
Protocol Title:	Evaluation of a vaccine against ovarian growth factors as single dose, long-lasting immunocontraceptive
Protocol Type:	IACUC
Date Submitted:	05/22/2019
Approval Period:	07/16/2019-07/15/2022
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* * * Personnel Information * * *

COLORADO STATE UNIVERSITY INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE
ANIMAL USE APPLICATION

IACUC approval of this completed form is necessary prior to animals being obtained, housed or manipulated for research, testing or teaching purposes; performed at CSU or by CSU at other locations.

When you have completed all applicable sections of the protocol, you must also complete the certifications section and then click "Submit Form" link on the left-hand column.

All individuals listed on the protocol must have certified completion of the online CSU Animal Care and Use Training. Additionally, a "Training Record" should be uploaded in the Attachments section for the PI, Co-PI, and each person who will handle animals as a part of this study. Also, all individuals working with animals must be enrolled in the CSU Occupational Health and Safety Program (OHSP) via annual submission of a Risk Assessment Form to the OHSP.

Please contact an IACUC Coordinator if you have any questions.

Principal Investigator*

Name [redacted]	**Title**	
Email [redacted]	**EID**	**Phone** ([redacted]
Department [redacted]	**Mail Code**	
Will PI work with animals as part of this project?	Y	

Co-Principal Investigator

Name [redacted]	**Title**	
Email [redacted]	**EID**	**Phone**
Department [redacted]	**Mail Code**	
Will Co-PI work with animals as part of this project?	Y	

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* * * Species * * *

Species to be Used

Common Name	Horse			
Scientific Name	Horse			
Animal Sex	Female			
Age Range	3	-	18	Year(s)
Weight Range	300	-	600	kg(s)
Strain/Breed/Subline	Any strain			
Housing Location	Other BLM Facilities , Reno NV			
Room Number	Pens			
Maximum number of animals for three year project period	32			

USDA Pain Category (Choose all that will apply)

X	**Pain Category B**	32
	Pain Category C	
	Pain Category D	
	Pain Category E	

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Pain Categories
Category B: Animals bred, conditioned or maintained for use in teaching, testing, or research, but not yet used for such purposes.
Category C: Animal use subjects them to no more than momentary or slight pain or distress and they do not receive pain-relieving drugs. Example : euthanasia prior to tissue collection; observation under normal conditions; positive rewards; routine injections (not Freund's adjuvant); tattooing; blood sampling.
Category D: Animal use subjects them to procedures where pain or distress is appropriately relieved with anesthetics, analgesics and/or tranquilizer drugs or other methods for relieving pain or distress which would otherwise be more than slight or momentary. Example: Needle biopsy non-survival or survival surgeries, terminal cardiac blood collection under terminal anesthesia; exposure of blood vessels for catheter implantation; induced infections or antibody production. PROCEDURES AT PAIN D REQUIRE VETERINARY CONSULTATION WITH THE UNIVERSITY VETERINARIAN OR DESIGNEE.
Category E: Animal use in which they must be subjected to unrelieved pain or distress for scientific reasons. Examples: toxicological or microbial testing or infectious disease research that requires continuation until severe clinical symptoms are evident or death occurs; application of noxious stimuli from which the animal cannot escape; prolonged restraint; use of paralyzing drugs for restraint of conscious animal; infliction of burns or trauma. PAIN E PROCEDURES REQUIRE CONSULTATION WITH THE UNIVERSITY VETERINARIAN OR DESIGNEE, AND MUST BE SCIENTIFICALLY JUSTIFIED IN THE PROTOCOL.

Source of Animals

Please indicate the source of the animals that will be used in the protocol. Be as specific as possible:
Outside Vendor (indicate whether purchased through LAR or by the investigator/department);
Transferred from another approved protocol (indicate protocol number);
Free-ranging Wildlife;
Faculty/Staff/Student-Owned ;
Client-Owned;
Other (please explain).

NOTE: If this is a study using Client Owned animals, you must provide a copy of the Informed Owner Consent Form along with approval from VMC Director in the Attachments section.

Bureau of Land Management

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* * * Are You Using? * * *

Please indicate if you propose to use any of the following so the IACUC may better assess your protocol.

1. Will you be using live animals for teaching? N

What are the goals of the course(s) and who is the intended audience(s)?

Please describe the preparation the students will have prior to handling live animals (e.g. lecture, demonstrations, anatomical model use, videos)

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2. Will you be using euthanized animals for teaching purposes? N

   What will be the source of the animals (LAR or Vendor) and what is the disposal plan?

   What are the goals of the course(s) and who is the intended audience(s)?

