**CNPRC**

**PROTOCOL: 10464**
**EXPIRES: 2/13/04**

**Investigator**

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**Contact**

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**Species (common names):**

<table>
<thead>
<tr>
<th>Species</th>
<th>Number</th>
<th>Source</th>
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<tbody>
<tr>
<td>Rhesus</td>
<td>13-15</td>
<td>CNPRC</td>
</tr>
<tr>
<td>Cynomolgus</td>
<td>13-15</td>
<td>CNPRC</td>
</tr>
</tbody>
</table>

**Total Primates:** 28 Max. CNPRC

**Project Title:** Reagent Production for Primate Retrovirus Diagnostics

**Overnight housing location:** CNPRC

**Day use only:**

- [X] Vivarium
- [ ] Investigator (If investigator maintained, attach husbandry SOP’s.)

**Procedures:** Provide a one or two sentence layman’s description of the procedures employed on the animals in this project. This information will help the animal care staff understand any conditions they may encounter while caring for your animals.

Two categories of animals will be used in this protocol - experimentally infected animals and animals with naturally-acquired infections identified during on-going colony testing. Data derived from both groups of animals will be for development, validation, and interpretation of viral diagnostic tests made available to many US primate facilities through the Simian Retrovirus Core Laboratory at the CNPRC, in support of SPF Macaque Colony development. Samples from experimentally infected animals will be used to characterize early immune responses including seroconversion panels. Samples from naturally infected animals will provide positive control sera and peripheral blood cells for culture, antigen and nucleic acid detection assays (e.g.: PCR).

**Special Husbandry Requirements:** Describe any special requirements your animals have with respect to food, water, temperature, humidity, light cycles, caging type, bedding, or any other conditions of husbandry.

Animals will be housed under BSL2 conditions.

**Other instructions for animal care staff:** (check applicable entries)

**Sick Animals**

- [X] Call Investigator
- [ ] Call Investigator
- [X] Clinician to treat
- [ ] Terminate
- [ ] Necropsy

**Dead Animals**

- [X] Call Investigator
- [X] Save for Investigator
- [ ] Bag for disposal
- [X] Necropsy

**Pest Control**

- [X] OK to use pesticides
- [ ] No Pesticides in animal area

**Hazardous Materials (only if in the animal room):**

- **Infectious Agents?**
  - [ ] Yes
  - [X] No
  - Agent(s): HIV-1, 2, SIV, HTLV, STLV, SRV, SFV (retroviruses), & RRV (a herpes virus)

- **Radioisotopes?**
  - [ ] Yes
  - [X] No
  - Agent(s): BAUA# B0520

- **Chemical Carcinogens?**
  - [ ] Yes
  - [X] No
  - Agent(s):

- **Toxic Chemicals?**
  - [ ] Yes
  - [X] No
  - Agent(s):
Summary of Procedures:

a) Briefly describe the overall intent of the study. Include in your description a statement of your hypothesis, the objectives and significance of the study. Your target audience is a faculty member from a discipline unrelated to yours. Do not use jargon.

The overall intent of this study is to provide quantities of blood, tissue, and body fluid specimens from documented time points following infection or immunization with various viruses or viral constituents (e.g. proteins, peptides or nucleic acids) in naturally infected animals. The specimens will be rigorously tested and characterized as to viral antibody, antigen, RNA and DNA and other markers of infection and/or immune response. This data will allow us to document the time course of response to various viruses and specific viral proteins. These specimens will ultimately be used as control and standard reagents for various viral assays.

b) Procedures employed in this project:

Please check the appropriate boxes if any of these procedures will be employed in your project:

- [ ] Monoclonal Antibody Production **
- [X] Polyclonal Antibody Production **
- [ ] LD 50 or ID50 studies.
- [X] catheters, blood collection, intubation
- [ ] Prolonged restraint (8 hrs+)
- [X] Fasting prior to a procedure.
- [ ] Food or water restriction
- [ ] Non-recovery surgical procedures
- [X] Survival surgical procedures
- [ ] Multiple survival surgery
- [ ] Special diets; food or water treatment.
- [ ] Induced illness, intoxication, or disease
- [X] Death as an endpoint (see i below)
- [ ] Trapping, banding or marking wild animals
- [ ] Behavioral modification.
- [ ] Aversive conditioning.

** If this protocol only describes antibody production, you may use the attached antibody production page in lieu of completing section c below.
c) **Describe the use of animals in your project in detail**, with special reference to any of procedures checked above. Include any physical, chemical or biological agents that may be administered. List each study group, and describe all the specific procedures that will be performed on each animal in each study group. Use terminology that will be understood by individuals outside your field of expertise. *(Note: This cell will expand to whatever length you require. You may make this section as long as you wish, but try to be concise. Some projects may require one or two pages.)*

Macques will be inoculated intravenously (IV) with virus or infected cells (vol < 5 ml). Other animals will be immunized intramuscularly (IM) or intradermally (ID) with viral antigens. Route of injection will be determined by the antigen preparation chosen. Blood for serum and plasma, and saliva will be collected and banked (frozen -70°C) weekly for 4-6 weeks and bi-weekly thereafter. Naturally infected animals will be maintained indefinitely as a source of positive control specimens and as a source of novel virus strains. Healthy, infected animals will be sampled sporadically, but not to exceed once per month. Bone marrow aspirates (1-2 ml), CSF taps (~1ml) and Lymph node biopsies may be performed to determine latency of virus in tissues other than peripheral blood lymphocytes. Each animal will receive a maximum of 2 biopsies, 2 CSF taps, and 2 aspirates, at least 1 month apart. Blood volume will not exceed 12ml/kg/month as per CNPRC SOP. When immunological response has peaked, maximal safe volumes of serum or plasma will be collected and stored as reference reagents. After peak response animals will be maintained as long as they are healthy, and sampled as above for naturally infected animals. All procedures will be performed with animals under Ketamine anesthesia. Lidocaine and Oxymorphone will be used pre-biopsy/aspiration and post-biopsy/aspiration for anesthesia/analgesia as deemed appropriate by the attending veterinarian.

<table>
<thead>
<tr>
<th>Virus/Antigen</th>
<th>No. and Species of Animals</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV1-2, or SHIV</td>
<td>2 (rhesus and/or cyno)</td>
</tr>
<tr>
<td>HTLV/STLV</td>
<td>4 (2 rhesus, 2 cyno)</td>
</tr>
<tr>
<td>SRV (simian type D retrovirus)</td>
<td>8 (3 rhesus, 5 cyno)</td>
</tr>
<tr>
<td>SFV (simian foamy virus)</td>
<td>8 (4 rhesus, 4 cyno)</td>
</tr>
<tr>
<td>RRV (rhesus rhadinovirus)</td>
<td>2 rhesus</td>
</tr>
<tr>
<td>SPF for the above (negative control)</td>
<td>4 (2 rhesus, 2 cyno)</td>
</tr>
</tbody>
</table>

**d) Study Groups and Numbers:** Define, in the form of a table, the numbers of animals to be used in each experimental group described above. The table may be presented on a separate page as an attachment to this protocol if you prefer. The Normal format should be three columns: Study Group, Procedure, Number of animals. The number of rows should follow from the number of study groups; **you may add as many rows as you require.** The chart must fully account for the number of animals you intend to use under this protocol. Assign each group to an invasiveness category according to the chart below.

<table>
<thead>
<tr>
<th>Group</th>
<th>Procedures / Drugs</th>
<th>Number of Animals</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>HIV1-2, or SHIV--blood collection, lymph node biopsy, bone marrow aspirates</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>HTLV/STLV--blood collection, lymph node biopsy, bone marrow aspirates</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>SRV--blood collection, lymph node biopsy, bone marrow aspirates</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>SFV--blood collection, lymph node biopsy, bone marrow aspirates</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td>5</td>
<td>RRV--blood collection, lymph node biopsy, bone marrow aspirates</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>6</td>
<td>SPF for the above--blood collection, lymph node biopsy, bone marrow aspirates</td>
<td>4</td>
<td>2</td>
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</tbody>
</table>
### Categories of invasiveness

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
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</thead>
</table>
| 1        | Little or no discomfort or stress  
**Examples:** domestic flocks or herds being maintained in simulated or actual commercial production management systems; the short-term and skilful restraint of animals for purposes of observation or physical examination; blood sampling; injection of material in amounts that will not cause adverse reactions by the following routes: intravenous, subcutaneous, intramuscular, intraperitoneal, or oral. |
| 2        | Minor stress or pain of short duration  
**Examples:** cannulation or catheterization of blood vessels or body cavities under anesthesia; minor surgical procedures under anesthesia, such as biopsies or laparoscopy; short periods of restraint beyond that required for simple observation or examination, but consistent with minimal distress |
| 3        | Moderate to severe distress  
**Examples:** major surgical procedures conducted under general anesthesia, with subsequent recovery; prolonged (several hours or more) periods of physical restraint; induction of behavioral stresses such as maternal deprivation |
| 4        | Severe pain near, at or above the pain tolerance threshold  
**Examples:** exposure to noxious stimuli or agents whose effects are unknown; exposure to drugs, chemicals, or infectious agents at levels that markedly impair physiological systems and which cause death, severe pain, or extreme distress; Surgical experiments which have a high degree of invasiveness. |

Further descriptions of these categories are included in the instructions following this document.

**e) Rationale for species and numbers:** How did you determine that 1) the species choice was appropriate and 2) the number of animals in each study groups was the minimum number necessary to achieve sound scientific results?

Rhesus and cynomolgus macaques are the most appropriate species for these studies because a review of the literature and our previous experience indicates we can readily infect and/or induce immune response with these agents. Macaques are the natural host species for SRV, STLV, SFV, and RRV. Reagents and samples generated in these studies will provide control/standards for virological and serological assays used primarily for testing of naturally and experimentally infected macaques. Naturally infected animals will provide source material for characterization of novel virus strains. The numbers were chosen to minimize animal use and yet reflects an increased need to maintain naturally infected animals with SFV and SRV. Blood volume will not exceed 12ml/kg/month as per CNPRC SOP.

**f) Surgery:** If the project involves survival surgery, where will the surgery be conducted?

<table>
<thead>
<tr>
<th>Building</th>
<th>Room</th>
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</table>

Who will be the surgeon?

**g) Anesthetics, Analgesics, Tranquilizers, Neuromuscular blocking agents:**

Post procedural analgesics should be given whenever there is possibility of pain or discomfort that is more than slight or momentary. If postoperative analgesics are not to be given, justify the practice under part (i) below.

Provide the following information about any of these drugs that you intend to use in this project.

<table>
<thead>
<tr>
<th>Species</th>
<th>Drug</th>
<th>Dose (mg/kg)</th>
<th>Route</th>
<th>When and how often will it be given?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rhesus &amp; cynomolgus</td>
<td>Ketamine HCl</td>
<td>10 mg/kg</td>
<td>IM</td>
<td>Once weekly</td>
</tr>
<tr>
<td>macaques</td>
<td>Oxymporine</td>
<td>0.15 mg/kg</td>
<td>IM</td>
<td>1 day</td>
</tr>
<tr>
<td></td>
<td>Lidocaine</td>
<td></td>
<td>SZ/ID</td>
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</table>

**h) Neuromuscular blocking agents** can conceal inadequate anesthesia and therefore require special justification. If you are using a neuromuscular blocking agent, please complete the following:

Why do you need to use a neuromuscular blocking agent?
What physiologic parameters are monitored during the procedure to assess adequacy of anesthesia?

