

IACUC NO.: [REDACTED]

NOT A FOIA DELETION

ANIMAL PROCEDURE STATEMENT
University of Louisiana at Lafayette – NEW IBERIA RESEARCH CENTER
Animal Welfare Assurance Identification No. A3029-01

Clarification

DO NOT INCLUDE PROPRIETARY INFORMATION ON THIS FORM. PLEASE ANSWER ALL QUESTIONS.

SECTION 1: INVESTIGATOR and PROJECT INFORMATION

Principal Investigator [REDACTED] NOT A FOIA DELETION

Organization and Department [REDACTED] NOT A FOIA DELETION

Office Phone [REDACTED] Emergency (Home) Phone [REDACTED] NOT A FOIA DELETION

e-mail address [REDACTED]

Other Phone [REDACTED] NOT A FOIA DELETION

Project Title Pharmacokinetic evaluation of potential new drug candidates

Study Title (b)(4) of novel compounds in chimpanzees

Planned Start Date November 2008

End Date October 2009

SECTION 2: TYPE OF APPLICATION

CHECK A or B. If B, enter the most recent IACUC No. assigned to this study.

A. Is this a new application? YES ___ NO X B. Is this an annual renewal? YES X NO ___ (Amended)

IACUC No.: [REDACTED]

Note: The Animal Procedure Statement must be resubmitted for IACUC review on an annual basis, if the research is to continue beyond the twelve-month IACUC approval period.

SECTION 3: EXPERIMENTAL DESIGN

1. State the purpose of the research - What are the objectives?

The objective of these experiments is to determine the (b)(4) in chimpanzees prior to dosing to humans. Because the chimpanzee has been shown to be a useful model for the selection of potentially important clinical drug candidates (Wong et al., Drug Metab Dispos. 32:1359, 2004; Wong et al., Xenobiotica 36:1178, 2006), (b)(4)

2. Animal Model

Species	chimpanzee (b)(4)	*Study Length	24 hr to 2 months
Sex	male or female	*Number of Studies per Year	6-8
*Weight	(b)(4)	*Number of Animal per Study	4-6 (IV and PO)
*Age		*Number of Animals per Study Group	2-3
* Ranges can be provided		*Total Number of Animals per Year	12-24



3. Pain and/or Distress Category Distribution

A painful procedure is any procedure that would reasonably be expected to cause more than slight or momentary pain or distress in a human being to which that procedure was applied, that is, pain in excess of that caused by injection or other minor procedures.

(Categories are designated in accordance with USDA APHIS FORM 7023, Aug 91)

[A and B designations are not pain and distress categories. A are animals covered by the AWA; B are the number bred, conditioned are held for use in research, testing, experiments or surgery but not yet used for these purposes.]

Note: C + D + E = 100%

% of Animals

C. Percent of animals upon which teaching, research, experiments, or tests will be conducted involving no pain, distress, or use of pain-relieving drugs. (Animals will suffer no pain or distress greater than that produced by routine injection or venipuncture.) 100 %

D. Percent of animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to which appropriate anesthetic, analgesic, or tranquilizing drugs will be used. 0 %

E. Percent of animals upon which teaching, research, surgery, or tests will be conducted involving accompanying pain or distress and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would adversely affect the procedures, results or interpretation of

teaching, research, experiments, surgery, or tests.

(An explanation of the procedures producing pain or distress in category E and the reasons drugs are to be withheld must be attached.)

Animal usage records must include accurate account of the number of animals assigned to the C, D, and/or E pain/distress categories. If, at any time during the conduct of the research, the pain/distress category distribution changes the IACUC must be notified. If the distribution changes from the C category to the D and/or E category, or from the D to the E category, the Animal Procedure Statement must be resubmitted for review.

