**CNPRC**

Investigator:  
Last Name:  
First:  
Middle:  
email:  
Department:  
Phone / Fax:  
After hrs. #:  

Contact:  
Last Name:  
First:  
Middle:  
email:  
Department:  
Phone:  
After hrs. #:  

**Species (common names):**  
rhesus  

**Number:**  
24  

**Source:**  
CNPRC  

---

**Project Title:**  
HIV vaccination strategies using mutant adenovirus constructs

**Overnight housing location:**  
CNPRC  

**Day use:**  
CNPRC (workrooms or animal quarters)

---

**Animals will be maintained by:**  
[ 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.

Animals will be vaccinated and boosted with a combination of killed or replication-defective viruses and then challenged with SHIV SF162PB (a pathogenic SIV with HIV envelope).

---

**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.

---

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

<table>
<thead>
<tr>
<th>Sick Animals</th>
<th>Dead Animals</th>
<th>Pest Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ X ] Call Investigator</td>
<td>[ X ] Call Investigator</td>
<td>[ ] Call Investigator</td>
</tr>
<tr>
<td>[ X ] Clinician to treat</td>
<td>[ ] Save for Investigator</td>
<td>[ X ] OK to use pesticides</td>
</tr>
<tr>
<td>[ ] Terminate</td>
<td>[ ] Bag for disposal</td>
<td>[ ] No Pesticides in animal area</td>
</tr>
<tr>
<td>[ ] Necropsy</td>
<td>[ X] Necropsy</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Infectious Agents?</th>
<th>[ X ] Yes</th>
<th>[ ] No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agent(s):</td>
<td>SHIV SF162PB</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Radioisotopes?</th>
<th>[ ] Yes</th>
<th>[ X ] No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agent(s):</td>
<td></td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Chemical Carcinogens?</th>
<th>[ ] Yes</th>
<th>[ X ] No</th>
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<tbody>
<tr>
<td>Agent(s):</td>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxic Chemicals?</th>
<th>[ ] Yes</th>
<th>[ X ] No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agent(s):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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.

Thus far, attenuated vaccines (SHIV 89.6) have shown the best protection against SIV (simian immunodeficiency virus) challenge. However, there is little chance an attenuated HIV virus will be used as a vaccine in humans. Thus, the search continues for an effective vaccine strategy. We hypothesize using either 1) Whole killed HIV + CpG (cytosine and guanine linked by a phosphate) ODN (oligodeoxynucleotide) vaccination followed by boosting with replication-incompetent mutant adenoviruses expressing immunogenic HIV epitopes or 2) Vaccination with replication-incompetent mutant adenoviruses expressing a combination of immunogenic HIV epitopes followed by boosting more mutant replication-incompetent adenovirus will provide protection against SHIV challenge.

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

** 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.)

The general schedule for this project will be as follows:

0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24

= blood collection

= Immunizations

Explanation of recombinant viruses used:

TCE4- replication incompetent recombinant adenovirus expressing multiple CTL(cytotoxic T lymphocyte) epitopes of HIV envelope, nef, reverse transcriptase and tat

NE- replication incompetent recombinant adenovirus expressing two neutralizing epitopes of HIV envelope.

Group A- Immunization with Whole Killed HIV and CpG ODN with Mutant Adenovirus boost will protect from SHIV challenge.