Under what circumstances will incremental doses of anesthetics-analgesics be administered?

i) Adverse effects:
Describe any potential adverse effects of the experiment on the animals (such as pain, discomfort; reduced growth, fever, anemia, neurological deficits; behavioral abnormalities or other clinical symptoms of acute or chronic distress or nutritional deficiency)

Natural infection and inoculation with SRV may result in immunosuppressive disease, characterized by fever, lymphnode and spleen enlargement, anemia, and infection with opportunistic infections. Inoculation or natural infection with HIV/SHIV, STLV, HTLV, RRV or SFV is not expected to result in and clinical illness. These agents appear to be nonpathogenic in macaques. Similarly, no adverse effects are expected following inoculation of recombinant proteins or synthetic peptides. The adjuvants selected for these immunizations do not result in severe localized inflammatory reactions. A transient mild to moderate local reaction may occur with Alum or Incomplete Freunds Adjuvant (IFA).

How will the signs listed above be ameliorated or alleviated? If signs are not to be alleviated or ameliorated by means of post-operative analgesics or other means, explain why this is necessary.

Analgesics and anesthetics will be provided. Local anesthetic (Lidocaine) will be used at the site of biopsy. Analgesics will also be administered following bone marrow aspiration and lymphnode biopsy procedures. If animals become seriously ill with progressive disease, unresponsive to supportive and specific treatments, they will be euthanized as deemed necessary and appropriate by the attending veterinarian.

Note: if any unanticipated adverse effects not described above do occur during the course of the study, a complete description of those effects and the steps taken to mitigate them must be submitted to the committee as an amendment to this protocol.

Is death an endpoint in your experimental procedure? [ ] Yes [X] No
(Note: “Death as an endpoint” refers to acute toxicity testing, assessment of virulence of pathogens, neutralization tests for toxins, and other studies in which animals are not euthanized, but die as a direct result of the experimental manipulation). If death is an endpoint, explain why it is not possible to euthanize the animals at an earlier point in the study. If you can euthanize the animals at an earlier point, describe the clinical signs which will dictate that an animal will be euthanized.

Animals will be euthanized before the end of the study if they become seriously ill and fail to respond to supportive or specific treatment, and when deemed necessary and appropriate by the attending CNPRC veterinarian.

j) Literature search for alternatives and unnecessary duplication:

Federal law specifically requires this section. You are required to conduct a literature search to determine that either 1) there are no alternative methodologies by which to conduct this class/lab, or 2) there are alternative methodologies, but these are not appropriate for your particular class/lab. “Alternative methodologies” refers to reduction, replacement, and refinement (the three R’s) of animal use, not just animal replacement. You must also show that this use of animals is not unnecessarily duplicative of other studies.

UC Davis provides on-line access to a number of databases that can be used to search for alternatives. Visit http://trc.ucdavis.edu/jawelsh/Databases/Databases_Med_Vet_Researchers.htm (email: jawelsh@ucdavis.edu) or http://www.vetmed.ucdavis.edu/Animal_Alternatives/main.htm (email: mwwood@ucdavis.edu)

What was the date on which you conducted this search? 11/26/02

List the databases searched or other sources consulted (there should be more than one). Include the years covered by the search.

<table>
<thead>
<tr>
<th>Database Name</th>
<th>Years Covered</th>
<th>Keywords / Search Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCBI PUB MED</td>
<td>~1965-2002</td>
<td>Simian retrovirus, human retrovirus + macaque, immune response, rhesus rhadinovirus, macaque</td>
</tr>
<tr>
<td>Current contents</td>
<td>1980-2002</td>
<td>Simian retrovirus, human retrovirus + macaque, immune response, rhesus rhadinovirus, macaque</td>
</tr>
</tbody>
</table>
What were your findings with respect to alternative methodologies?

Literature search reveals no non-animal alternatives to the in vivo studies we are proposing. Control reagents must be from macaques to validate procedures. Procedures proposed are minimally invasive.

Has this study been previously conducted?  [  ] Yes  [  ] No

If the study has been conducted previously, explain why it is scientifically necessary to replicate the experiment.