3. Will you be collaborating with another institution(s)? Y

Institution(s)

Institution Name	Other
Other (please specify)	USDA - APHIS
PHS Assurance #	
USDA Registration #	
Collaboration institution personnel	Doug Eckery

Briefly explain how the collaboration or subcontract is structured

BLM is contracted with USDA-APHIS. CSU subcontracts with APHIS

Please summarize if animals will be purchased by, housed, or have procedures performed by CSU personnel at this other institution.

[redacted] will travel to NV to collect monthly blood samples and perform pregnancy test via transrectal ultrasound exam

4. Will you be using biohazardous agents?

   a) Recombinant DNA (rDNA), human fluids or human tissues N

   b) Infectious Agents? N
   If you indicated "Yes" to 4a. or b. above, please provide IBC protocol "PARF" number, or indicate "Submitted" or "Submission Pending," as appropriate.

   c) Will this protocol involve the generation of new transgenic or knockout lines using rDNA? N

   d) If using an infectious agent or toxin, is it on the USDA or CDC Select Agent List (see Select Agents for the two lists of agents)? N

5. Will studies be performed under Good Laboratory, Good Clinical, or Good Manufacturing Practices (GLP/GCP/GMP)? Such studies are regulated by the Food and Drug Administration (FDA) or the Environmental Protection Agency (EPA). N

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Please contact the CSU Quality Assurance Manager for additional review and approval of GLP/GCP/GMP documentation.

If yes, please provide the name of the individual who will be the Study Monitor, and briefly describe how the project involves GLP/GCP/GMP or preliminary product testing.

6. Will you be using controlled drugs?

Will controlled drugs (including HCG and Ketamine) be used? N

If yes, list whose CSU "drug cabinet" will be accessed.

7. Will carcinogenic or chemical substances that are hazardous to humans or animals be used? N

Toxic Agent(s)

8. Will you be using radiological agents N

Isotope(s)

9. Will this be a field study (i.e. conducted on free-living wild animals in their natural habitat)? In addition to IACUC approval, the investigator is responsible for obtaining all necessary federal/state or other government permits for wildlife studies. N

Field Study or Wildlife Study

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* * * Funding Sources * * *

Funding Checklist

Funding - Grants/Contracts

Funding - Other

Dept. Funding

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Other Funding

This protocol is funded (in whole or in part) with funding from an agency in the U.S. Department of Defense (DoD)? This includes direct grant/contract funding or subcontract work that is flow-through of funding from DoD. N

If DoD funding is involved, the PI will be responsible for obtaining approval from the DoD Animal Care and Use Research Office (ACURO) for all new protocols and amendments to existing protocols prior to initiation of the work/change to the protocol.

Check here if this project is self-funded (No aspect of this work will have charges to a sponsored project, departmental account, other CSU-related account associated with it.)

NOTE: Applicable Federal Grant Application, including competing renewals must be attached. Applicable investigator's brochure and sponsor's protocol must be attached for all industry sponsored clinical trials. You will be prompted for these in the Attachments section.

Has this protocol received other internal reviews (check all that apply):

Reviewed for CRC Funding	**Yes**	**No** X
Reviewed by VTH/Clinical Sciences Clinical Research Review Board:	**Yes**	**No** X
I assure that the activities described with in this document submitted for IACUC review are consistent with those described in any related grant, contract, or subcontract that has been submitted or awarded.	**YES** X	**NO**

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* * * Rationale * * *

1. PROJECT INFORMATION

a) **Protocol title**

Evaluation of a vaccine against ovarian growth factors as single dose, long-lasting immunocontraceptive

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b) Application type

Note: If you are editing a previously approved protocol for an Amendment or Continuing Review, please leave the answer to the questions under b. below as they were in the originally approved protocol.

This project is a: (check only one)

X New project

4th year renewal (please enter number of protocol that you are renewing below)

If this is a 4th year renewal, please indicate the number of the protocol it is renewing.

2. LAY SUMMARY

a) What is the overall goal or purpose of this animal use?
Provide a brief description which would convey to a lay audience the purpose for the proposed use of animals. Use language understandable to a layperson. Avoid overly technical terms and define acronyms. The readability should be similar to a newspaper article. For example, the goal of a study could be expressed as follows: "Disease XYZ is a serious threat to the health of…. This project will seek to test the efficacy of treatment ABC." Or, "This project seeks to understand the cellular mechanisms that influence X through in vitro analysis utilizing tissues harvested from the proposed species Y."
Note: A section from your grant application using highly technical terms is not acceptable.