Six juvenile males will be immunized with 500 ug whole killed HIV and 500 ug CpG ODN in 1 ml phosphate buffered saline on Day 0 by intra-muscular injection. Blood will be drawn on Day 0 as a baseline (10-20 mls, not to exceed 12 ml/kg/month in compliance with Primate Center blood collection guidelines (SOP GG-5)) and also on week 3 to assess systemic immune responses. Animals will be boosted on week 6 with a mixture of two replication-incompetent adenoviruses presenting HIV epitopes (different parts of the HIV genome) TCE4 and NE. 5x10⁸ pfu/virus in 1 ml phosphate buffered saline will be given by intra-muscular injection. Blood will be drawn on week 6 and week 10 (10-20 mls, not to exceed 12 ml/kg/month in compliance with Primate Center blood collection guidelines (SOP GG-5)) to assess systemic immune responses. Animals will be boosted again on week 14 with a mixture of two replication-incompetent adenoviruses presenting HIV gag epitopes (different parts of the HIV genome) TCE4 and NE. 5x10⁸ pfu/virus in 1 ml phosphate buffered saline will be given by intra-muscular injection. Blood will be drawn (10-20 mls, not to exceed 12 ml/kg/month) on weeks 14 and 17 to assess systemic immune responses. On week 20, animals will be challenged with 10⁵ TCID₅₀ SHIV SF162 PB (a pathogenic SHIV) in 1 ml phosphate buffered saline intravenously. Blood (10-20 mls, not to exceed 12 ml/kg/month in compliance with Primate Center blood collection guidelines (SOP GG-5)) will be collected on weeks 20, 21, 22, and 24 to monitor immune responses and viral status and once a month thereafter until necropsy 6 months post-challenge. Lymphoid tissues will be collected at the time of necropsy to study immune responses and viral populations.

Group B- Immunization and boost with Mutant Adenovirus boost will protect from SHIV challenge.

Six juvenile males will be immunized with a mixture of two replication-incompetent adenoviruses presenting HIV epitopes (different parts of the HIV genome) TCE4 and NE. 5x10⁸ pfu/virus in 1 ml phosphate buffered saline will be given by intra-muscular injection. Blood will be drawn on Day 0 as a
baseline (10-20 mls, not to exceed 12 ml/kg/month in compliance with Primate Center blood collection guidelines (SOP GG-5)) and also on week 3 to assess systemic immune responses. Animals will be boosted on week 6 with a mixture of two replication-incompetent adenoviruses presenting HIV gag epitopes (different parts of the HIV genome) TCE4 and NE. 5x10⁸ pfu/virus in 1 ml phosphate buffered saline will be given by intra-muscular injection. Blood will be drawn on week 6 and week 10 (10-20 mls, not to exceed 12 ml/kg/month in compliance with Primate Center blood collection guidelines (SOP GG-5)) to assess systemic immune responses. Animals will be boosted again on week 14 with a mixture of two replication-incompetent adenoviruses presenting HIV gag epitopes (different parts of the HIV genome) TCE4 and NE. 5x10⁸ pfu/virus in 1 ml phosphate buffered saline will be given by intra-muscular injection. 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### Categories of invasiveness

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</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 skillful 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?

The rhesus macaque animal model is the most generally accepted model predication of human immune responses and primates must be used for pre-clinical virus challenge studies. The minimum number of animals that can be used to determine statistically significant differences between groups when using an intravenous SHIV challenge is six animals. Fisher’s Exact Test will be used to determine statistical significance.

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

Building:  
Room:  
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</td>
<td>ketamine</td>
<td>5-10 mg/kg</td>
<td>IM</td>
<td>Prior to all procedures</td>
</tr>
<tr>
<td>rhesus</td>
<td>buprenorphine</td>
<td>0.01-0.03mg/kg</td>
<td>IM</td>
<td>As needed in judgement of CRPRC vets</td>
</tr>
</tbody>
</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)

Any injection or venipuncture has the potential to cause minor pain or discomfort, but the animals are immobilized for the procedure and should not experience pain.
SIV/pathogenic SHIV infection of rhesus macaques results in a fatal immunodeficiency and wasting syndrome. The animals will be euthanized before, or when, they experience 3 of the following: weight loss >15% in two weeks or >30% in 3 months; persistent hypothermia <96F even with heat supplementation; leukopenia (total WBC<3,000); lymphopenia (lymphocytes <800); anemia (hemoglobin <10); dehydration >10%; nonresponsive to therapy for opportunistic infections; persistent anorexia (>3 days); animal significantly obtunded. These criteria are based on CRPRC guidelines.

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.

All possible efforts will be made to minimize animal pain and discomfort.
Analgesics have no effect on the proposed studies and they will be administered at the discretion of the CRPRC veterinary staff.

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.