This is an ongoing study; No previous studies have generated adequate volumes of samples at specific time points to provide standards and controls for large-scale diagnostic use.

k) Disposition of animals: At what point in the study, if any, will the animals be euthanized?

Animals infected with HIV, HTLV, STLV and SRV will be euthanized at the end of the study period if they cannot be used in other studies. Animals naturally infected or inoculated with SFV or RRV could potentially return to the colony, as these viruses are naturally occurring endemic infections in macaques and are thought to be nonpathogenic.

l) Methods of euthanasia: Even if your study does not involve killing the animals, you should show a method that you would use in the event of unanticipated injury or illness. If anesthetic overdose is the method, show the agent, dose, and route.

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>Drug</th>
<th>Dose (mg/kg)</th>
<th>route</th>
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</thead>
<tbody>
<tr>
<td>Rhesus, Cyno</td>
<td>Overdose</td>
<td>Pentobarbital</td>
<td>60 mg/kg</td>
<td>IV</td>
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m) Surplus animals: What will you do with any animals not euthanized at the conclusion of the project?

Uninfected animals immunized with viral antigens and animals infected with SFV and SRV may be returned to the CNPRC research pool.
n) Project Roster: Please provide the names of all the individuals who will work with animals on this project. This page will not be made available to the public. Give either the University Employee ID # or a valid UC Davis email address so that we can document training and occupational health compliance for regulatory agencies. Include all investigators, student employees, post-doctoral researchers, staff research associates, post-graduate researchers and laboratory assistants who will actually work with the animals. You don't need to include the staff of the vivarium in which your animals will be housed.

The principal investigator is responsible for keeping this roster current. If any staff is added or subtracted from this project, you must amend the protocol by sending the campus veterinarian a memo describing any changes.

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<tr>
<th>Last Name</th>
<th>First Name</th>
<th>Middle Name</th>
<th>UC ID Number or SSN</th>
<th>Email Address</th>
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Occupational Health Program:

Supervisors must enroll their employees in the campus Occupational Health Program if the workers are at increased risk of illness or injury (such as allergy, physical injury, or infectious disease) because of their work. Enroll workers by having them complete an "Animal Contact History Form", available from Employee Health Services (phone 752-2330). For further information, visit our web site at http://clueless.ucdavis.edu/health/ or read the UC Davis Policy & Procedure Manual 290-25.

Training:

Supervisors are responsible for insuring that their employees are adequate trained, both in the specifics of their job and in the requirements of the Federal Animal Welfare Act. EH&S offers free, basic wet labs in laboratory animal handling and techniques, and lecture format classes in the requirements of the Animal Welfare Act. To schedule a class for your unit, contact EH&S at 2-2364. Autotutorials are also available on the world wide web at http://clueless.ucdavis.edu/.
Assurances for the Humane Care and Use of Vertebrate Animals:

Principal Investigator's Statement:

I have read and agree to abide by the UC Davis Policy and Procedure Manual section 290-30 (Animal Use and Care). This project will be conducted in accordance with the ILAR Guide for the Care and Use of Laboratory Animals, and the UC Davis Animal Welfare Assurance on file with the US Public Health Service. (These documents are available from the Campus Veterinarian and at http://ehs.ucdavis.edu/). I will abide by all Federal, state and local laws and regulations dealing with the use of animals in research.

I will advise the Animal Use and Care Administrative Advisory Committee in writing of any significant changes in the procedures or personnel involved in this project.

<table>
<thead>
<tr>
<th>Principal Investigator</th>
<th>Rank / Title</th>
<th>Date</th>
</tr>
</thead>
</table>

** Conditions necessary for Committee Approval:

Final Disposition of this protocol:

- [ ] Approved
- [ ] Not Approved
- [ ] Withdrawn by Investigator

Date of Action: _____ / _____ / _____

I verify that the Institutional Animal Care and Use Committee of the University of California, Davis, acted on this protocol as shown above.

<table>
<thead>
<tr>
<th>Campus Veterinarian</th>
<th>Date</th>
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</table>

Campus Veterinarian
Antibody Production Project Description

If your project involves only antibody production, either polyclonal or monoclonal, you may complete this page in lieu of section c), project description.

c) Will these animals be used for antibody production? [X] Yes [ ] No

1. Polyclonal or Monoclonal antibodies? Polyclonal
   If Monoclonal, will you be producing ascites tumors in the animals? [ ] Yes [ ] No

2. What type(s) of antigen will be used? Whole, inactivated virus, infected cells, recombinant proteins, synthetic peptides.
   Will the antigens be sterile? Yes

3. What adjuvant will be used for the initial injection? MDP, SAF, Alum, IFA [MDP and SAF are both emulsified lipid/aqueous suspensions with Muramyl Dipeptide (a highly active epitope from mycobacterium cell walls.) They produce stimulation similar to Freunds adjuvant without the injection-site trauma common with Freunds, in primates. Adjuvant choice will be based on the ability to produce appropriate response with as little trauma as possible.]
   What adjuvant will be used for subsequent injections? MDP, SAF, Alum, IFA

4. What route will be used for injections? IV, IM or ID
   What anatomical location will be injected? Saphenous vein (IV), Thigh muscle (IM)
   How many injections at one time? 2 maximum
   How frequently will injections be given? > biweekly
   What volume will be injected at each site? < 1ml

5. Polyclonal Blood collection Procedures:
   Who will collect the blood? Research Services SRA
   From what anatomical location? Femoral Vein
   How frequently will blood be collected? weekly
   Will the animals be sedated? [X] Yes [ ] No

6. Will monoclonal antibodies be produced in mice bearing ascites tumors? [ ] Yes [ ] No
   How often will the animals be assessed for abdominal distention?
   How often will they be tapped?
   How many times will they be tapped?
   Will the animals be sedated for tapping?

Note: If you are producing monoclonal antibodies using ascites tumors in mice, section j), alternatives, must explain why an in-vitro system is not suitable for your study.

7. Sedation / Anesthesia for blood or ascites collection: If the animals will be sedated for either injections or collections, please indicate the species, drug, dose and route:

<table>
<thead>
<tr>
<th>Species</th>
<th>Drug</th>
<th>Route</th>
<th>Dose (mg / kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rhesus, Cyno</td>
<td>Ketamine HCl</td>
<td>IM</td>
<td>10 mg/kg</td>
</tr>
</tbody>
</table>
h) What criteria will be used to determine that the animals should be euthanized rather than continue to be used?

Animals will be euthanized before the end of the study if they become seriously ill and fail to respond to supportive or specific treatment, and when deemed necessary and appropriate by the attending CRPRC veterinarian.
ANIMAL ROOM SAFETY INFORMATION

Complete this form if you will be using biohazards, radioisotopes, carcinogens, or toxic chemicals in the animal room.

PROTOCOL #__10464_
EXPIRES: ________

Identity of Hazard: Human & Simian Viruses –HIV, SHIV SIV HTLV, STLV, SRV, SFV, RRV,

Investigator Last Name: ___________________________ Department: ___________________________
First Name: ___________________________ Phone: ___________________________
Email: ___________________________ Fax: ___________________________

Provide a short description of the agent:

SHIV, SIV and SRV may cause immune deficiency. HTLV/STLV is associated with rare T-cell lymphoma; SFV is non-pathogenic, RRV is not known to be pathogenic.

This agent / material is hazardous for: [ ] Humans only [ ] Animals only [X] Humans and Animals

For which Animal Species? Non-human primates

The agent can be spread by: [X] Blood [X] Feces/urine [X] Saliva/nasal droplets [ ] Does not leave animal

Describe any human health risk associated with this agent:

Human infections with SRV, SIV and SFV, without clinical illness, have been documented. SIV is similar to HIV-2 and may ultimately cause immune deficiency disease in infected humans. HIV causes AIDS. HTLV causes rare T-cell lymphoma.