Overpopulation of the wild horse continues to be both a welfare issue for the horses as they are overgrazing land and subjected to drought and thus dehydration. In addition, the horses are negatively affecting the range lands. We are attempting to determine the efficacy of a single dose, long lasting immunocontraceptive on wild mares. Mares will either be immunized with a combined vaccine against BMP-15 and GDF-9 (n=16) or treated as controls and not vaccinated (n=16). Mares will then be placed in three large paddocks (n=8 mares / paddock(4 treated;4 control)) with a stallion. Researchers will visit the facilities monthly to draw jugular blood samples to determine progesterone levels and antibody titers. In addition, mares will be tested for pregnancy to determine efficacy of the vaccine.

b) What will the impact of the use of live animals in this project be for human OR animal health, the advancement of knowledge, or the good of society?
Regulations and ethical standards require that procedures involving the use of animals in research or teaching be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge or the good of society. Provide a brief description which would convey to a lay audience the impact the proposed research will have for one or more of the above considerations. For example, "1 million people are estimated to contract disease XYZ each

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year. The proposed project will further the cause of developing effective treatments for the disease." Or "The cellular mechanisms X have previously been studied, but no studies have looked at aspect C of this mechanism. This study will advance the scientific understanding of X by exploring aspect C."
Note: Projects are not required to have application for human health to receive IACUC approval.

Hope to be able to provide a means to remotely treat and possibly permanently sterilize wild horses.

3. JUSTIFICATION FOR USE OF ANIMALS

For parts a. and b. below, please answer "Yes" or "No" for each question.
There should be a Yes/No answer in all questions a)i. through a)vii. and b)i. through b)v.

a) Living animals are required for this project because:
(You should select either Y or N for each query.)

i)	Y		Complexity of the processes studied cannot be duplicated/modeled using in vitro models
ii)		N	Not enough information known about processes being studied to design non-living models
iii)		N	Pre-clinical studies in living animals are necessary prior to human testing
iv)		N	This study requires tissue harvested from animals prior to in vitro testing
v)		N	Currently this is the best method to accomplish the required teaching
vi)	Y		Populations are being studied in natural or semi-natural environments
vii)		N	Animal behavior is being studied

viii) Other (please specify):

b) This species has been selected because:
(You should select either Y or N for each query.)

i)	Y	Anatomy, physiology, behavior or agent susceptibility of species uniquely suited to the study

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ii) N Lowest phylogenetic species providing adequate size, tissue, or anatomy for proposed study

iii) N This species provides a particularly good model for the human or other animal disease or process

iv) N Previous studies which form the background for this project used this species

v) Y The objective of this study is to provide information about the target species

vi) Other (please specify):

4. JUSTIFICATION FOR NUMBER OF ANIMALS TO BE USED

The IACUC requires justification of proposed animal use numbers. A power calculation, confidence interval width, or an explanation why a power calculation is not feasible for this project should be provided. Complete one or more of the following (as appropriate) to justify the number of animals you will use (you may refer to Russ Lenth's U. Iowa stats website for statistical calculations). For experimental designs with multiple groups/treatments, it is suggested that a table of animal numbers per group be provided in the Attachments section. In addition make sure the animal numbers justified here agree with those mentioned in other sections of the application.

Answer N/A for any question (a-i) that is not applicable. There should be an answer or N/A in all boxes a-i.

a) This is an exploratory or pilot study. Describe how the proposed number of animals needed was determined. Note: A total of more than 12 animals indicates to the IACUC that the project may not be a pilot:

n/a

b) The group size was determined using a statistical package. Specify the statistical package used, effect size(s), estimate of variation used, and power level expected. (If multiple response variables are to be measured, the power calculation should be based on the most critical measures. When the objective is not to test but to estimate differences between mean or proportions, sample size may be justified based on confidence interval width criteria.):

The power calculation suggests the need for an n=2, which in this case is actually pen as animals within the pen are treated similarly. We have chosen 3 pens because the actual fertility of the animals will be unknown as we have been asked to use the captured wild horses.

c) This is a teaching protocol. Specify student-to-animal ratio, and explain how that was determined.

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There should be a clear correlation between the teaching objective and the number of animals per student:

n/a

d) This study involves tissue or cells harvested from animals for in vitro studies. Explain the number of animals requested for the amount of tissue needed to obtain a specified level of precision desired, or if an experiment involving the tissue samples will be conducted as part of this protocol, provide power calculations as described in b above. Cleary show the relationship between the number of animals requested and the number needed for the in vitro work:

n/a

e) This study involves breeding animals for later use in research, testing, or teaching. List the number of breeding males and females to be used/number of offspring produced each year, and describe how the animals are expected to be allocated to the subsequent experiment(s). If only a portion of the offspring will be usable in experiments, please indicate the number and reason for this:

n/a

f) This is a study of feral or wild animals where animals will be captured and released attempting to maximize sample size within logistical constraints. Describe and suggest a level of precision necessary to obtain useful information and the sample size required to obtain this precision:

n/a

g) This is an observational, non-manipulative study in which animals will only be observed and animal numbers cannot be predicted. The animals will not be captured nor will their behavior be manipulated:

n/a

h) Sample size is government driven or agency mandated. Provide appropriate references documenting this requirement (e.g. product safety testing as mandated by FDA regulations):

