4a

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

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

# ANNUAL REPORT OF RESEARCH FACILITY
*(TYPE OR PRINT)*

1. **REGISTRATION NO.** 57-F-0003 **CUSTOMER NO.** 948

FORM APPROVED
OMB NO. 0579-0036

2. **HEADQUARTERS RESEARCH FACILITY** *(Name and Address, as registered with USDA, include Zip Code)*
DEPT. CLINICAL INVESTIGATION
ATLANTA, GA

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

**FACILITY LOCATIONS***(sites)*

(b)(2)High, (b)(7)(F)

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

| A. Animals Covered By The Animal Welfare Regulations | B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. | C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. | D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used. | E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic,analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)* | F. TOTAL NO. OF ANIMALS (Cols. C + D + E) |
|---|---|---|---|---|---|
| 4. Dogs | | | | | |
| 5. Cats | | | | | |
| 6. Guinea Pigs | | | | | |
| 7. Hamsters | | | | | |
| 8. Rabbits | | | 93 | | 93 |
| 9. Non-Human Primates | | | | | |
| 10. Sheep | | | | | |
| 11. Pigs | | | 36 | 6 | 42 |
| 12. Other Farm Animals | | | | | |
| | | | | | |
| 13. Other Animals | | | | | |
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**ASSURANCE STATEMENTS**

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

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

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

4) The attending veterinarian for this research facility has appropriate authority to ensure the 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)**
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

| SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL | NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)* | DATE SIGNED |
|---|---|---|
| (b)(6),(b)(7)(c) | (b)(6),(b)(7)(c) | 11/24/2008 |

**APHIS FORM 7023** **(AUG 91)** **(Replaces VS FORM 18-23 (Oct 88), which is obsolete**

**PART 1 - HEADQUARTERS**

NP

**APHIS Form 7023 Column E Explanation**

This form is intended as an aid to completing the APHIS Form 7023 Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

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1. Registration Number: 57-F-0003

2/3. Species (common name) & Number of animals used in this study:

Pigs (6)

4. Explain the procedure producing pain and/or distress.

The goal of the study is to test a novel surgical treatment in a pig model for the management of short bowel syndrome patients by using a commercially produced graft to lengthen the small bowel through mechanical tension as well as the provision of a scaffold for the growth of new intestinal tissue. The first step will be to create a condition of short bowel syndrome in the pig. This will be done using a modification of technique described by Chang with a resection of 90% of the small bowel, but no creation of bowel dilation first (Chang et al 2006). Measurement of bowel for resection will begin at the Ligament of Treitz and resection will leave approximately equal amounts of jejunum and ileum. Negative control animals will then have the abdomen closed and recovered from surgery. In the experimental group, the remaining small bowel will receive a commercially produced graft to lengthen and provide mechanical tension and a scaffold for the growth of new intestinal tissue.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

The negative control animals may be in the unalleviated Painful/Distressful Procedure USDA category. These are animals in which the Short Bowel Syndrome has been created but not treated. Symptoms of Short Bowel Syndrome are associated with malabsorption. Although all of the animals will receive the same rations, by definition the Short Bowel Syndrome animals will not be able to absorb the normal amount of nutrients. This may result in clinical signs such as weight loss, diarrhea, abdominal bloating and fatigue. These clinical signs will not be alleviated since negative controls are necessary to determine that the experimental animals would also have had Short Bowel Syndrome if the corrective surgery had not been performed. There are no in vitro systems which can be used as a substitute for this animal model. The complex nature of short bowel syndrome, with subsequent repair with the graft cannot be duplicated in vitro, ex vivo or in a computer model. These animals may have unrelieved distress but not unrelieved pain. All painful procedures will be done under anesthesia. Pain will be relieved by analgesics. All surgery and immediate post-operative care will be performed using appropriate anesthesia and analgesia. Endpoint guidelines have been determined.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency: NA CFR: