

NOV 30 2012

Attachment to APHIS FORM 7023
Explanation of Column E Procedures
Vanderbilt University 63-R-0005
October 1, 2011 to September 30, 2012

1. The following protocols involve experiments reported in Column E. Experiments were approved by the Vanderbilt University (VU) Institutional Animal Care and Use Committee (IACUC) after determination of scientific justification.

M/09/349: Species Used: Swine (*Sus scrofa domestica*)
Number Used: 19

M/10/027: Species Used: Swine (*Sus scrofa domestica*)
Number Used: 2

Explain the procedure producing pain and/or distress. Provide scientific justification why pain and/or distress could not be relieved. State methods used to determine that pain and/or distress relief would interfere with test results. (For Federally-mandated testing, see next response.):

These experiments examine the effects of low levels of oxygen (hypoxia) on tiny blood vessels in the lungs of newborn pigs. Piglets are placed in an environmental chamber and a hypoxic atmosphere is provided by delivering 10% O₂ at atmospheric pressure. Although animals are not expected to experience significant discomfort, piglets are monitored for difficult breathing and other signs of respiratory distress and euthanized if such signs are observed. Any potential discomfort was felt to be scientifically justified since maintaining the piglets in a hypoxic environment is the only known method for replicating the condition seen in human infants. To date, no signs of overt distress have been observed and no animals have been euthanized.

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: *Not applicable* CFR: *Not applicable*

2. The following protocol involves experiments reported in Column E. Experiments were approved by the VU IACUC after determination of scientific justification.

M/09/147: Species Used: Gerbils (*Meriones unguiculatus*)
Number Used: 120

Explain the procedure producing pain and/or distress. Provide scientific justification why pain and/or distress could not be relieved. State methods used to determine that pain and/or distress relief would interfere with test results. (For Federally-mandated testing, see next response.):

The gerbils reported in pain category E were infected with Helicobacter pylori, which is a well-established model of gastric cancer and inflammation. Treatment for the infection and its sequelae cannot be administered as it would compromise the model. However, if signs of lethargy, piloerection,

NOV 30 2012

sluggish movement, poor daily food intake, or loss of more than 20% of body weight are observed, then the animals are euthanized and removed from the study.

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: *Not applicable*

CFR: *Not applicable*

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NOV 30 2012

Attachment to APHIS FORM 7023
Summary of Exceptions to Regulations and Standards
Vanderbilt University 63-R-0005
October 1, 2011 to September 30, 2012

1. The following protocols involve exceptions to the requirements for watering non-human primates. Fluid access is controlled for operant conditioning. Experience has demonstrated that short periods (e.g., 24 hours or less) of markedly reduced or no fluid intake may be required during the initial phases of operant conditioning. Once an animal has learned a behavior, the daily amount of fluid provided is increased to the maximum level that will ensure adequate performance of the task. Animals are monitored closely to ensure adequate hydration is maintained. Each exception was approved by the Vanderbilt University (VU) Institutional Animal Care and Use Committee (IACUC) after determination of scientific justification.

M/07/044: Species Used: Macaques (*Macaca mulatta*, *M. radiata*)
Number Used: 1

M/07/354: Species Used: Macaques (*Macaca mulatta*, *M. radiata*)
Number Used: 2

M/08/162: Species Used: Macaques (*Macaca mulatta*, *M. radiata*)
Number Used: 10

C/10/062: Species Used: Macaques (*Macaca mulatta*, *M. radiata*)
Number Used: 8

M/11/131 Species Used: Macaques (*Macaca mulatta*, *M. radiata*)
Number Used: 2

M/11/210 Species Used: Macaques (*Macaca mulatta*, *M. radiata*)
Number Used: 6

2. The following protocol involves an exception to the space requirements for non-human primates. Animals may be housed in a portable pet carrier for up to 72 hours post-operatively. This facilitates intensive post-operative care by providing necessary access to animals for administration of medicines, including analgesic drugs and fluid therapy. The pet carrier also facilitates the provision of special food and ancillary heat. Each exception was approved by the VU IACUC after their determination of scientific justification.

C/10/062: Species Used: Squirrel monkeys (*Saimiri sciureus*)
Number Used: 6

NOV 30 2012

3. The following protocol involves an exception to the lighting requirements for cats. Total darkness is required to eliminate all visual experience during development in a reversible manner. Procedures such as enucleation or eyelid-suturing are inadequate because they are not reversible or allow a significant amount of light to penetrate the lids. The exception was approved by the VU IACUC after determination of scientific justification.

M/09/058: Species Used: Cats (*Felis catus*)
Number Used: 6

4. The following protocol involves an exception to the provision of food to dogs. Dogs are fasted for 42 hours prior to performing a metabolic study. This is the minimal time the experimental techniques and methods allow the investigators to assess significant changes in gluconeogenic rates. The exception was approved by the VU IACUC after determination of scientific justification.

M/08/053: Species Used: Dogs (*Canis familiaris*)
Number Used: 22

5. The following studies involve an exception to the provision of atmospheric conditions for swine. Some animals are raised in a hypoxic environment to replicate the pulmonary hypertension seen in human infants. The animals are kept warm with a heat lamp and the ambient temperature and humidity are monitored and recorded once daily. The exception was approved by the VU IACUC after determination of scientific justification.

M/09/349: Species Used: Swine (*Sus scrofa*)
Number Used: 19

M/10/027: Species Used: Swine (*Sus scrofa*)
Number Used: 2

6. Vanderbilt University has the following active USDA/APHIS/AC approved exceptions to AWAR §2.31(d)(1)(x) that states that no animal will be used in more than one major operative procedure from which it is allowed to recover. The exceptions are listed in the order they were approved (with most recent listed first).

M/07/354: Species Used: Macaques (*M. mulatta*)
Number Used: 1

In 2011, a request was approved by USDA/APHIS/AC to extend a previously approved exception (submitted in 2008) to perform multiple major survival surgeries in an animal. The 2011 extension was needed in order to complete the surgeries approved in the 2008 request. The extension was approved through the period from August 13, 2011 to August 13, 2014.

C/10/062 (Replaces protocol C/06/564): Species Used: Macaques (*M. mulatta*)
Number Used: 2 (Both animals were euthanized per protocol during the 2011-2012 USDA year.)

In 2011, a request was approved by USDA/APHIS/AC to extend a previously approved exception (submitted in 2008) to perform multiple major survival surgeries in two animals.

For one animal, the 2011 extension was needed in order to complete the surgeries approved in the 2008 request. The extension for this animal was approved through the period from August 13, 2011 to August 13, 2014. This animal was euthanized per protocol.

For the other animal, the 2011 extension was needed in order to complete all experimental sessions. The extension for this animal was approved through the period from August 13, 2011 to August 13, 2012. This one animal was euthanized per protocol.

M/07/354: Species Used: Macaques (*M. radiata*)
 Number Used: 1

In 2012, a request was approved by USDA/APHIS/AC to extend a previously approved exception (submitted in 2009) from September 13, 2012, through September 13, 2013. The 2012 extension was needed in order to complete experimental sessions.