

Placement of Research Animals After Study Completion

Version 1

November 18, 2019

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A. PURPOSE

The Food and Drug Administration (FDA), Office of the Chief Scientist (OCS), Animal Welfare Council (AWC) has developed the following policy and procedures for the transfer, adoption, retirement or other handling of research animals that have completed their assigned study.

There are occasions in which healthy live animals are available following their intended use in regulatory investigations. FDA fully supports the transfer of such study animals to other approved FDA animal program protocols, government agencies, accredited academic institutions, or accredited laboratory animal facilities for further research; to long-term private homes or farms for adoption as pets; to AWC approved organizations preparing animals for adoption as pets; or to AWC approved retirement sanctuaries that can provide suitable and humane living conditions for these animals. Adoption of research animals is valued by the public, laboratory animal professionals, and the entire research community. Transfer of study animals housed at FDA facilities must follow this policy. However, it is the responsibility of the individual animal program Institutional Official (IO) with the aid of the Institutional Animal Care and Use Committee (IACUC) and Attending Veterinarian (AV) to establish animal program-specific policies and procedures required for the placement of study animals after study completion. All applicable state and local laws related to animal ownership, transfer, transportation and other handling must be taken into consideration. Consultation with the Office of Chief Counsel (OCC) during the development of procedures is recommended.

B. POLICY

Per the United States Department of Agriculture's Title 9 Code of Federal Regulations recordkeeping regulations and as supported by the Office of Laboratory Animal Welfare (OLAW), the FDA supports the transfer, adoption or retirement of FDA-owned research study

animals that have completed their assigned research study and met all other criteria as detailed in this guideline. The IO or designee and Animal Program Director (APD)/AV are responsible for approving and deeming eligible animals for transfer to other approved protocols, government agencies, accredited academic institutions, and accredited laboratory animal facilities for further research and to approved FDA employees or other persons for adoption as pets. Animals may be otherwise transferred to an approved foster/retirement organization as approved by the IO or designee and APD/AV.

C. SCOPE

This guideline provides the policy and procedures for the transfer, adoption, and other handling of all FDA-owned study animals that have completed a research study and have no apparent health or behavior concerns. For eligible species as outlined below, animals may only be transferred or adopted with the approval of the animal program IO or his/her designee with assistance from the APD/AV, IACUC and clinical veterinarian(s).

D. ELIGIBILITY

To be eligible for transfer/adoption, the following criteria must be met:

1. Proposed disposition of the animal is approved in the protocol by the animal program IACUC.
2. The APD/AV or designee has determined species eligibility based upon the prior research scope, legal considerations, biosecurity issues and other suitability issues for proposed transfer/adoption/retirement. Eligible species for adoption include common pets such as but not limited to dogs, cats, rabbits, guinea pigs, and, in certain circumstances, farm animals such as pigs and sheep. Nonhuman primates (NHPs) can only be transferred to another approved protocol, government agency, accredited academic institution or accredited laboratory animal facility, or retired to an approved sanctuary.
3. Animals for transfer or adoption must not have any signs of compromised health, either natural or experimentally derived. The animal must be in good health and of acceptable behavior as determined by the AV, working with the clinical veterinarian, veterinary behaviorist and/or Principal Investigator, based on physical examination, research and clinical history, and animal behavior evaluation. NHPs are not eligible for adoption under any circumstances.
4. If the animal has received test articles, the appropriate wash-out period (based on available data) must occur prior to transfer or adoption.
5. The animal must be transferred to an approved protocol, an appropriate government agency, accredited academic institution or accredited lab animal facility with approval and expertise to care for and use the animal; or adopted as a pet to a home or transferred to an approved organization for fostering or retirement, and subsequently must not be sold, released into the wild, subject to zoo or public exhibition displays or used for food.
6. Direct adoptions of eligible species can only be to FDA employees or animal care contractors working at FDA who meet eligibility guidelines.

The AWC will establish a list of approved retirement sanctuaries and foster/rehoming organizations and will be available to consult with animal programs to select a suitable

foster/rehoming organization or retirement sanctuary. Eligible animals, including nonhuman primates, may only be transferred to an approved organization for fostering or retirement.

E. DEFINITIONS

Adoption: As defined by this policy, the completion of research use and transfer of full ownership from the FDA to a permanent home as a pet with an approved private individual (adopter).

Transfer: As defined by this policy, transfer of full ownership from the FDA to another government agency (federal, state or local), academic institution, accredited laboratory animal facility, or approved foster/retirement organization. Transfer may also refer to the transfer to another animal program IACUC approved protocol, or a carcass to an outside organization for disposal.

Retirement: As defined by this policy, transfer of full ownership from the FDA to an approved organization with resources to provide lifelong care of the animal(s), to include proper housing, enrichment, diet and veterinary care.

Foster: As defined by this policy, the transfer of full ownership to an approved, established organization with experience in and available resources to facilitate the subsequent adoption of the study animal to a permanent home as a pet.

