to be done so that the purpose is clear. **Specific information needs to be provided** (e.g., number of animals to be subjected to each procedure; needle gauge and length; injection site location; number of times a procedure will be performed; approximate length of time a procedure will take; method/length of time of restraint; approximate length of study period/experiment). Please define any acronyms upon first use.]:
- \*Note: A detailed description of euthanasia procedures (if applicable) should be provided in Section XII.**
1. Two month old or older cats (both male and females, cats of all ages can be used for this study) are housed individually in cages in building (b) (6). Cats are housed in cages for collection of feces. Each cat is microchipped and a blood sample is collected at the time of weaning in building (b) (6).
  - A. 2. To maintain a source of oocysts from known Toxoplasma strains for experiments and for bioassays to assess food samples of unknown status, approximately 100 cats per year are allowed to consume suspect animal tissues free choice (up to 600 grams or as much as a cat normally consumes over a 2-4 day interval) over a period of 2-4 days. During this interim, tissues to be tested are stored in refrigerator. Feces produced by cats are collected daily from the litter box provided in each cat cage to prevent sporulation (infectious stage) of oocysts and using separate gloves and tongue depressors between cages to avoid cross-contamination. Separate refrigerators are available for storage of cat feces and suspect food samples. Infection is determined by the identification of oocysts in the feces. During the period of oocyst shedding (between 3 and 14 days after feeding test tissue), special care is taken while handling cages and cats to avoid inadvertent exposure of personnel. Cats are sacrificed at the end of oocyst shedding period (usually 2 weeks after infection). In addition, appropriate biohazard signs are posted on cages. Remains of all cats are incinerated to prevent spread of Toxoplasma. The following procedure is followed for fecal collection.
  - B. The fecal collection period begins the third day from the day a cat was first fed meat (ex. If a cat was fed on the 17th the first day of collection begins on the 20th) and continues until the cat is euthanized or a caretaker is otherwise instructed to



stop collections \*The day the cat was first fed meat is recorded on the cage\*

1. Plastic cups and lids are provided for fecal collection
2. Label each cup with the cat identification number and the date
3. Use a gloved hand to collect ALL the fecal material out of the litter box
4. Add 50ml of water to each fecal cup before closing
5. Cups are to be placed in the designated refrigerator after collection
6. If a cat does not defecate, do the following:
  - A. Administer LAXATONE by smearing a 1 inch long streak on either their face or front paws – do not put it in the food dish because they will not eat it.
  - B. Record the date, number and problem in the animal health log book
7. \*CHANGE GLOVES IN BETWEEN EACH CAGE, WEAR PROTECTIVE GEAR ( boot covers, coverhaul) AND A MASK\*
8. Once the collection period has begun, DO NOT empty the bottom cage pans until the cat is euthanized to minimize spread of oocysts in the feces that might have fallen in the bottom tray.
9. ALL bedding is to be emptied into biohazard boxes (it is best to use 1 box for every 2 racks).
10. Sweep the floor and clean the sink every day
11. Cages will be removed from the building and run through the cage washer upon termination of the experiment.
12. The building is to be steam cleaned before the cages are returned to the building.

#### Summary of of fecal collection

| Day of experiment | Procedure                            | Storage in refrigerator                      |
|-------------------|--------------------------------------|--|
| 0                 | cats identified, cages marked        |  |
| 0-2               | cats fed meat sample,                | Remaining meat sample stored in refrigerator |
| 3                 | Start fecal collection               | Store feces in refrigerator                  |
| 4-14              | Continue fecal collection            |  |
| 15 or earlier     | Euthanasia, cage marked contaminated |  |
| 16 or later       | Remove cages for cleaning            |  |

1.

- C. Expected results/use of this research: **The overall objective is to find sources of Toxoplasma infection for humans and food animals and to plan control strategies, including development of a vaccine.**

### **IX. Description of Health Complications and/or Adverse Reactions Associated with Non-Surgical Procedures**

(This section is NOT intended to include a detailed description of the procedure itself, but rather a description of health concerns/complications that could arise as a result of performing a given **non-surgical** procedure. Detailed descriptions of the actual procedures should be provided in Section VIII.B.).

C. Name of procedure(s).

1. procedure #1: **Feeding Toxoplasma infected tissues to cats for collection of oocysts**
2. procedure #2:
3. procedure #3:
4. procedure #4:

D. Give signs of disease/illness that may be expected to occur as a result of the procedure(s) listed in IX.A.

1. procedure #1: **Cats fed Toxoplasma-infected tissues usually do not become sick. Most cats are euthanized 1 week after they start shedding oocysts (total period of 2 weeks from the time they are fed infected tissues). Some cats become constipated and are given laxatone. If any cats become sick the attending veterinarian has the authority to treat or euthanize the cat.**
2. procedure #2:
3. procedure #3:
4. procedure #4:

E. Give methods of care/treatment that may be provided to alleviate the disease/illness that may arise for each procedure listed in IX.A:

1. procedure #1: **Veterinarian has the authority to treat.**
2. procedure #2:
3. procedure #3:
4. procedure #4:

F. If an animal develops signs of disease regardless of whether it is related to the above procedures, will analgesics and/or other palliative care be provided at the discretion of the P.I., RSS, and/or Veterinary Services?

Yes X ☐

No ☐

If yes, please indicate if there are any limitations to the care/treatment that can be provided (e.g., restricted use of antibiotics):

If no, please provide a scientific justification:

G. What other special care/handling is necessary for these animals? The procedure is detailed in section VIII.

# **X. Description of Health Complications and/or Adverse Reactions Associated with Surgical Procedures**

(This section is NOT intended to include a detailed description of the procedure itself, but rather a description of health concerns/complications that could arise as a result of performing a given **surgical** procedure. Detailed descriptions of the actual procedures should be provided in Section VIII.B.). **NO SURGICAL PROCEDURES**

**A. Name of surgical procedure(s). NONE**

1. procedure #1:
2. procedure #2:
3. procedure #3:
4. procedure #4:

**B. Percentage of Animals Subjected to Survival Surgery: Non-Survival:**

**C. Procedure(s) for which anesthesia, analgesia or tranquilization is used to prevent or diminish pain or distress:**

(For **each** procedure, please include drug, dose, and route of administration.)

|    | <u>Drug</u> | <u>Dose</u> | <u>Route</u> |
|----|-------------|-------------|--------------|
| 1) |             |             |              |
| 2) |             |             |              |
| 3) |             |             |              |
| 4) |             |             |              |
| 5) |             |             |              |

**D. Describe the monitoring procedures of animals receiving anesthesia, analgesics or tranquilizers while undergoing surgical procedures and during the immediate post-operative recovery period:**

**E. Post-operative pain or distress.**

Will analgesics/tranquilizers be used for post-operative pain?

If Yes, Drug/Dose/Route/Durations:

|    | <u>Drug</u> | <u>Dose</u> | <u>Route</u> | <u>Duration</u> |
|----|-------------|-------------|--------------|-----------------|
| 1) |             |             |              |                 |
| 2) |             |             |              |                 |
| 3) |             |             |              |                 |
| 4) |             |             |              |                 |
| 5) |             |             |              |                 |

If NO, justify:

Describe the monitoring procedures of animals receiving post-operative analgesics or tranquilizers:

F. Post-operative care.

Post-operative routine:

How Long?

Who will provide?

What drugs/antibiotics administered? (type/doses/frequency)

What post-operative complications may be expected and what is the preferred treatment for such complications?

G. Multiple surgical procedures.

Will individual animals be subjected to more than one major survival surgical procedure?

If Yes, give explanation/justification:

**XI. Disposition of Animals Used in this Protocol**

If more than one method of disposition is to be used, be explicit concerning circumstances and number of animals.

- A. Live, healthy animals will be disposed of as surplus government property.

Yes ☐ %

No x ☐ 100 %

- B. Animals will be returned to the BARC herd/flock/colony.

Yes ☐ %

No X ☐ 100 %

If yes, is there a post-experimental withdrawal period?

- C. Animals will be transferred to another BAACUC protocol.

Yes ☐ %

No X ☐ 100 %

If yes, please identify the P.I. and the BAACUC-assigned number of the protocol to which the animals will be transferred?

- D. Animals will be euthanized.

Yes x ☐ 100 %

No ☐ %

**If animals will be euthanized, please complete section XII.**

## XII. Description of Euthanasia Procedures

\*Please note that with the exception of some physical means of euthanasia, the BAACUC requires that both a primary and secondary euthanasia procedure be performed. Please refer to this policy at: <http://staffonly.ba.ars.usda.gov/animal-care/policy-010.html>

A. Location where euthanasia will be performed (Bldg./Room#): (b) (6)

B. Will other animals be present in the same room where euthanasia will occur?

Yes ☐

No x ☒

If yes, the *AVMA Guidelines on Euthanasia* and the *Guide for the Care and Use of Laboratory Animals* state that to minimize animal stress other animals should not be present when euthanasia is performed. Please indicate what steps will be taken to shield other animals from visual, acoustic, and/or pheromonal signals of animals undergoing euthanasia. Separate room

C. Primary method of euthanasia.

1. Name of method: **chemical**

2. Description of method: Ketamine at 10 mg/kg body weight in combination with xylazine at 1 mg/kg body weight administered intramuscularly or subcutaneously to anesthetize cats before intracardiac administration of a barbiturate overdose (Beuthanasia, Schering-Plough Animal Health at 1mg/10 lb body weight )Beuthanasia, Schering-Plough Animal Health administered intracardiac at 1 mg/10 lbs body weight. For this cat is held firmly by grasping back of the neck and anesthetic (0.25-0.5ml) injected at the back of the neck. When cat has been fully anesthetized, the cat is laid on its side on a table lined with absorbent pad inside a biohazard bag so that any spilled material remains contained in the bag. The beating of the heart is sensed by fingers over the thorax and euthanasia solution (1.0-2.0 ml) is injected directly in the heart. After heart beat is no longer felt, the thorax is opened to complete the euthanasia procedure.

3. In accordance with the most recent *AVMA Guidelines on Euthanasia* ([http://www.avma.org/issues/animal\\_welfare/euthanasia.pdf](http://www.avma.org/issues/animal_welfare/euthanasia.pdf)) for the species to be euthanized, indicate whether this method is:

Acceptable x ☒

Conditionally Acceptable ☐

Unacceptable ☐

If this is a conditionally acceptable or unacceptable method, please provide a scientific justification for using this method:

D. Secondary method of euthanasia.

1. Name of method: **Thoracotomy**

2. Description of method: An incision is made through an intercostal space to

ensure pneumothorax.

E. Method of carcass disposal (list percentages of animals next to appropriate method).

Incineration: x ☐ 100 %

Other: ☐ %

If "other", please specify method:

**The biohazard bag containing the cat carcass are tied and then enclosed in another biohazard bag for safety; the bagged cat is put in boxes labeled for incineration.**



## **Animal Use Protocol Amendment**

**AUP Approval #: 15-018**

**Date submitted: 8-10-2017**

**AUP Approval Date: 5/19/2015**

**Protocol Title: Toxoplasmosis in cats**

**Species Approved: Cats**

**Principal Investigator: Jitender Dubey**

**Location: APU, Beltsville, MD**

**Telephone: 301-504-8128 Fax: 301-504-9222**

**The purpose of this protocol amendment is to seek exemption for sanitization of cat cages infected with *Toxoplasma gondii*. Animal Welfare Regulation (AWR) 9 CFR, §3.11, 2 states that "used primary enclosures and food and water receptacles for dogs and cats must be sanitized at least once every 2 weeks". We are asking to sanitize the primary enclosure every 3 weeks; however, caging will be spot cleaned with appropriate disinfectant if needed. In addition, we will need to change the euthanasia timeframe of the cats from 2 weeks to 3 weeks' post infection.**

**1. ORIGINAL PROTOCOL:** Please provide below a description and copy of what was previously approved in the above AUP. (Recommended to cut and paste from originally approved protocol all pertinent information).