The precautions checked below apply to this experiment:

[ ] The researcher or his/her technicians are responsible for the feeding and care of these animals.
[ ] The following items must be assumed to be contaminated with hazardous material and must be handled only by the researcher or his/her technicians.
  _______ Cage _______ Stall _______ Water Bottle _______ Animal Carcasses
  _______ Bedding _______ Other:

[ ] Cages must be autoclaved before cleaning.
[ ] Label cages and remove label after decontamination.
[ ] Animal carcasses must be labeled and disposed of as follows:
  [X] Incineration [ ] Biohazardous Waste Container
  [ ] Bag and Autoclave [ ] EH&S will pick-up (2-1493).
[ ] All contaminated waste (soiled bedding or other animal waste) must be properly labeled and disposed of as follows
  [ ] Incineration [ ] Biohazardous Waste Container
  [ ] Bag and Autoclave [ ] EH&S will pick-up (2-1493).

Personal Protective Equipment Required:

[ ] The following personal protective equipment must be worn/used in the room:
  [X] Lab Coat/Coveralls [X] Shoe Covers/Booties
  [X] Disposable Gloves [ ] Head Cover
  [ ] NIOSH Certified Dust Mask [ ] Disinfectant footbath
  [X] Eye Protection/Face Shield [ ]
  [ ] Fitted Respirator ___________ Type: ___________________________
  [ ] Other: ___________________________ Describe: ___________________________

[X] Personal protective equipment must be removed before leaving the room.
[ ] Personal protective equipment must be discarded or decontaminated at the end of the project
[ ] Hands, arms, and face must be thoroughly washed upon leaving the room
[ ] Full shower, including washing of hair, must be taken upon leaving the room.
[ ] Decontaminate Room (Inform ARS area supervisor when cage and/or room can be returned to general use).

Provide any other information needed to safely work in this room:

University of California, Davis
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1/23/03

Hi,

I have received and pre reviewed the recently submitted protocol which has been assigned accession number 10464 for future reference. I have attached the protocol for ease of making revisions since I have a few questions.

For this protocol to be considered on the 2/13 committee agenda, please forward your revised protocol to me on or before noon 1/28.

thanks in advance,

Protocol 10464 (

1. On page 1 you list 13-15 animals per species, section c, list 13-15 per species and in section d, list 28 and the justification in section e appears incomplete or does not explain what you mean by "provide adequate samples for controls". There is no mention of controls. Since we do not separate the primate species in our database and just list "primate", is your total number over three years 30 or 28, or what number total over three years for page 1. You can break things down in sections c,d and e, but all numbers need to correspond. Please clarify.

2. In section c, you mention collecting blood weekly or bi-weekly. What determines the sampling period?

3. You state that naturally infected animals will be maintained for control specimens. Will these animals be kept for more than 16 weeks? If so, ho long?

4. What do you mean be "sporadic" sampling for stable animals? What samples will you collect and for how long?

5. What determines who or how many animals will get IM vs ID inoculations? What do you mean by sequential samples?

6. What happens after sample collection at peak response?

7. In section e, do you need a certain volume of samples for developing your assays and the numbers of animals proposed will provide you with that volume? Please clarify the differences in numbers.

8. You use acronyms for the adjuvants. What is MDF and SAF? What determines which adjuvant is used?
Answers to questions:

1. SRV (simian type D retrovirus); SFV (simian foamy virus); RRV (rhesus rhadinovirus)

2. "increased" in the sentence is misleading/confusing and should be deleted. The numbers of animals indicated in the application reflect an increased need to maintain animals naturally infected with SFV and SRV.

----- Original Message -----
Hi,

I have received the following questions for the protocol on this week's committee agenda. Please forward the response as soon as possible to provide clarification prior to final review by the committee.

Thanks in advance,

>>#10464>

>>Why is there such a wide variation in numbers of animals between the treatment groups (2 -8)? the numbers justification is confusing. Please clarify.