The power calculation suggests the need for an n=2, which in this case is actually pen as animals within the pen are treated similarly. We have chosen 3 pens because the actual fertility of the animals will be unknown as we have been asked to use the captured wild horses. The number within the pens was requested by BLM

i) Other. Please describe in detail:

n/a

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* * * Procedures * * *

Blood Collection in conscious animals

Procedure Type: Blood Collection in conscious animals

Procedure Title: jugular venipuncture

Species: Horse (BLM Facilities , Reno NV)

Pain/Distress Category: B

Approximate number of animals to be used in this procedure: 0

All D and E studies require date of consultation with the University Veterinarian; or, the name of other vet who was consulted:

Use Location (Campus) NV

Building Name: NV

Room Number: 001

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* * * Procedure Description * * *

Procedure Description

Procedure Description. Provide a brief description of how the procedure will be conducted. For blood/fluid collections include the route(s) of collection, volume, and frequency. For drug/compound dosing include route(s) of administration, volume, and frequency. For inoculations, include agent/vaccine information, route(s) of administration, volume, frequency, and dose. For procedures requiring administration of anesthesia, analgesia, provide the doses/route of administration; and for procedures requiring aseptic preparation, briefly describe animal, surgeon, and instrument preparation. Please DO NOT simply cut-and-paste from laboratory SOPs with superfluous or overly general information in them.

Blood will be collected via jugular venipuncture. One vacutainer (up to 2 x 10ml per time point) - collected once a month.

Horses will be held the stocks and there will be no need for sedation or twitching

Please list any clinical effects or changes from normal health and behavior which may occur as a result of this procedure. This should include both short and longer-term effects of the procedure, as applicable.

none expected. In the rare case that hematoma occurs or bleeding cannot be stopped the attending veterinarian will be consulted.

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Describe post procedure monitoring that will be performed. This should clearly indicate the frequency of monitoring, who will conduct it, and address the short- and longer-term complications that may result from the procedure.

Site will be observed for a few minutes after procedure to make certain bleeding is stopped.

What criteria will be used to determine if animals exhibiting clinical or behavioral changes should be given rescue analgesia, other clinical treatments, or euthanasia. Please include any scoring system that will be used to determine when humane intervention will be triggered in the Attachments section or provide the scoring criteria below, as applicable.

Site should be unnoticeable soon after procedure. If not, attending veterinarian will be contacted

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* * * Anesthetic Regimen * * *

Anesthetic Regimen

Note: Documentation of training is not required if you are using VMC or LAR services

Anesthetists

Parameters monitored during surgery:

Anesthetic Agents

Paralytic Agents

Other premedications not already listed above

Palpation

Procedure Type: Palpation

Procedure Title: palpation

Species: Horse (BLM Facilities , Reno NV)

Pain/Distress Category: B

Approximate number of animals to be used in this procedure: 0

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All D and E studies require date of consultation with the University Veterinarian; or, the name of other vet who was consulted:

Use Location (Campus)	NV	**Building Name:**	NV
		Room Number:	001

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* * * Procedure Description * * *

Procedure Description

Procedure Description. Provide a brief description of how the procedure will be conducted. For blood/fluid collections include the route(s) of collection, volume, and frequency. For drug/compound dosing include route(s) of administration, volume, and frequency. For inoculations, include agent/vaccine information, route(s) of administration, volume, frequency, and dose. For procedures requiring administration of anesthesia, analgesia, provide the doses/route of administration; and for procedures requiring aseptic preparation, briefly describe animal, surgeon, and instrument preparation. Please DO NOT simply cut-and-paste from laboratory SOPs with superfluous or overly general information in them.

Mares will be placed in examination stocks. The examiner will wear an obstetrical sleeve, obstetrical lubricant will be applied to the hand and arm which will be introduced into the rectum. The examiner will palpate the abdominal contents and specifically examine the ovaries, uterus and cervix of the mare. Ultrasound examination will entail similar procedures, but will allow for visualization of the internal organs.

Mares will be checked approximately every other week until a follicle of 25 mm in diameter is observed. At that point the mares will be monitored weekly until a follicle of 30 mm is observed. At that point they will be examined every other day until a follicle of 35 mm is observed. At that point they will be monitored daily until ovulation is detected. No sedation is required.