Consideration of Alternatives to Painful/Distressful Procedures: The Investigator "must" provide a written narrative description of the methods and sources used to consideration of alternatives to procedures that cause more than momentary or slight pain or distress to the animal(s). Reference AWA Sec. 13(a)(3)(B), 9 CFR, Part 2, Sec 2.31 (d)(1)(ii) and (e); Sec 2.32 (c)(2) and (5)(ii); see, www.aphis.usda.gov/ac/policy for Animal Welfare Act Policy 12 (12 June 2000) requirements.

USDA supports the performance of a database search to demonstrate compliance with the requirement, although other methods may be appropriate in some circumstances. One search source is the Animal Welfare Information Center (AWIC); e-mail awic@nal.usda.gov, see web site at <http://www.nal.usda.gov/awic>. A written narrative for federally-mandated animal testing needs only to include a citation of the controlling agency's regulation and guidance documents. **When a database search is used the narrative must include:**

1. **name of the database(s) searched** – PubMed, ALTBIB, ECVAM
2. **date of the search** – Oct 5, 2008
3. **period covered by the search** – to date
4. **key words and/or the search strategy used** – alternatives to in vivo pharmacokinetics, replacing in vivo pharmacokinetics, chimpanzee pharmacokinetics

The proposed studies will require anesthetized animals to be dosed by (b)(4) followed by the collection of serial blood samples using venipuncture. These procedures are necessary to minimize the stress that may be associated with dosing and sample collection. Relevant literature searches as suggested by the ALT and CAAT websites (JHU) produced no appropriate references to alternative experimental designs that would eliminate the need for anesthesia as required for dosing and venipuncture. Moreover, no alternatives were identified that can provide the data required.

4. Animal Research Protocol

Provide a concise description of the animal research plan in sequential order. Describe materials and procedures to be used. Include the dose, volume, route and frequency of agents administered. Describe the route, volume and frequency of tissue, blood or fluid collection. (Non-terminal blood collection volumes (ml) should not exceed guidelines; maximum blood collection will be determined on a case-by-case basis.) Describe procedures for preparing sites for injection or surgical procedures. Describe surgical procedures. Indicate any potential adverse effects on the animals well-being. Include the time schedule for observing animals during the study and post-procedure periods, and the steps which will be taken if any adverse reaction occurs. (Do not attach research publications or detailed procedures excerpted from grant applications or SOPs in lieu of a succinct description of the research protocol.)

Do not include proprietary information

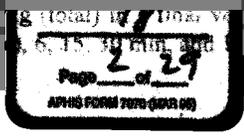
(b)(4)

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(b)(4)

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(b)(4)



5. What experimental requirements necessitate the use of this species?

Recent publications (Wong et al, 2004 and 2006 cited earlier) have demonstrated that the oral clearance in humans of 12 new drug candidates of varying structures were significantly correlated (p=0.015) with the same parameter for chimpanzees but not for rats, dogs or macaques, other nonclinical species typically used to profile potential new drugs prior to dosing to humans. These studies also carefully documented important biochemical (cytochromes P450 activity) and physiological (renal excretion) similarities and differences that exist between chimpanzees and humans, thus enabling rational application of this animal model in the drug discovery process. Additional studies of (b)(4) will provide either more results reinforcing the appropriateness of this species as a pharmacokinetic surrogate for humans or key evidence that would limit its use in drug discovery and development.

6. Has this research been conducted using other species of animals?

YES X NO _____

If **YES**, list these animal species and indicate any adverse reactions or toxicity observed.

This research will use the pharmacokinetics of (b)(4) therefore the PK will have been studied in humans, rodents (most likely rats) and dogs or macaques. Specific safety information will be provided prior to dosing of any compound.

(If this study proposes the use of a threatened species, provide specific toxicity data from studies conducted in lower species of animals including the species used, route and frequency of test material administration, dose concentration and vehicle description)

7. What experimental requirements necessitate use of the quantity of animals proposed? Provide an explanation and justification for the number of animals per study group, the number of groups per study, and the total number of animals projected for use.