### **VIII. Description of Experiment(s) in this AUP**

**B. Procedures [Explain ALL animal manipulations in all of the proposed procedures and specific animal care requirements for each procedure. Attach extra page(s) if needed as well as any referenced SOP's. Use flow sheet or outline style whenever possible with details of each animal procedure described in the sequence to be done so that the purpose is clear. **Specific information needs to be provided (e.g., number of animals to be subjected to each procedure; needle gauge and length; injection site location; number of times a procedure will be performed; approximate length of time a procedure will take; method/length of time of restraint; approximate length of study period/experiment). Please define any acronyms upon first use.]:****

**\*Note: A detailed description of euthanasia procedures (if applicable) should be provided in Section XII.**

**During the period of oocyst shedding (between 3 and 14 days after feeding test tissue), special care is taken while handling cages and cats to avoid inadvertent exposure to personnel. Cats are sacrificed at the end of the oocyst shedding period (usually 2 weeks after infection).**

2. **PROPOSED CHANGE:** Please provide below the proposed change(s) in detail.  
(Please include another page if necessary):

Cats are normally euthanized within 2 weeks after feeding Toxoplasma and after the cats have stopped shedding oocysts. However, in some cases cats can shed oocysts for up to 3 weeks. Request is being proposed to delay euthanasia until day 22 of the experiment.

All other aspects of the experiment remain unchanged.

Principal Investigator:  Date: 8/10/17  
Signature

Research Leader:  Date: 8/10/17  
Signature

**No changes in Animal Use Protocols may be initiated prior to receiving IACUC approval.**

## Animal Use Protocol Amendment

**AUP Approval #: 15-018**

**AUP Approval Date: 5/19/2015**

**Protocol Title: Toxoplasmosis in cats**

**Species Approved: Cats**

**Principal Investigator: Jitender Dubey**

**Location: APU, Beltsville, MD**

**Telephone: 301-504-8128 Fax: 301-504-9222**

**The purpose of this protocol amendment is to add personnel to the originally approved protocol and change category from C to category E—section VII**

### ORIGINALLY APPROVED

**Name: J.P.Dubey**

**Duties: A ☐, B ☐, C ☐, D ☐, E ☐, F ☐, G X ☒, H ☐**

**Degree and/or relevant certifications: B.V.Sc., P.H.D.**

**Title: Microbiologist**

**Qualifications: Dr. Dubey has 40 years of experience in handling cats, inducing minor anesthesia, drawing blood samples from peripheral veins or heart, and sacrificing cats**

I certify that I have read and understand the protocol, and that I either have or will develop the necessary skills/expertise to perform my assigned duties so as to ensure the humane treatment of animals and to minimize animal discomfort. Further, I certify that I am aware of the Employee Animal Exposure Surveillance Program (EAESP) (<http://staffonly.ba.ars.usda.gov/animal-care/health.html>) or that I am covered by a similar program in force at another institution.

**\*\*Signature: \_\_\_\_\_**

**Name: (b) (6)**

**Duties: A ☐, B ☐, C ☐, D ☐, E ☐, F ☐, G X ☒, H ☐**

**Degree and/or relevant certifications: D.V.M.**

**Title: Visiting scientist**

**Qualifications: (b) (6) has 1 year experience of anesthesia, drawing blood samples from peripheral veins or heart, and sacrificing cats-she learnt as part of her DVM training.**

I certify that I have read and understand the protocol, and that I either have or will develop the necessary skills/expertise to perform my assigned duties so as to ensure the humane treatment of animals and to minimize animal discomfort. Further, I certify that I am aware of the Employee Animal Exposure Surveillance Program (EAESP) (<http://staffonly.ba.ars.usda.gov/animal-care/health.html>) or that I am covered by a similar program in force at another institution.

**\*\*Signature:** \_\_\_\_\_

Name: (b) (6)

Duties: A ☐, B ☒, C ☐, D ☐, E ☐, F ☐, G ☒, H ☒

Degree and/or relevant certifications: Ph.D.

Title: Visiting Scientist

Qualifications: Two years experience of anesthesia, drawing blood samples from peripheral veins or heart, and sacrificing cats. Has obtained training in inserting microchips in cats.

**\*\*Signature:** \_\_\_\_\_

Name: RSS

Duties: A ☒, B ☐, C ☐, D ☐, E ☐, F ☐, G ☐, H ☐

Degree and/or relevant certifications: **Varying degrees of formal education and AALAS certification, depending on the individual.**

Title: Animal care taker

Qualifications: **These individuals have varying levels of experience in the routine husbandry and care of laboratory animals and will not perform technical procedures without BAACUC approval and only with proper training and supervision.**

I certify that I have read and understand the protocol, and that I either have or will develop the necessary skills/expertise to perform my assigned duties so as to ensure the humane treatment of animals and to minimize animal discomfort. Further, I certify that I am aware of the Employee Animal Exposure Surveillance Program (EAESP) (<http://staffonly.ba.ars.usda.gov/animal-care/health.html>) or that I am covered by a similar program in force at another institution.

**\*\*Signature:** \_\_\_\_\_

**\*\*Signatures from the personnel listed above should be obtained after the protocol has received verbal "final" approval from the BAACUC and prior to submitting a hardcopy to the Animal Care Compliance Office.**

**Principal Investigator Certification**

Please check the appropriate box below:

☒ I certify that **all** of the individuals listed above have the appropriate expertise and/or training to perform the techniques associated with their assigned duties.

☐ I certify that **one or more** of the individuals listed above require further experience and/or training to enable them to perform their assigned duties.

Please indicate the individuals that require further training, who will supervise their training, and how they will be trained:

PI Initial: JR



**VII. Consideration of Alternatives to Pain and Distress****A. Classification of Pain and Distress**

Check the appropriate category and indicate the approximate number of animals in each category. The sum of all categories should equal the number of animals indicated in Section V.

