

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 23-R-0033
CUSTOMER NUMBER: 337

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Childrens Hospital Of Philadelphia
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Philadelphia, PA 19104

Telephone: (215)-590-3800

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

FACILITY LOCATIONS (Sites) - See Attached Listing

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

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	0	0	29	0	29
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	89	39	0	128
9. Non-human Primates	0	0	141	0	141
10. Sheep	0	0	19	0	19
11. Pigs	1	0	21	0	22
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual res teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary in brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

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E SIGNED

11/17/03

which is obsolete.)

NOV 20 2003

[Handwritten Signature]

The IACUC has approved protocols that require multiple survival surgeries:

Procedure for monitoring these activities:

Monitoring plans are developed on a protocol-by-protocol basis. Veterinary Technicians check on all of the animals every day in the (b)(2)High, (b)(7)f (b)(2)High, (b)(7)f staff monitor animals during the course of their daily activities and any animals in need of care are brought to the attention of the Attending Veterinarian and/or the Veterinary Technicians.

Protocols approved for multiple survival surgeries:

- a) A protocol is approved to study in utero bone marrow transplantation and postnatal engraftment enhancement techniques in a canine model (06-707). At gestational day 37, fetuses undergo in utero bone marrow transplant. Between one and six months of age, some of these animals undergo skin grafting to assess immune tolerance. In a different aim, similar studies involve fetal in utero bone marrow transplant at gestational day 37, and between one and six months of age these animals receive a second postnatal bone marrow transplant. The IACUC also approved performing the in utero bone marrow transplant as described and if necessary, for medical reasons, performing a C-section to protect the bitch or the fetus.
- b) A protocol is approved to determine the degree and manner in which relief of pulmonary artery stenosis affects the amount of pulmonary valve leakage/insufficiency in a swine model (05-736). Two groups of animals are studied. One group undergoes surgical creation of pulmonary insufficiency (PI group). The second group undergoes surgical creation of pulmonary insufficiency as well as creation of left pulmonary artery stenosis (PI/PAS group). In the second group, left pulmonary artery stenosis is created to simulate the branch pulmonary artery stenosis seen in repaired tetralogy of Fallot. Following this surgical stage, pulmonary regurgitant fraction is measured in both groups using MRI techniques. Both groups undergo cardiac catheterization. **This protocol was terminated by the investigator on 4/29/08. No animals were used for this reporting period.**
- c) A protocol is approved to determine if delivery of the iNOS gene via gene-coated stent can be used to prevent the development of in-stent restenosis by eliminating neo-intimal proliferation within stented pulmonary arteries in a swine model (06-788). Initially an animal model of proximal left pulmonary artery stenosis and pulmonary valve insufficiency is created. Six weeks later, each animal undergoes a cardiac catheterization to deploy a gene-coated stent into the stenotic pulmonary artery. One month following stent placement, the animals undergo a second cardiac catheterization to evaluate for in-stent restenosis.
- d) A protocol is approved to determine if non-surgical implantation of a pulmonary valve within the proximal right and left branch pulmonary arteries is effective at reducing pulmonary valve insufficiency in a swine model (06-789). Initially an animal model of postoperative pulmonary insufficiency and branch pulmonary artery stenosis is created. Two months following the surgery, the animals undergo cardiac catheterization with placement of a surgically created "valved-stent" into both the proximal right and left pulmonary arteries. One week following placement of the valved-stents, the animals undergo a second catheterization to evaluate the short term functionality of the valved-stents.

Food or Fluid Restriction

Experimental situations that require food and/or fluid restriction:

Title of Experiment	Justification	Species	Length of Restriction
1. Post-Infarction Ventricular Remodeling in Fetal Sheep (07-803)	Prevention of vomiting and aspiration of stomach contents during anesthetic induction of pregnant sheep.	Sheep	Food withheld for 24-48 hours prior to surgery with unrestricted access to water.

→ **Number of Sheep Affected for this Reporting Period: 19**
(2 were fasted for 24 hours; 17 were fasted for 48 hours)

Variables that are monitored to ensure animal health during the restricted period.

When sheep are fasted for 24-48 hours, a form is placed on the cage where urine/fecal output is noted daily. If a decrease in fecal or urine output is noted, a Veterinary Technician is notified.

Steps taken to ensure adequate nutrition/hydration during the restricted period.

The sheep are allowed free access to water at all times. We have not observed detrimental effects in the sheep from food restriction, and have a low rate of complications with survival sheep fetal surgeries.