Two to 3 individual animals is the fewest number of animals that will allow for a rigorous comparison of the PK parameters, given the expected biological variability of this heterogeneous species. The use of both (b)(4) in one study will provide important measures of compound availability using the intended clinical route of administration as well as important information on distribution and elimination. The number of animals chosen should also provide information on the potential variability in metabolite formation and excretion in the urine. The total number of animals to be used in (b)(4) will allow for the potential testing of different compounds using the same animals as well as the opportunity to complete the evaluation of different compounds at the same time using different animals, thus using animal and staff resources expeditiously.

If the proposed number of animals per group is the minimum required to obtain statistically significant data, indicate if this is based on:

Supporting Historical Data _____ Published Literature _____ Biometric Analysis _____

Are the proposed numbers of animals per group dictated by regulatory requirements? YES _____ NO X

(If it is necessary to exceed the total number of animals approved by the IACUC, an addendum justifying the need to increase animal use must be submitted to the IACUC Chairperson, prior to the conduct of the research.)

8. Will animals be used in more than one study? YES X NO _____

If **YES**, complete the following:

a.) What is the duration of rest periods between studies?

(b)(4)

b.) How many studies will be conducted on an individual animal?

An individual animal may participate in 1 to 6 studies, depending on the availability and need for compound evaluation.

c.) Will study animals be active in any other research programs? YES _____ NO X

If **YES**, EXPLAIN:

9. Can similar data be obtained by mathematical models, computer simulation, in vitro biological methods or other non-animal alternatives? YES _____ NO X If YES, explain.

10. Do literature references or in vitro data support this experimental design and species selection (i.e., is this an established animal model)? YES X NO _____ EXPLAIN and/or PROVIDE LITERATURE REFERENCE:

As discussed previously, recent publications (Wong et al, 2004 and 2006 cited earlier) have demonstrated that the oral clearance in humans of 12 new drug candidates of varying structures were significantly correlated (p=0.015) with the same parameter for chimpanzees but not for rats, dogs or macaques, other nonclinical species typically used to profile potential new drugs prior to dosing to humans. These studies also carefully documented important biochemical (cytochromes P450 activity) and physiological (renal excretion) similarities and differences that exist between chimpanzees and humans, thus enabling rational application of the drug discovery process. Additional studies of (b)(4) chimpanzees provide either more results reinforcing the appropriateness of this species as a pharmacokinetic surrogate for humans or key evidence that would limit its use in drug discovery and development. In silico approaches for estimating key pharmacokinetic properties such as volume of distribution (Vss) and half-life (T1/2) are imprecise and in many cases, inaccurate because of the assumptions inherent in their development. At this time, in vivo pharmacokinetic experiments are still required.

11. What measures are taken to assure that this work does not unnecessarily duplicate previous work?

This work is not unnecessarily duplicative since the (b)(4) and have not been studied by other sponsors. Preliminary pharmacokinetic studies in rodents or dogs may have been completed but the extrapolation of these data to the human pharmacokinetics is unknown.

SECTION 4: OPPORTUNITY FOR NONHUMAN PRIMATE ENVIRONMENTAL ENRICHMENT PROGRAMS

If the research protocol proposes the use of nonhuman primates, please answer the following question. NOT APPLICABLE _____

1. Will restrictions be placed on the study animals' participation in the facility's program for environmental enrichment?

YES _____ NO X

SECTION 5: ANESTHETICS, ANALGESICS, TRANQUILIZERS

1. List the pain relieving agents used (tranquilizers, analgesics, anesthetic) for each procedure.

Procedure	Drug	Dose	Route	Frequency
Bleeds/Dosing	Ketamine	Approx. 10 mg/kg	IM or IV	As required
Bleeds/Dosing	Telezol	2-5 mg/kg	IM or IV	As required

2. Will paralyzing agents be used? YES _____ NO X If YES, describe (include drug, dose, route and frequency).

NOTE: Paralyzing agents "must" be used with the benefit of anesthesia.