- ☒ Category C - Minimal, transient, or no pain or distress: **300**  
☐ Category D - Pain or distress relieved by appropriate measures<sup>\*\*\*</sup>:  
☐ Category E - Unrelieved pain or distress<sup>\*\*\*</sup>:

**PROPOSED CHANGES**

**(b) (6)** is being added to the protocol to oversee the breeding and routine husbandry of the cat colony.

Name: **(b) (6)**

Duties: A ☒, B ☐, C ☐, D ☐, E ☐, F, G, H

Degree and/or relevant certifications: AALAS certification

Title: Animal caretaker

Qualifications: **11 years experience of management of cat breeding, and routine cat husbandry at BARC.**

I certify that I have read and understand the protocol, and that I either have or will develop the necessary skills/expertise to perform my assigned duties so as to ensure the humane treatment of animals and to minimize animal discomfort. Further, I certify that I am aware of the Employee Animal Exposure Surveillance Program (EAESP) (<http://staffonly.ba.ars.usda.gov/animal-care/health.html>) or that I am covered by a similar program in force at another institution.

**(b) (6)**  
 \*\*Signature: \_\_\_\_\_

**\*\*Signatures from the personnel listed above should be obtained after the protocol has received verbal "final" approval from the IACUC and prior to submitting a hardcopy to the Animal Care Compliance Office.**

**Principal Investigator Certification**

Please check the appropriate box below:

- ☒ I certify that **all** of the individuals listed above have the appropriate expertise and/or training to perform the techniques associated with their assigned duties.
- ☐ I certify that **one or more** of the individuals listed above require further experience and/or training to enable them to perform their assigned duties.

Please indicate the individuals that require further training, who will supervise

their training, and how they will be trained:

PI Initial: \_\_\_\_\_

## **VII. Consideration of Alternatives to Pain and Distress**

**\*\*\*FOR ANIMALS INDICATED IN CATEGORY D and E, A WRITTEN SCIENTIFIC JUSTIFICATION IS REQUIRED TO EXPLAIN WHY THE APPROPRIATE USE OF ANESTHETICS, ANALGESICS, SEDATIVES OR TRANQUILIZERS ARE CONTRAINDICATED IN THIS PROTOCOL. ATTACH AS SEPARATE SHEET(S).**

### **A. Principal Investigator Certification**

FOR ALL CATEGORY D AND E PROPOSALS, I certify that I have reviewed the pertinent scientific literature and the sources and/or databases noted below and have found no valid alternative to any procedures described herein which may cause more than momentary pain or distress to animals whether it is relieved or not. Further, I certify that the proposed research in this protocol is not an unwarranted duplication of previously conducted research. (Please attach a copy of the literature review.)

Date search performed: **10-26-2016**

Databases searched (more than 1 database must be searched):

Keywords used in search: DigiTop Navigator which includes Agricola, Biosis, CAB Abstracts, Medline, Zoological Record

Time period covered by search: 2006-2016

Results of search:

Were any applicable alternatives for the reduction, refinement, and/or replacement of animals to be used in your proposed research identified?

Yes ☐ No ☒

Does your proposed research represent an unnecessary duplication of previously conducted research? Yes ☐ No ☒

PI Initial: gA

**\*Note:** The Animal Welfare Information Center (AWIC) is available for conducting searches for alternative or duplicative use of animals. The purpose of the alternative search is to address the 3'Rs of Alternatives: Reduction, Refinement and Replacement of animal models. Their contact information is listed below:

**The Animal Welfare Information Center, ARS, NAL**  
**10301 Baltimore Avenue, 5<sup>th</sup> Floor Beltsville, MD 20705-2351**  
**Phone: (301) 504-6212 | FAX: (301) 504-7125 | E-mail: awic@nal.usda.gov**  
**Internet: www.nal.usda.gov/awic**

Appropriate anesthetics, sedatives, and tranquilizers will be used by the attending veterinarian. Euthanasia will be performed if symptoms are not relieved.

**B. Classification of Pain and Distress**

Check the appropriate category and indicate the approximate number of animals in each category. The sum of all categories should equal the number of animals indicated in Section V.

- ☐ Category C - Minimal, transient, or no pain or distress:  
☒ Category D - Pain or distress relieved by appropriate measures\*\*\*: 298  
☒ Category E - Unrelieved pain or distress\*\*\*: 2

**IX. Description of Health Complications and/or Adverse Reactions Associated with Non-Surgical Procedures**

(This section is NOT intended to include a detailed description of the procedure itself, but rather a description of health concerns/complications that could arise as a result of performing a given non-surgical procedure. Detailed descriptions of the actual procedures should be provided in Section VIII.B.).

**A. Name of procedure(s).**

1. procedure #1: **Feeding Toxoplasma infected tissues to cats for collection of oocysts**
2. procedure #2:
3. procedure #3:
4. procedure #4:

**B. Give signs of disease/illness that may be expected to occur as a result of the procedure(s) listed in IX.A.**

1. procedure #1: Cats fed Toxoplasma-infected tissues usually do not become sick. Most cats are euthanized 1 week after they start shedding oocysts (total period of 2 weeks from the time they are fed infected tissues). Some cats become constipated and are given laxatone. If any cats become sick the attending veterinarian has the authority to treat or euthanize the cat. Rarely (less than 3%) cats can die of acute toxoplasmosis, without prior clinical signs.

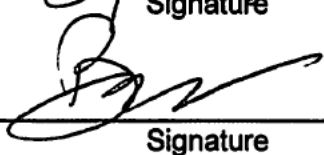
Cats will be monitored twice daily for alertness, eating food, and general appearance using a scoring system. Daily records of health are available in the cat room Building (b) (6)

**JUSTIFICATION**

For the present research, viable Toxoplasma oocysts are needed for experiments and for collaborative research with other investigators. For unknown reasons, viable oocysts cannot be produced by *in vitro* methods and can only be propagated in the intestine of cats. The oocysts are typically shed in the feces 5 -14 days after infection, during which time most cats remain asymptomatic until euthanasia at 22 days post-infection. These animals are classified as USDA Pain/Distress Category D because animals are given appropriate analgesics and/or anesthetics to relieve pain/distress that may occur. Occasionally a small percentage of cats (estimated 3%)

may die acutely without presenting signs or develop other complications that may not respond to treatment following infection. These animals will be reported as Category E.