Please list any clinical effects or changes from normal health and behavior which may occur as a result of this procedure. This should include both short and longer-term effects of the procedure, as applicable.

None anticipated. There is the potential for rectal tear

Describe post procedure monitoring that will be performed. This should clearly indicate the frequency of monitoring, who will conduct it, and address the short- and longer-term complications that may result from the procedure.

None anticipated. There is the potential for rectal tear

What criteria will be used to determine if animals exhibiting clinical or behavioral changes should be given rescue analgesia, other clinical treatments, or euthanasia. Please include any scoring system that will be used to determine when humane intervention will be triggered in the Attachments section or provide the scoring criteria below, as applicable.

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Only in the event of a rectal tear, will further examination and medical treatments be indicated. A full thickness rectal tear as a result of transrectal palpation is very uncommon, but may occasionally occur and would result in euthanasia of the mare. Any question regarding a rectal tear would be evaluated by the veterinarian listed on this protocol.

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* * * Anesthetic Regimen * * *

Anesthetic Regimen

Note: Documentation of training is not required if you are using VMC or LAR services

Anesthetists

Parameters monitored during surgery:

Anesthetic Agents

Paralytic Agents

Other premedications not already listed above

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* * * Perioperative Care * * *

Perioperative Care

Pre-emptive agents (analgesics given prior to procedure)

Intra-operative analgesics (local blocks;intracavity blocks).

Describe what parameters will be monitored during anesthesia/surgery to assure proper anesthesia.

Antibiotics or Anti-Microbials

Post Operative Monitoring

Analgesic Agents

Recovery Location Building Name	
Room Number	
Responsible Personnel	
Parameters Monitored Note: Include any pain scale or scoring system as an attachment in attachments section.	
Monitoring Duration	
Monitoring Frequency	

Other

Procedure Type: Other

Procedure Title: vaccination

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Species: Horse (BLM Facilities , Reno NV)

Pain/Distress Category: B

Approximate number of animals to be used in this procedure: 32

All D and E studies require date of consultation with the University Veterinarian; or, the name of other vet who was consulted:

Use Location (Campus) Reno NV

Building Name: Reno NV

Room Number: BLM

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* * * Procedure Description * * *

Procedure Description

Procedure Description. Provide a brief description of how the procedure will be conducted. For blood/fluid collections include the route(s) of collection, volume, and frequency. For drug/compound dosing include route(s) of administration, volume, and frequency. For inoculations, include agent/vaccine information, route(s) of administration, volume, frequency, and dose. For procedures requiring administration of anesthesia, analgesia, provide the doses/route of administration; and for procedures requiring aseptic preparation, briefly describe animal, surgeon, and instrument preparation. Please DO NOT simply cut-and-paste from laboratory SOPs with superfluous or overly general information in them.

A 2mL dose of vaccine will be administered intramuscularly in the hip only once at the beginning of the trial. A 20 ga 1 1/2 inch needle will be used.

Please list any clinical effects or changes from normal health and behavior which may occur as a result of this procedure. This should include both short and longer-term effects of the procedure, as applicable.

None expected as none were observed in previous trials even after multiple injections

Describe post procedure monitoring that will be performed. This should clearly indicate the frequency of monitoring, who will conduct it, and address the short- and longer-term complications that may result from the procedure.

Horses are observed daily by BLM staff and issues handled by BLM staff veterinarian

What criteria will be used to determine if animals exhibiting clinical or behavioral changes should be given rescue analgesia, other clinical treatments, or euthanasia. Please include any scoring system that will be used to determine when humane intervention will be triggered in the Attachments section or provide the scoring criteria below, as applicable.

Managed by BLM staff and veterinary staff

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* * * Surgeon Details * * *

Surgeon Details

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* * * Anesthetic Regimen * * *

Anesthetic Regimen

Note: Documentation of training is not required if you are using VMC or LAR services

Anesthetists

Parameters monitored during surgery:

Anesthetic Agents

Paralytic Agents

Other premedications not already listed above

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* * * Perioperative Care * * *

Perioperative Care

Pre-emptive agents (analgesics given prior to procedure)

Intra-operative analgesics (local blocks;intracavity blocks).

Describe what parameters will be monitored during anesthesia/surgery to assure proper anesthesia.