SECTION 6: PHYSICAL RESTRAINT

1. Will animals be confined for longer than one hour to an area less than the USDA or NIH standards for housing?

YES _____ NO X If YES, complete numbers 2 through 8, below.

2. Justify the use of restraint.

3. Describe the device, including dimensions.

4. State the duration of restraint (include length of intervals, number of intervals, rest periods between intervals).

5. Describe the preconditioning method(s) used.

6. List the procedures performed while the animal is confined.

7. List the criteria used to evaluate the animals well-being and the frequency of observations.



8. Will pain-relieving agents be used while the animal is restrained? YES _____ NO _____ (If YES, list agent, dose, route and frequency in "Anesthetic, Analgesics, Tranquilizers" section).

SECTION 7: SURGICAL PROCEDURES (complete for survival surgery only) Check if NOT APPLICABLE X

1. Will sterile surgical techniques and equipment be used? YES _____ NO _____

2. Describe post-surgical care (include frequency of examinations, supportive therapy used, criteria used to assess pain, and long-term care).

3. Location of surgery-

4. Location of post-surgical recovery-

5. Will pain-relieving agents be used pre- or post-operatively? YES _____ NO _____ (If YES, list agent, dose, route and frequency in "Anesthetics, Analgesics, Tranquilizers" section.)

6. Will the animal undergo multiple survival procedures? YES _____ NO _____ If YES, please justify.

SECTION 7: BIOHAZARDOUS AGENTS

1. Will potentially hazardous agents be used? YES _____ NO X UNKNOWN _____

2. If YES or UNKNOWN, specify agent, hazard and quantity.

- Pathogen (Bacterial, Viral, Fungal) _____
- Cell or tumor line _____
- Recombinant DNA _____
- Viral Vector (attenuated or otherwise) _____
- Toxin _____
- Chemical carcinogen/mutagen _____
- Radioisotope _____
- Hazard unknown _____
- Other _____

3. If YES, list precautions to be used.

SECTION 8: EUTHANASIA (A euthanasia agent MUST BE specified for all studies, even if death is not an intended endpoint.)

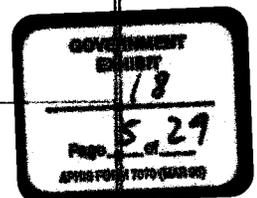
Agent	Dose	Route
Sodium pentobarbital	80-100 mg/kg	IV

SECTION 9: PERSONNEL

List all personnel performing animal procedures: (include summer interns and temporary employees). If known NIRC personnel will be responsible for specific procedures, please identify them.

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Name	Work Phone	Emergency Phone	Non-Surgical	Surgical	Post-Op Care	Euthanasia
[REDACTED]	[REDACTED]		X	X	X	X
DVM [REDACTED]	[REDACTED]		X	X	X	X
[REDACTED]	[REDACTED]		X	X	X	X



[REDACTED]	[REDACTED]		X	X	X	X
[REDACTED]	[REDACTED]		X		X	
[REDACTED]	[REDACTED]		X		X	
[REDACTED]	[REDACTED]		X		X	
[REDACTED]	[REDACTED]		X		X	

Do all personnel have the experience or training necessary to perform the procedures? YES X NO _____
 (A statement of experience and training must be on file at NIRC. Outside sponsors and technicians intending to perform animal procedures must provide a current curriculum vitae or other evidence of experience and training.)

SECTION 10: ASSURANCE STATEMENT

As the principal investigator, I acknowledge responsibility for the conduct of these procedures with animals. I hereby certify that the information provided is correct and reflects the procedures approved by the Committee and conform to NIRC standard operating procedures. I will submit a revised animal procedure statement and obtain IACUC approval prior to making changes in the procedures as approved by the IACUC. [Note: Submission of the APS by the PI in the form of electronic mail is taken as evidence of this Assurance.]