Principal Investigator:  Date: 8/10/17  
Signature

Research Leader:  Date: 8/10/17  
Signature

**No changes in Animal Use Protocols may be initiated prior to receiving IACUC approval.**



**Animal Use Protocol Amendment**

AUP Approval #: 15-018  
AUP Approval Date: 5-19-2015  
Protocol Title: Toxoplasmosis in cats  
Species Approved: Cats  
Principal Investigator: Jitender P. Dubey  
Location: USDA, BARC, APDL  
1001, Beltsville, MD20705  
Telephone: 301-504-8128 Fax: 301-504-9222

The purpose of this amendment is to modify the originally approved protocol to include an SOP for breeding cats. See attached SOP.

- 1) **ORIGINAL PROTOCOL:** Please provide below a description and copy of what was previously approved in the above AUP. (Recommended to cut and paste from originally approved protocol all pertinent information).

**V. Animals to Be Used in This Protocol****A. Description of animals to be used.**

Species: **Feline**  
Sex: **male & female**  
Breed/Strain: **Domestic short hair, mixed**  
Age: **2 months to 6 years**  
Weight: **500 grams or more**

|                                 |                    |
|---------------------------------|--------------------|
| B. Estimated number of animals. | Year 1: <b>100</b> |
|                                 | Year 2: <b>100</b> |
|                                 | Year 3: <b>100</b> |
|                                 | Total: <b>300</b>  |

In the past 3 years the PI has used only cats from BARC facility, except replacement breeder male.

2. **PROPOSED CHANGE:** Please provide below the proposed change(s) in detail. (Please include another page if necessary):

**V. Animals to Be Used in This Protocol****A. Description of animals to be used.**

Species: **Feline**  
Sex: **male & female**  
Breed/Strain: **Domestic short hair, mixed**  
Age: **2 months to 12 years**  
Weight: **500 grams or more**

Please see below the addition of the toms and queens to be used per year.

|                                 |  |
|---------------------------------|--|
| B. Estimated number of animals. | Year 1: <b>2 toms, 14 queens, 100 kittens</b>        |
|                                 | Year 2: <b>2 toms, 14 queens, 100 kittens</b>        |
|                                 | Year 3: <b><u>2 toms, 14 queens, 100 kittens</u></b> |
|                                 | Total: <b>2 toms, 14 queens, 300 kittens</b>         |

In the past 3 years the PI has used only cats from BARC facility managed under the breeding SOP, except replacement breeder male.

Principal Investigator: J.P. Dubey  Date: 7-2-2015

Research Leader:  Date: 9/16/2015

**No changes in Animal Use Protocols may be initiated prior to receiving BAACUC approval.**

# **Standard Operating Procedures**

USDA, APU, RSS

Small Animal Unit, Building (b) (6), BARC

**TITLE: Feline Breeding Husbandry**

**SCOPE: Animal Care Personnel**

**RESPONSIBILITY: Facility Manager, Technical Staff, Veterinary Staff**

**PURPOSE:** To outline the proper procedures for breeding, pregnancy, parturition and husbandry practices related to cats and the maintenance of the expansion colony, to produce a sufficient number of study animals to be used for Toxoplasmosis research. **The breeding cat colony is non-infectious and is located in building (b) (6). Cats are moved to another location for experimental purposes.**

## **I. PURPOSE**

1. To provide the highest quality of animal care and preclude the development of spontaneous diseases or disorders, which could compromise the integrity of studies and the interpretation of results.
2. To ensure the proper handling of cats and that personnel perform their duties in a manner that complies with all current governing laws, regulations and guidelines.

## **II. RESPONSIBILITY**

1. Veterinary Services will oversee all aspects of animal health with assistance from the animal husbandry and research staff as needed.
2. Animal husbandry staff is responsible for the daily husbandry procedures of the breeding animals and offspring.

## **III. PROCEDURES**

### **Breeding Toms**

1. Toms **MUST** have a health check by Veterinary services at a minimum of once per year.
2. Toms must be physically and emotionally mature and be of at least 12 months of age prior to mating. Routine care will be according to the "Cat Husbandry" SOP.
3. Toms are to be fed a high fat diet 50/50 kitten/cat chow mix, 1 month prior to breeding and continue on said diet throughout the course of breeding.
4. Toms must be rested for 2 days after 35 consecutive days of breeding.

5. Toms will be individually housed except when breeding to prevent fighting. Toms will be provided at minimum 30 minutes outside of the cage per week and be given personal attention by the caretaker every day as additional environmental enrichment.

### **Breeding Queens**

1. Queens **MUST** have a health check by Veterinary services at a minimum of once per year.
2. Queens must be physically and emotionally mature and be of at least 12 months of age prior to mating.
3. Do NOT allow a queen to come into heat more than 3 times without breeding as this could cause her to develop pyometra ( i.e. an infection of the uterus) or may leave queen with "cystic ovaries" which may render the queen infertile.
4. Queens come into estrus (heat) many times during the year. It is the time when the female is sexually receptive to the male. The heat period usually lasts 3 to 16 days with the average being 7 days. If the queen is not bred, she will come back into heat in 1 or 2 weeks. The cycle continues for several heat cycles, or until the queen is bred. Queens in estrus become very affectionate, rubbing on you, rolling on the floor, and constantly wanting attention. When you stroke along her back, she'll raise her hindquarters and tread with her back legs (royal stance). Another obvious sign of heat in cats is that they become very vocal.
5. Cats are induced ovulators. The act of mating stimulates or induces ovulation; release of the eggs (ova) from the ovaries.
6. Breeding Queens are to be fed a high fat diet of 50/50 kitten/cat chow mix *ad libitum*, starting 1 month prior to breeding. Queens are to stay on said diet throughout breeding, pregnancy and the nursing period.
7. The condition of the animals, and the time period between the previous parturition is to be taken into consideration prior to breeding. Individual Queens may have **NO** more than 2 litters in a 12 month period.

### **Breeding Procedure**

1. Prior to breeding check the lineage of the toms and queens in the *Cat Record Book* kept in the anteroom of room (b) (6). Do **NOT** in-breed (father/daughter or mother/son) and do **NOT** second degree in-breed (grandfather/granddaughter or grandmother/grandson).
2. Cats will be bred in a group mating system where one male will be kept with a group of females. With this system it is expected that an exact date of mating often is not always known and pregnancy is determined by a female gaining weight (see "**Pregnancy**" below). Not more than 7 females will be housed with a tom to maintain spacing requirements.

3. Select your breeding tom and place him in group room A or B within room (b) (6). Make certain to preselect your queens to be bred to your selected tom. After 35 days to allow for variations in estrus cycles, remove the breeding tom and return him to his cage in room (b) (6).
  - *If you witness a mating you **MUST** record the date(s) when the queen was bred so that you can accurately calculate her expected delivery date.*

### Pregnancy

1. Pregnant and/or bred queens will remain group housed until moved to an individual cage in room (b) (6) (see "Parturition" below).
2. Queens may experience morning sickness early in pregnancy and experience reduced appetite; once this has passed their appetite will increase.
3. Gestation lasts an average of 63 days, although anywhere between 60 and 67 days may be considered normal. To accurately calculate the expected delivery date, it is necessary to know the breeding date.
4. Pregnancy can be reliably diagnosed by abdominal palpation at 21-28 days pregnant where a "string of marbles" can often be palpated. This can be performed by individuals trained by Veterinary Services. In the event that a breeding date is not available, pregnancy can be assessed by monitoring weight gain. By approximately 5 weeks of gestation a queen will have gained about 0.5kg on average. During breeding weight should be measured at minimum bi-weekly.
5. There will be an obvious increase in the size of her belly and mammary glands as time progresses.
6. Nearing the time of parturition you may notice the queen looking for a quiet dark space or begin nesting; this is the time to move her to an individual cage in room (b) (6) if you have not already.

### Parturition

1. A minimum of 1 week prior to parturition/estimated due date as determined by breeding date, palpation or weight gain, queens are moved to room (b) (6) to a solitary cage and given two boxes, one to be used as a litter box, the other to be used as a nesting box.
2. The time between each kitten birth should be less than an hour and may be as little as a couple minutes. In rare instances, a cat may deliver a few kittens and then wait 24 hours to deliver the remainder of the litter. If parturition is not progressing normally the PI or Veterinary Services should be contacted (see "Complications" below). Litters range from one to eight kittens with three to four being the average.



### Complications During and After Parturition

1. A **Contact Sheet** is placed in each **Room Log Book** that identifies an individual(s) of the research staff to be contacted in the event of an emergency, their phone or pager #, and specific instructions for animals found moribund or dead for each IACUC protocol.
2. If a breeding related problem is encountered, animal care staff reviews the **Contact Sheet** for any specific instructions from the research staff.
3. Staff should immediately report all medical emergencies verbally directly to the Facility Supervisor or their designee, and to the PI or their designee, or if a Facility Supervisor is not available, to the Clinical Veterinarian or their designee.
4. When an animal is found with a breeding complication, the Facility Manager or their designee must notify the attending research staff immediately of the animal's condition, and request that the research staff assess the animal's condition immediately to resolve the problem, and if necessary contact the Clinical Veterinarian to ensure prompt resolution of the animal's condition. The animal care staff records that this communication took place in the Notes section of the **Daily Log Book** by recording the name and phone number of the person contacted.

| Vitals for Kittens & Cats |                           |                              |
|---------------------------|---------------------------|------------------------------|
| Parameter                 | Normal (based on average) | Emergency Value              |
| Temperature               | 100-102°F<br>(38-39° C)   | Below 97° F<br>Above 104° F  |
| Pulse                     | 120-160bpm                | Below 100bpm<br>Above 200bpm |
| Respiration               | 15-30bpm                  | Below 10bpm<br>Above 45bpm   |

#### **Specific complications that may arise:**

1. **Dystocia**- Difficult birth, may occur as a result of maternal or fetal factors, and can occur during any stage of the labor. Abnormalities of presentation, posture, and the position of the fetus within the uterus can negatively affect the temporal relationship between the birthing offspring and the maternal birth canal. This may occur because the mother's uterus is too small or too weak, because the mother has an infection or is too fatigued, or because the kitten has died. On average kittens are born every 2-30 minutes during labor. If a queen is in active labor and no progress has been made in over an hour the PI and veterinarian should be contacted. If a kitten is in the canal for more than 15 minutes, the pressure on the umbilical cord can fatally deprive it of oxygen. If a kitten is visibly present in the canal and no progress has been made in 10 minutes, gentle manual traction can be applied by the caretaker to assist the birth. *If the kitten is not born or other signs of dystocia occur call the veterinarian immediately.*