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_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? 2/26/03

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>PubMed</td>
<td>1990–present</td>
<td>Adenovirus, SIV, CpG motif, vaccine</td>
</tr>
</tbody>
</table>
What were your findings with respect to alternative methodologies?

The rhesus macaque animal model is the most generally accepted model for the prediction of human immune responses and primates must be used for pre-clinical studies. Recombinant replication-defective adenoviruses have shown high efficacy as vaccine carriers for various antigens, including HIV in multiple animal models. Various mutant viruses have already been tested in the rhesus macaque model, usually testing one antigen, for example gp120 (envelope). Upon challenge with SIV, the vaccine provides partial protection. It has been found that a vaccine + boost regimen is best for immune response generation. There is a possibility that adenoviral DNA may block immune activation by stimulatory CpG motifs.

This study will multiple antigens presented by mutant adenoviruses, and takes into account the possibility of blocking immune activation by using CpG+ whole killed HIV followed by a mutant adenovirus boost. We hypothesize this strategy will provide better protection upon SHIV challenge.

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>Drug</th>
<th>Dose (mg/kg)</th>
<th>route</th>
</tr>
</thead>
<tbody>
<tr>
<td>rhesus</td>
<td>IV</td>
<td>pentobarbital</td>
<td>60 mg/kg</td>
<td>IV</td>
</tr>
</tbody>
</table>

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

Animals will be euthanized according to CNPRC criteria listed above, or at the end of the study.

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.

m) Surplus animals: What will you do with any animals not euthanized at the conclusion of the project?

All animals will be euthanized at the end of the study, or possibly recycled into therapeutic intervention studies for AIDS.
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.

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>Middle Name</th>
<th>UC ID Number or SSN</th>
<th>Email Address</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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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://ehs.ucdavis.edu/animal/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. Information is available on the world wide web at http://ehs.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.

______________  |  ______________  |  ______________  
Principal Investigator  |  Rank / Title  |  Date

Committee Use Only Below

** 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.

______________  |  ______________  
Campus Veterinarian  |  Date  

)}
Identity of Hazard: SHIV

Investigator Last Name: [Redacted]  Department: [Redacted]
First Name: [Redacted]  Phone: [Redacted]
Email: [Redacted]  Fax: [Redacted]

Provide a short description of the agent:
SHIV and SIV are primate lentiviruses which can infect human cells and potentially humans.

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

The agent can be spread by:
[X] Blood  [X] Saliva/nasal droplets  [X] Other: All mucosal secretions are potentially contaminated

Describe any human health risk associated with this agent:
SHIV can infect humans; thus, it is possible that SHIV could cause fatal, AIDS-like disease in humans. Infectious virus and SHIV antibodies have been detected in SHIV-infected humans but there have been no reports of disease in SHIV-infected people.

The precautions checked below apply to this experiment:
[X] The researcher or his/her technicians are responsible for the feeding and care of these animals.
[X] The following items must be assumed to be contaminated with hazardous material and must be handled only by the researcher or his/her technicians.
[X] Animal carcasses

Personal Protective Equipment Required:
[X] The following personal protective equipment must be worn/used in the room:
[X] Lab Coat/Coveralls  [X] Disposable Gloves  [X] NIOSH Certified Dust Mask  [X] Eye Protection/Face Shield
[X] Fitted Respirator  [X] Other: Describe: Type: Plastic dissa

Provide any other information needed to safely work in this room: Biosafety Level 2+ precautions must be used at all times.
5/23/03
Protocol 10620

Hi,

I have received and pre reviewed the recently submitted protocol which has been assigned accession number 10620 for future reference. I have attached a copy of the protocol with the number embedded for ease of making revisions.

For this protocol to be considered on the June 5th committee agenda, please forward the revised protocol to me on or before noon, May 27th.

Thanks in advance,

Protocol 10620 ( )

1. There were a number of boxes left blank. Please complete the sections for the funding source; and, whether the protocol was previously approved.

2. In section c, you used the acronym, "CTL" but have not defined this acronym. Please expand to describe what CTL stands for.

3. CNPRC has blood collection guidelines. Please reference those guidelines within your information provided about your blood collection.