Antibiotics or Anti-Microbials

Post Operative Monitoring

Analgesic Agents

Recovery Location Building Name	
Room Number	
Responsible Personnel	
Parameters Monitored Note: Include any pain scale or scoring system as an attachment in attachments section.	
Monitoring Duration	
Monitoring Frequency	

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* * * Other Drugs Utilized * * *

Other Drugs Utilized

Other Drugs Agents

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* * * Surgery Info * * *

Surgery Info

Specific room number where surgery is performed:

Surgery Type:

ALSO NOTE: The Guide defines major surgery as one that penetrates and exposes a body cavity or produces substantial impairment of physical or physiological functions, and the USDA defines a major operative procedure as any surgical intervention that penetrates and exposes a body cavity or any procedure that produces permanent impairment of physical or physiological functions.

Will this project include Multiple Major Survival Surgery (MMSS)?

PLEASE NOTE: If multiple major survival procedures are to be performed, you will be asked for specific justification in Project Overview section of this form.

Number of animals per year:

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* * * Alternative Search * * *

Alternatives Search

Federal regulations require that the fewest number of live animals necessary are used for research, testing, or teaching, and that investigators document that they have given all due consideration to reducing or eliminating the use of potentially painful or distressful procedures (Pain Category D or E). The USDA considers automated literature searches the most effective and efficient method for demonstrating compliance with the above requirements.

For ALL projects, regardless of pain categorization, please conduct a literature search utilizing terms that would allow you to demonstrate that the proposed research or other animal use is not unnecessarily duplicative of previously documented work. Please enter the appropriate Search Data (click the "Add" button) and answer Question 1 below.

If the proposed project involves procedures at Pain Categories D and/or E, documentation of a literature search which demonstrates that the fewest number of the lowest order of animals will be used to obtain valid results, and alternatives to EACH potentially painful/distressful procedure proposed have been sought. Therefore please enter the appropriate Search Data and answer Questions 2 & 3 below. See

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USDA Policies #11 and 12).

For assistance with alternatives searches, please consult the CSU Libraries IACUC Alternatives Search Help page, see the Alternatives to Painful or Distressful Procedures document (prepared by the University Veterinarian), or contact an IACUC Coordinator.

Click the "Add" button below to enter information pertinent to your search(es). Please then address question 1 and, as appropriate to the procedures to be conducted, address, questions 2-3.

Search Data

Search Range From: 1/01/2000
To: 5/21/19
Search Date: 05/21/2019

Search Terms

Please provide the Keywords and the Boolean terms such as AND, OR used to relate keywords (e.g. term#1 [AND] term#2) for searches for each of the three components of the Alternatives Search indicated above:

immunocontraceptive AND equine AND BMP15 AND GDF9

Databases Searched (you must search at least 2 databases):

Agricola Data Base	X	Google Scholar
ALTBIB - Bibliography on Alternatives to Animal Testing		HSVMA Alternatives in Education Database
SCIRUS		Lab Animal
AnimAlt-ZEBET		Lab. Animals Journal
ATLA (FRAME--Alternatives to Laboratory Animal Journal)	X	Medline / PubMed
BioOne (access from CSU Libraries website)		NORINA
BIOSIS (Note: CSU Libraries does not subscribe to this database)		TOXLINE
CAB Abstracts (access from CSU Libraries website)		Web of Science (access from CSU Libraries Website)
		Other, please specify:

1. N **Did the search reveal that your project is duplicative of previously documented work?**

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a) Please provide the number of hits and an overview of the results.

1 - Davis et al. The manuscript written by this lab which led to this research.

b) If "Yes," please provide a list of the relevant citations and a discussion of how you determined that it is necessary to conduct the project anyway.

2. N **Did the search reveal any possible reductions or replacements that would allow the use of fewer animals or animals of a lower order?**

a) Please provide the number of hits and an overview of the results.

1 Davis et al. The manuscript written by this lab which led to this research.

b) If "Yes," please provide a list of the relevant citations and a discussion of how you determined that it is necessary to conduct the project as proposed.

3. N **Did the search reveal any possible refinements that would allow the use of alternative procedures to those that will potentially cause pain and/or distress for the animals (Protocols utilizing procedures at pain category D and/or E)?**

a) Please provide the number of hits and an overview of the results.

1 Davis et al. The manuscript written by this lab which led to this research.

b) If "Yes," please provide a list of the relevant citations and a discussion of how you determined that it is necessary to conduct the project as proposed.

Teaching Protocols

1. If this is a teaching protocol, please specify why there are no alternatives to using live animals.

Protocols Involving Unrelieved Pain or Distress

1. For Pain Category E procedures, explain why drugs or other ameliorative treatments cannot be used to fully alleviate pain/distress. Please provide citations to the relevant literature.