2. **Cross Fostering kittens-** is usually done to equalize litter size. Individual animals born in large litters are faced with much more competition for resources, such as breast milk, food and space, than individuals born in smaller litters. Sometimes it is needed for the health of the animal due to an inexperienced or overbearing mother. Place the kitten with a litter about the same age and size. Try to get the scent of the foster mother on the new kitten and closely monitor that the foster kitten is being accepted by the foster mother.
3. **Premature delivery-** when kittens are born several days early (prematurely), they are small, thin, and have little or no hair. They require round-the-clock care if they are to survive. Vaginal bleeding before the due date may indicate spontaneous abortion or the impending birth of premature kittens.
4. **Kittens birthed too close together-** This may cause the mother to fail to properly wash each kitten so that its breathing passages are not cleared, and it dies. Gently wash the kittens with a soft damp cloth to help the mother.
5. **Stillborn kittens-** It is relatively common for one or two kittens in a litter to be stillborn; to die shortly before or during delivery. The stillborn kitten may be delivered normally, or it may disrupt the birthing process and need to be removed for labor to proceed. If several kittens in a litter are stillborn, you should contact the veterinarian to determine the cause. Follow the steps at the start of this section if this situation is to occur.
6. **Umbilical Cord strangulation of limb-** Check kittens' umbilical cords immediately after parturition, the cord may get wrapped around the kittens' limb and cut off blood flow resulting in loss of limb or necessary euthanasia of the animal.
7. **Placental problems-** The mother may fail to cut off the placenta or may cut it too close to the abdomen, leading to a hole requiring surgery. The mother may also retain the placenta herself, which can lead to an infection called **metritis**, resulting in weight loss and neglect of her newborns.
8. **Uterine inertia** - (inactivity) may be primary or secondary, and can lead to dystocia.
  - Primary inertia is symptomized by a failure of the body to commence synchronous uterine contractions.
  - Secondary inertia is symptomized by a cessation of uterine contractions due to uterine fatigue. This latter condition sometimes occurs when labor has gone on longer than the uterine muscles are capable of meeting the demands for.
9. **Incompatible antibodies-** Most cats have type A blood, but if the mother has type B and her kitten type A, the antibodies in the mother's milk may harmfully destroy the kitten's red blood cells.

10. **Eclampsia**- milk fever; loss of calcium from the mother's body as a result of milk production. It is most likely to occur; when milk production is at its highest, which in cats is usually when the kittens are older (around 3 weeks of age) but still nursing. Eclampsia is more likely in cats with large litters. Signs include muscle spasms, stiff or spastic movements, and heavy panting. Eclampsia can be fatal; *call the veterinarian immediately if a nursing cat shows these signs.*

### **Breeding and Birthing Record**

1. A detailed record of breeding is to be kept in the *Cat Record Book* which is to include:
  - A. Animal ID's
  - B. Date animals entered the room
  - C. Room #
  - D. Heats Observed
  - E. Copulation observed
  - F. Estimated Due Dates
  - G. Date moved to cage for kitting
2. A detailed record is to be kept at the time of parturition which is to include:
  - A. Date
  - B. Cage #
  - C. Ease of delivery on a scale of 1-10 (1 is smooth delivery without any complications, 10 is complications requiring surgical intervention)
  - D. Overall Health of the kittens and Queen
  - E. Time of stages 1-3 if applicable
  - F. # of live births
  - G. # of stillborns

➤ *Note: There **MUST** be a minimum of 60 days between parturition and breeding. Animals overall health must be taken into consideration. ALL breeding information and observations **MUST** be entered into the Cat Medical Record as well as the Daily Log Book found in the anteroom of room (b)*

### **Retiring Breeders**

1. Breeders should be retired at 12 years of age or if production falls off. Genetic values should also be taken into consideration throughout the duration of mating.

### **Kitten Care**

1. Kittens will be examined by caretaker staff within 24 hours after parturition, or as soon as possible, to examine for birth defects. Any abnormalities should be communicated to the PI and veterinarian to determine the course of action.
2. Kittens will remain housed with the queen in an individual cage up until weaning. Caretaker staff should examine queen and kittens daily to ensure adequate milk and suckling.



3. Beginning at 3 weeks of age, kitten food moistened with warm water will be provided daily to encourage solid food consumption.
4. Queens typically begin self weaning the kittens around 6 weeks of age by spending more time away from the kittens and adopting postures that make her nipples inaccessible.
5. Daily observation of the queen and kittens will help determine the ideal time to separate the queen and kittens. Kittens should be observed eating the moistened kitten food. All kittens should be weaned by 8 weeks of age and moved to a separate cage, but often can be weaned at 6-7 weeks of age if the queen has fully weaned them already.
6. Once weaned, kittens will be cared for according to the “**Cat Husbandry**” SOP. PI and research staff will determine the animals that will proceed to go on study or those that will be selected to remain as the breeding stock.

# Exhibit K



September 18, 2018

The Honorable Sonny Perdue  
United States Secretary of Agriculture  
1400 Independence Ave. SW  
Washington, D.C. 20250

Dear Secretary Perdue,

On behalf of the New England Anti-Vivisection Society (NEAVS), I am writing to offer that NEAVS will, at no cost, help you fulfill the bipartisan Congressional guidance USDA has received, which is to work to adopt out the cats and kittens that USDA otherwise kills.

### **Background**

As you know, it was recently revealed that a series of experiments have been taking place at a USDA Animal Research Service (ARS) facility in Beltsville, Maryland for over 40 years involving kittens and cats. Every year at this facility, as many as 100 kittens are being fed food filled with sickening parasites so that the parasites can be harvested from their feces for other tests. After the tests are over, the otherwise healthy and adoptable cats and kittens are killed and incinerated. USDA data shows that 221 cats and kittens have been killed in this manner over the past 5 years alone, and nearly 3,000 since 1982 when the project began at the USDA.

There is no question that these kittens can be safely rehomed. The American Veterinary Medical Association (AVMA), the American Association of Veterinary Medical Colleges (AAVMC), and the U.S. Centers for Disease Control and Prevention (CDC) have confirmed that cats and kittens exposed to the virus in question—the Toxoplasma parasite—can be easily treated for this parasite.

### **Congressional Concern**

As you know, Congressional interest in this issue continues to grow. Bipartisan legislation has been introduced to end these tests. In addition, the upcoming bill to fund the USDA includes bipartisan report language that describes this set of tests as “painful and terminal laboratory experiments.” In that bill, which will soon be signed into law, Congress also explicitly directs USDA to “develop a program to adopt out cats no longer needed in research.”

