

ACORP Appendix 3, DRAFT TEST SUBSTANCES

1. **Toxic Agents.** Will toxic chemicals, toxic pharmacologic agents, known or suspected mutagens, carcinogens, teratogens, DNA-binding, or other similar agents be used in animals?

No. Proceed to item 2.

Yes. Complete items 1.a, 1.b, 1.c, and 1.d, then proceed to item 2.

a. Table of toxic agents.

Agent	Diluent	Route of admin.	Dose (e.g. mg/kg) and Volume (ml)	Frequency and duration of administration	Reason for admin., and expected effects

b. Indicate which of the above agents, if any, are known or suspected mutagens, carcinogens, or teratogens.

c. Are any of the agents above on the CDC list of “select agents” that might have bioterrorism uses? Check the appropriate response below and proceed to item 2.d.

No.

Yes. Ask your research office to contact the VAHQ Biosafety Officer for further instructions as soon as possible. You will have to obtain a CDC license and HQ approval before beginning your studies with this agent.

d. Will the animals be anesthetized or sedated when these agents are administered?

No. Proceed to item 2.

Yes. Detail the method of anesthetic, sedative, or tranquilizer administration including agent, dose and volume, and route; then proceed to item 2.

2. **Infectious Agents.** Will bacterial, viral, rickettsial, fungal, protozoal, or other infectious agents be used in animals? If the agent will have a radioactive label added, also complete item 4 below. Likewise, if the infectious agent contains recombinant nucleic acid, fill out item 6 below for the agent as well.

No. Proceed to item 3.

Yes. Complete items 2.a, 2.b, 2.c, and 2.d; then proceed to item 3.

a. Complete the table below.

Agent and strain or construct	CDC Biosafety Level of agent (BSL1, 2, 3, 4)	Route of admin.	Dose (e.g. CFU, PFU) and volume administered (ml)	Frequency of administration

b. Has an antibiogram, anti-viral drug sensitivity screen, or other appropriate drug sensitivity panel been determined for the agent(s) listed to assist physicians in selecting proper therapy if an inadvertent human infection occurs?

c. Will the animals be anesthetized or sedated when these agents are administered?

- No. Proceed to item 2.d.
- Yes. Detail the method of anesthetic, sedative, or tranquilizer administration including agent, dose and volume, and route; then proceed to item 2.d.

d. Are any of the agents on the CDC list of “select agents” that might have bioterrorism uses? Check the appropriate response below and proceed to item 3.

- No.
- Yes. Ask your research office to contact the VAHQ Biosafety Officer for further instructions as soon as possible. You will have to obtain a CDC license and HQ approval before beginning your studies with this agent.

3. **Biological Materials.** Will serum, cell lines, tissue, nucleic acid or other biological materials be administered to animals? If any of the agents are radioactive or will have a radioactive label added, also complete item 4 for that agent.

- No. Proceed to item 4.
- Yes. Complete items 3.a., 3.b., and 3.c.; then proceed to item 4.

a. Table of biological materials.

Material (e.g. fluid, cells, tissues)	Diluent	Source (e.g. vendor, other animals, colleague)	Route of admin.	Dose (e.g. ml/kg, mg/kg, cells/kg) and volume (ml)	Frequency and duration of admin.	Reason for admin., and expected effects

b. Will the animals be anesthetized or sedated when these agents are administered?

- No. Proceed to item 4.
- Yes. Detail the method of anesthetic, sedative, or tranquilizer administration including agent, dose and volume, and route; then proceed to item 4.

c. How will these materials be screened to make sure they do not harbor infectious agents that could infect other laboratory animals or people?

4. **Radioactive Agents.** Will radioactive compounds or agents be administered to animals?

- No. Proceed to item 5.
- Yes. Complete items 4.a., 4.b., and 4.c.; then proceed to item 5.

a. Table of radioactive agents.

Radioactive Agent (include isotope)	Diluent	Agent dose (mg/kg) and Vol. (ml)	Activity (e.g. mCi/kg)	Route of admin.	Frequency and duration of admin.	Reason for admin., and expected effects

b. Which investigator has been given permission by the Radiation Safety Committee or equivalent committee to utilize the isotope(s) indicated above?