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Other Means of Determining Non-Duplication and Alternatives

The Animal Welfare Act allows other means of determining whether your project is duplicative AND whether it can be refined to decrease the animal number or order, AND to determine if alternatives to a potentially painful/distressful procedure can be used. For example, under some circumstances, colloquia, subject expert consultants, or other sources may provide relevant and up-to-date information regarding alternatives. When other sources are the primary means of considering alternatives, sufficient documentation, such as the consultant's name and qualifications and the date and content of the consult should be provided. If you used an alternative search strategy, provide information on the strategy, methods, sources, and relevant findings.

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* * * Project Overview * * *

Project Overview

Provide a clear and concise sequential description of the procedures the animals will undergo. The description should include information on the experimental groups and the study endpoints. It should allow the reader to see the timing and relationship of all procedures that will be conducted with the animals. For lengthy or complex experiments with many groups and/or procedures, a table or flowchart showing the experimental manipulations by group should also be uploaded into the Attachments section. A response here is required.

Mares will be vaccinated with either vehicle or combination of BMP-15 and GDF 9 vaccine once.
Mares will be re-based into a pen with a fertile stallion.
Mares will be palpated monthly for pregnancy determination.
Serum samples will be collected monthly for progesterone assay and antibody titer levels.

Multiple Major Survival Surgery(MMSS) Description:

Describe why it is necessary to perform multiple major surgical procedures on the same animal.

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* * * Husbandry * * *

Animal Care/Husbandry

Emergency Contact Information

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List all individuals/phone numbers that are to be notified by veterinary staff or others in the event of an emergency:

[redacted]

Will Lab Animal Resources provide the daily care N

If "No," specify who will provide the daily care:

on BLM facility

If "No," justify why LAR will not be providing animal care:

not a CSU Facility

What veterinarian will provide medical care to animals? Other

If "Other" specify who:

BLM Staff veterinarian

Contact information:

BLM Facility

If "Other" justify why LAR will not be providing medical care:

off campus

Location of medical records (indicate building/room or other applicable information):

CSU

Special Husbandry or Care

List any special or unusual requirements for care of the animals and who will provide this care (e.g. special diet, altered light cycle, variation from standard enrichment, etc.):

Non-standard Experimental Requirements (Procedures requiring Exemptions from the Guide).

Social Housing

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If you are using a social species there are mandatory housing requirements. CSU considers social housing to include compatible housing with conspecifics, as well as housing in the same secondary containment with visual, auditory, olfactory or tactile contact with conspecifics. See the "Policy on Social Management of Animals" on the IACUC Policies and Guidelines Page.

Please indicate which of the following is true:

X 1. Animals will be provided with social housing (unless an animal has individual incompatibility or vet care concerns, or due to cohort attrition).

X 2. Animals will not be housed at CSU.

3. Animals will be housed singly because that is appropriate for this species (including hamsters, rabbits, male mice, tom cats, and livestock in stalls).

4. Animals will be housed singly because such housing is necessary for research, testing or teaching goals.

If you will be housing animals singly for research, testing or teaching purposes (#4 above), you must provide a written justification which indicates the experimental constraints that make the housing necessary:

Food or Fluid restriction (other than up to 12 hours prior to surgery/general anesthesia) X None

Food or Fluid restriction

Species	Food Restriction	Length of Restriction	Fluid Restriction	Length of Restriction	Reason for Restriction
Horse (BLM Facilities , Reno NV)					

Description

Restraint of Conscious Animals (other than momentary restraint for routine procedrues, e.g. blood collections, injections, and such) X None

Restraint of Conscious Animals

Species	Type restraint (manual, commercial, manual and commercial)	Please describe Acclimation to restraint	Length of restraint
Horse (BLM Facilities , Reno NV)			

Description

Non-standard housing requirements X None

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Non-standard housing requirements

Species	Cage/Pen size	Cage Sanitation Interval	Wire-bottom rodent cages or grids	Animals outside dedicated animal housing for greater than 12 hours	Exemption from exercise (dogs only)
Horse (BLM Facilities , Reno NV)					

Description

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* * * Disposition of Animals * * *

Please provide the information requested below regarding what will happen to animals at study end. (Check all that apply)

	Animals will be adopted (Note, PI is required to follow the IACUC "Policy on Animal Adoptions" which is located on the page IACUC Policies and Guidelines Page.
	Sold at auction (hoof stock only)
	Released into home territory (wildlife studies)
X	Returned to client
	Transferred to other studies (please specify below)
	Animals will be euthanized (Please add method below)

If using CO2 as the method of euthanasia for mice and rats, please be aware that the IACUC requires use of the "Directions for CO2 Euthanasia of Rodents" (available on the IACUC Policies and Guidelines Page) unless the protocol provides scientific justification why that procedure cannot be used.