### **Our Offer**

NEAVS strongly supports the Congressional call for USDA to explore how to avoid these unnecessary deaths with an adoption model. To facilitate this, NEAVS is prepared to cover any and all expenses associated with rehabilitating these kittens from your Beltsville facility, and will happily accept responsibility for them. NEAVS is willing to incur the costs for providing these cats and kittens with the required antibiotics, as well. NEAVS has relationships with many rescue groups, which we utilize in the rehoming of these animals. Our doing so would both help USDA achieve the Congressional mandate, and result in a net savings of taxpayer dollars to



USDA, as our intervention would save USDA the expenses associated with euthanization and disposal.

We hope you will consider this offer, which is made in good faith. We are eager to be helpful in sparing these animals from unnecessary euthanasia, and we appreciate your consideration.

Sincerely,

Nathan Hershler  
Executive Director  
New England Anti-Vivisection Society

CC: Chavonda Jacobs-Young, Administrator, ARS, USDA

# Exhibit L



November 20, 2018

The Honorable Sonny Perdue  
United States Secretary of Agriculture  
1400 Independence Ave. SW  
Washington, D.C. 20250

Dear Secretary Perdue,

On behalf of the New England Anti-Vivisection Society (NEAVS), I am writing regarding the September 18, 2018 offer NEAVS made to your office about the adoption of cats and kittens that are otherwise being killed unnecessarily after experiments taking place at the USDA Animal Research Service (ARS) facility in Beltsville, Maryland.

### **Federal Law Allows States to Set Additional Animal Welfare Standards**

The Animal Welfare Act (AWA), which governs the care of animals used in research, states plainly that if states set higher standards for animal care than the AWA does, that the federal government will follow state law in that state unless a federal law conflicts.<sup>1</sup>

The only exception to this is if the animal, at the end of the experiment, was determined to be in “*severe or chronic pain or distress that cannot be relieved.*”<sup>2</sup> That is not the case in these experiments, in which the kittens are only exposed to an extremely common parasite,<sup>3</sup> for which antibiotics are used as treatment. Most cats recover upon receiving a complete course of the antibiotics.<sup>4</sup> Considering that this parasite is widespread in cats and most cats can be effectively treated with antibiotics, the cats in these particular experiments fall outside the explicit euthanasia exception in the AWA. Moreover, some of these kittens are in a control group and are never exposed to the virus. Therefore, Maryland law applies.

### **Maryland Law Now Mandates Adoption Efforts**

As you may know, since we last wrote your office regarding this matter, a new law<sup>5</sup> has taken effect in the state of Maryland that obligates research facilities doing business within Maryland to try to adopt out cats or dogs after experiments have concluded.

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<sup>1</sup> Animal Welfare Act of 1966, 7 U.S.C. § 2143(1) (2018) (stating the “Secretary shall promulgate standards to govern the humane handling, care, treatment, and transportation of animals by dealers, research facilities, and exhibitors”); *id.* § 2143(8) (stating further that “Paragraph (1) shall not prohibit any State (or a political subdivision of such State) from promulgating standards in addition to those standards promulgated by the Secretary under paragraph (1)”).

<sup>2</sup> Animal Welfare Regulations, 9 C.F.R. § 2.31(d)(1)(v) (2018).

<sup>3</sup> Arnold Plotnick, MS, DMV, ACVIM, *Toxoplasmosis*, Manhattan Cat Specialists, <https://www.manhattancats.com/article-archive/infectious-diseases/toxoplasmosis/> (last visited Nov. 20, 2018).

<sup>4</sup> *Toxoplasmosis in Cats*, Feline Friends, <http://www.feline-friends.org.uk/topics/toxoplasmosis-in-cats/> (last visited Nov. 20, 2018).

<sup>5</sup> Research Facilities that Use Dogs or Cats, Code of Md. tit 15, § 15-101 (requiring research facilities in Maryland to “take reasonable steps to provide for the adoption of a dog or cat that, in the determination of the research facility, is no longer needed for scientific research purposes by:” establishing a private placement process, creating a list of animal rescue organizations to be used for adoptions, *and* using the animal rescue organizations on the list in the event that the private placement process does not lead to adoption).



Thanks to Delegate Ben Kramer, Senator Michael Hough, and Governor Larry Hogan, the Humane Adoption of Companion Animals Used in Research Act of 2018 passed both chambers unanimously<sup>6</sup> and took effect on October 1, 2018. The purpose of this new law is to require: *“certain scientific research purposes to take certain steps to provide for the adoption of a certain dog or cat under certain circumstances; authorizing certain research facilities to enter into certain agreements with certain animal rescue organizations for certain purposes.”*

The Maryland law stipulates that if research facilities are unable to place these cats and kittens into adopted homes through a private placement process, the facility must offer *“the dog or cat to the animal rescue organizations...if the research facility is unable to place the dog or cat through its private placement process.”*

### **U.S. Congress Explicitly Encourages Adoption**

The most recent federal guidance issued on this topic is consistent with Maryland’s new law. The United States Congress recently encouraged USDA to explore adoption in these situations in the FY19 appropriations process.

We see no compelling reason why the USDA should consider itself exempt from the Maryland law, and we hope the USDA will work to accommodate the spirit and intent of the Maryland law. We remain steadfast in our commitment to helping get these cats and kittens adopted out. Your partnering with us, or any other rescue organization like ours, would also ensure that the USDA remains compliant with Maryland state law.

### **Please Respond Before the Next Round of Euthanasia**

Given that it is unclear to us exactly when the newest group of cats and kittens are scheduled to be euthanized and incinerated at the Beltsville, MD facility, we urge you to contact us before the next round of unnecessary euthanasia takes place. We have the capacity and resources to ensure that these adoptions take place without any cost to the government.

Thank you for your attention to this matter.

Sincerely,

Mike Ryan  
Director  
Policy & Government Affairs  
New England Anti-Vivisection Society (NEAVS)

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<sup>6</sup> SB 675/CH 236, Humane Adoption of Companion Animals Used in Research Act of 2018.



CC: Chavonda Jacobs-Young, Administrator, ARS, USDA