F. RESPONSIBILITIES

FDA AWC:

1. Maintain this policy in compliance with all regulatory and legal requirements.
2. Consult with the General Services Administration (GSA), as appropriate, for disposal, adoptions and transfers.
3. Establish a list of approved retirement sanctuaries and foster/rehoming organizations.
4. Provide situational awareness to the Chief Scientist, Principal Deputy Commissioner, Commissioner, and other applicable agency leadership.

Animal Program IO or designee:

1. Works with the APD/AV; approves the transfer or adoption.

Animal Program Management or IACUC:

1. Notifies the FDA AWC of its intent to adopt, transfer outside of FDA or retire the animal(s), with sufficient advanced notice, for support and feedback.
2. Ensures description of the disposition of animals, alive or dead, in the animal study protocol and approval by the animal program IACUC.
3. Screens potential transferees and adopters for suitability to accept or adopt the animal. This will include determining whether the potential transferee or adopter has:
 - a. standing to legally accept ownership and responsibility in writing for the animal;
 - b. knowledge of and ability to properly care for the animal; and
 - c. sufficient resources, including proper space and access to veterinary care, required for lifelong animal care and well-being.
4. Develops and follows standard disposal of carcasses procedures, covered in an IACUC guideline or IACUC reviewed or approved SOP.

5. Develops and follows a non-standard disposal of carcasses (e.g., to wildlife rehabilitation facilities, zoos, etc.), as applicable, covered in an IACUC guideline or IACUC reviewed or approved SOP. NHPs cannot be disposed of by a non-standard method.

After a candidate organization has been selected for an animal transfer or an individual has applied for the adoption of a FDA study animal, and been approved as described above, the following items must be completed prior to the actual transfer of ownership:

Veterinary Examinations:

1. A complete physical examination must be performed by a clinical veterinarian for all potential transfers or adoptions to verify that the animal(s) is in good health and of acceptable behavior.
2. When appropriate, the FDA animal program should vaccinate and surgically sterilize animals prior to transfer or adoption for the health and welfare of the animal and to reduce the potential for accidental or intentional breeding. Diagnostic testing and/or appropriate vaccinations and surgical sterilization must be administered prior to transfer or adoption, as deemed necessary, by the AV or designee.
3. If an animal has been previously microchipped, that microchip will be re-registered to the new owner prior to the animal's transfer from FDA.

Records Review:

1. A comprehensive review of research and medical records is completed by the Principal Investigator and clinical veterinarian, respectively, to confirm the animal meets the eligibility criteria.
2. For dog and cat transfers/adoptions and NHP transfers/retirements, compliance with relevant USDA Animal Welfare Act Regulations in Section 2.35 paragraphs (b), (c), and (e), and Section 2.38 is required.

Transfer of Ownership:

1. The transferee or adopter of the animal must bring an appropriately-sized transport crate to transfer the adopted animal from the FDA to its new location on the transfer day. The FDA does not provide transport crates for the adoption or transfer of animals unless agreed to or required by contract.
2. At the time of transfer, documentation will be made in the animal's record indicating the disposition of the animal and will include all necessary approvals from the IO or designee, IACUC, APD/AV, clinical veterinarian, Principal Investigator, and/or veterinary behaviorist.
3. The Animal Transfer of Ownership Agreement (Attachments A, B & C) will be signed and distributed as follows: one copy will be provided to the adopter/transferee, one copy will be included in the animal's permanent record with the originating FDA Animal Program and one copy provided to the FDA AWC.
4. Once the animal leaves the FDA campus, and is in the possession of its new owner, the FDA will no longer be responsible for veterinary care of the transferred or adopted animal.

G. RECORDS RETENTION AND DISPOSAL

All records (email and non-email) pertaining to this policy must be retained and disposed per FDA Records Management Schedule. Note, all email messages sent or received in the conduct

of Government business are considered Federal records, as well as Government property, and are subject to the Freedom of Information Act (FOIA).

H. INTERNAL CONTROLS

Frequency of Review: Every three years.

Method of Review: The FDA AWC will review the records related to this policy to ensure that all steps are being followed and all approvals are documented.

This policy will remain in effect until otherwise revised or rescinded.

I. REFERENCES

Carbone L, Guanzini L, McDonald C (2003). Adoption Options for Laboratory Animals. Lab Animal, 32(9): 37-41.

ACLAM Position Statement on Adoption of Research Animals:
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5710161/>

AVMA Policy on Adoption of Research Dog and Cats:
<https://www.avma.org/KB/Policies/Pages/Research-Dogs-and-Cats-Adoption.aspx>

CFR (Code of Federal Regulations) 2019. Title 9, Animals and Animal Products, Subchapter A (Animal Welfare). Washington, D.C.: Office of the Federal Register
<https://www.govinfo.gov/content/pkg/CFR-2019-title9-vol1/pdf/CFR-2019-title9-vol1.pdf>

Frequently Asked Questions: PHS policy on Humane Care and Use of Laboratory Animals:
<http://grants.nih.gov/grants/olaw/fags.htm#675> (question F.11)