Euthanasia Method

Please briefly describe what will happen with the animals at the conclusion of the study in the text box below:

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* * * Attachments * * *

PLEASE ATTACH ANY RELEVANT DOCUMENTS, INCLUDING:

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Grant applications to any PHS agency, NSF, and USDA related to this activity
Training Records for all personnel on this protocol
Any scientific literature or articles relevant to the review of this project.

Please upload training records for the PI, Co-PI, and all individuals who will be working with animals as a part of this protocol. Click here to obtain the template for the Training Record.

Document Type	**Grant or Grant Proposal**
Attachment	BLM- APHIS Proposal 5.21-final
Document Name	BLM- APHIS Proposal 5.21-final

Document Type	**Training Record**
Attachment	BruemmerJ_TrainingRecord
Document Name	BruemmerJ_TrainingRecord

Document Type	**Training Record**
Attachment	EckeryD_TrainingRecord
Document Name	EckeryD_TrainingRecord

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* * * Guidelines * * *

Guidelines

The CSU IACUC Policies and Guidelines page can assist you and your staff in the protocol development and animal study process.

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* * * Certifications * * *

I understand that changes in the approved protocol must be submitted in writing to the IACUC as a protocol amendment and approved by the IACUC prior to implementation. Such changes include, but are not limited to: species, animal numbers, animal-related procedures, animal restraint, food/water deprivation, euthanasia,

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PI, research staff, and the like. Minor changes can be reviewed by the IACUC via the designated member review process throughout the month; significant changes (e.g. a large increase in animal numbers, adding an invasive procedure) usually require a new protocol be submitted for review by the IACUC at its next regularly scheduled meeting.

Please contact an IACUC Coordinator if you have any questions about preparing new protocol applications, amendment requests, or continuing reviews.

Certification Test

By submitting this protocol to the CSU Institutional Animal Care and Use Committee (IACUC), the Principal Investigator certifies the following:

1) I assure that myself and all students, staff, and faculty on this project are familiar with the Animal Welfare Act (AWA) and AWA Regulations and the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, the Guide for the Care and Use of Laboratory Animals, and the Guide for the Care and Use of Agricultural Animals in Research and Teaching, as applicable, and all recognize their responsibility in strictly adhering to approved protocols.

2) I assure that all individuals listed on this project are qualified through education and/or training to conduct procedures involving animals under this proposal and have taken the online CSU Animal Care and Use Training, which includes information on the regulatory responsibilities of the institution, the IACUC, and investigators, as well as the concepts of research or testing methods that limit the use of animals or minimize distress, and the methods for reporting animal welfare concerns. Additionally, as applicable to their work with animals, all individuals on the protocol have received training in the biology, handling, and care of the species to be used; aseptic surgical methods and techniques; and the proper use of anesthetics, analgesics, and tranquilizers.

3) I assure that all procedures will be conducted in accordance with all applicable Colorado State University IACUC policies as well as Occupational and Biosafety requirements, including those pertaining to the use of personal protective equipment.

4) I assure that all individuals working on this proposed protocol are participating in the Occupational Health and Safety Program (OHSP).

5) I assure that ANY change in the care and use of animals involved in this protocol will be promptly forwarded to the IACUC for review. Such changes will not be implemented until approval is obtained from the IACUC. Animals will not be transferred between investigators without prior approval.

6) I assure that I have reviewed the pertinent scientific literature and the sources and/or databases and have found no valid alternative to any procedures described herein which may cause more than momentary or slight pain, distress, or generalized discomfort to animals, whether it is relieved or not.

7) I assure that every effort has been made to minimize the number of animals used and reduce the amount of pain, distress, and/or discomfort these animals must experience.

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of pain, distress, and/or discomfort these animals must experience.

8) I assure that the activities described in this document submitted for IACUC review are consistent with those described in any related grant, contract, or subcontract that has been submitted or awarded.

9) I assure that the information contained in this application for animal use is accurate to the best of my knowledge.

10) I understand that this application and/or my animal use privileges may be revoked by the IACUC if I violate any of the aforementioned assurance statements.

X The Principal Investigator has read and agrees to abide by the above assurances

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* * * Event History * * *

Event History

Date	Status	View Attachments	Letters
05/21/2019	NEW FORM CREATED		
05/22/2019	NEW FORM SUBMITTED	Y	
05/28/2019	NEW FORM PANEL ASSIGNED		
05/28/2019	NEW FORM REVIEWER(S) ASSIGNED		
05/28/2019	NEW FORM PANEL REASSIGNED		
05/31/2019	NEW FORM REVIEWER(S) ASSIGNED		
06/18/2019	NEW FORM SUBMITTED (CYCLE 1)	Y	
07/03/2019	NEW FORM REVIEWER(S) ASSIGNED		
07/16/2019	NEW FORM APPROVED	Y	Y