- c. Will the animals be anesthetized or sedated when these agents are administered?
- No. Proceed to item 5.
 - Yes. Detail the method of anesthetic, sedative, or tranquilizer administration including agent, dose and volume, and route; then proceed to item 5.

5. **Other Agents.** Will other substances not listed previously in this appendix be administered to animals? Do not include anesthetics/analgesics/sedatives you will describe elsewhere in the ACORP as part of surgery and postoperative care.

- No. Proceed to item 6.
- Yes. Complete items 5.a. and 5.b.; then proceed to item 6.

a. Table of other agents.

Agent	Diluent	Agent dose (e.g. mg/kg) and Vol. (ml)	Route of admin.	Frequency and duration of admin.	Reason for admin., and expected effects

- b. Will the animals be anesthetized or sedated when these agents are administered?
- No. Proceed to item 6.
 - Yes. Detail the method of anesthetic, sedative, or tranquilizer administration including agent, dose and volume, and route; then proceed to item 6.

6. **Recombinant nucleic acid and recombinant infectious agents.**

a. Do any of the agents noted above in items 1-5 above have recombinant nucleic acid in them?

- No. Proceed to item 7.
- Yes. Answer item 6.b.

b. Are the recombinant constructs exempt from the animal research guidelines included in the latest version of the *NIH Guidelines for Recombinant DNA and Gene Transfer* publication?

- No. You must conduct the animal experiments involving recombinant nucleic acid according to the *NIH Guidelines for Recombinant DNA and Gene Transfer*. Consult with your Biosafety Committee and veterinarian to make sure you comply. Go to item 7.
- Yes. Go to item 7

7. **Pain or Distress.** Will animals potentially experience pain and/or distress as a result of the administration of agents listed above in items 1, 2, 3, 4, 5, or 6?

- No. Proceed to item 8.
- Yes. Describe the nature of the pain and/or distress that animals might experience and describe measures that will be taken to alleviate any pain and/or distress. Then proceed to item

8. **Hazardous/Toxic Agents.** Are any of the agents listed above in items 1-6 hazardous or toxic to humans or animals, or covered by the *NIH Guidelines for Recombinant DNA and Gene Transfer*?

- No. **You have completed this appendix; no further information is required in this appendix. Go to item Q on the ACORP. YOU DO NOT NEED TO GET SIGNATURES IN ITEM 9. BELOW!**
- Yes. Complete items 8.a., 8.b., and 9; then return to item Q on the ACORP.

a. Table of hazardous agents, committee approvals, and personnel exposed.

Toxic or hazardous agent(s) from items 1-5 above, or non-exempt agent(s) from item 6.	Safety, biosafety, or radiation safety committee that has approved the use of this hazardous agent	Is this a VA or affiliate committee?	List all animal facility staff who will come in contact with animals given these agents or with contaminated bedding, cages, or other items.
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b. Discuss how the individuals listed in the table above (item 8.a.) have been (or will be) informed of the possible risks of exposure, and have been (or will be) trained to avoid exposure to these agents.

9. **Signatures.** By our signatures, we certify that:

- a. Before any animal experiments involving the agents listed in item 8.a. are performed, SOPs designed to protect all animal facility staff as well as non-study animals will be developed and approved by the appropriate VA or affiliated university safety committee and the IACUC; and
- b. All staff that might be exposed to these agents will be informed of possible risks and will be properly trained to follow the SOPs to minimize the risk of exposure. As is appropriate, concurrence signatures from biosafety or radiation safety personnel are also required as shown.

Principal Investigator(s)	Signature(s)	Date
Institutional Veterinarian	Signature	Date
Biosafety Officer or Chair, Research Safety or Biosafety Committee (typed)	Signature	Date
Radiation Safety Officer, or Chair, Radiation Safety or Isotope Committee (typed)	Signature	Date
IACUC Chair (typed)	Signature	Date