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 Principal Investigator's Typed Name

 Principal Investigator's Signature

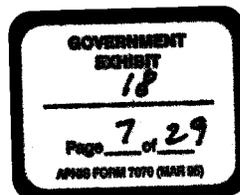
24 November 2008
 Date

-END OF PROCEDURE STATEMENT-

This space may be used, if additional comments are necessary



UL-Lafayette NIRC APS Revised, 19 Feb 2001



revised

ANIMAL PROCEDURE STATEMENT
University of Louisiana at Lafayette – NEW IBERIA RESEARCH CENTER
Animal Welfare Assurance Identification No. A3029-01

DO NOT INCLUDE PROPRIETARY INFORMATION ON THIS FORM. PLEASE ANSWER ALL QUESTIONS.

SECTION 1: INVESTIGATOR and PROJECT INFORMATION

Principal Investigator [REDACTED]

NOT A FOIA DELETION

Organization and Department [REDACTED]

Office Phone [REDACTED]

Emergency (Home) Phone [REDACTED]

e-mail address [REDACTED]

NOT A FOIA DELETION

NOT A FOIA DELETION

Other Phone [REDACTED]

Project Title Pharmacokinetics of (b)(4)

Study Title Pharmacokinetics of [REDACTED]

NIRC Study Director:

NOT A FOIA DELETION

Planned Start Date **August 2008**

End Date **August 2009**

SECTION 2: TYPE OF APPLICATION

CHECK A or B. If B, enter the most recent IACUC No. assigned to this study.

A. Is this a new application? YES ___ NO X B. Is this an annual renewal? YES X NO ___

IACUC No.: [REDACTED]

NOT A FOIA DELETION

Note: The Animal Procedure Statement must be resubmitted for IACUC review on an annual basis, if the research is to continue beyond the twelve-month IACUC approval period.

SECTION 3: EXPERIMENTAL DESIGN

1. State the purpose of the research- What are the objectives?

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The objective of this research is to determine the pharmacokinetics and pharmacodynamics of (b)(4), such as [REDACTED]. Studies may include a single administration of test article followed by blood collection or (b)(4) [REDACTED] with blood collection at various time points. Repeat dosing studies may be used to determine the (b)(4) [REDACTED].

2. Animal Model

Species	Cynomolgous monkeys	*Study Length (<i>in vivo</i> portion only)	1 Week-3 Months
Sex	M/F	*Number of Studies per Year	6-12
*Weight	2-10 Kg (typical)	*Number of Animal per Study	3-20
*Age	2-10 Years	*Number of Animals per Study Group	2-6
* Ranges can be provided		*Total Number of Animals per Year	160



3. Pain and/or Distress Category Distribution

A painful procedure is any procedure that would reasonably be expected to cause more than slight or momentary pain or distress in a human being to which that procedure was applied, that is, pain in excess of that caused by injection or other minor procedures.

(Categories are designated in accordance with USDA APHIS FORM 7023, Aug 91)

[A and B designations are not pain and distress categories. A are animals covered by the AWA; B are the number bred, conditioned are held for use in research, testing, experiments or surgery but not yet used for these purposes.]

Note: C + D + E = 100%

FOIA10-568-000255

C. Percent of animals upon which teaching, research, experiments, or tests will be conducted involving no pain, distress, or use of pain-relieving drugs. (Animals will suffer no pain or distress greater than that produced by routine injection or venipuncture.) 100 %

distress to which appropriate anesthetic, analgesic, or tranquilizing drugs will be used.

E. Percent of animals upon which teaching, research, surgery, or tests will be conducted involving accompanying pain or distress and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would adversely affect the procedures, results or interpretation of teaching, research, experiments, surgery, or tests. _____ %

(An explanation of the procedures producing pain or distress in category E and the reasons drugs are to be withheld must be attached.)

Animal usage records must include accurate account of the number of animals assigned to the C, D, and/or E pain/distress categories. If, at any time during the conduct of the research, the pain/distress category distribution changes the IACUC must be notified. If the distribution changes from the C category to the D and/or E category, or from the D to the E category, the Animal Procedure Statement must be resubmitted for review.

Consideration of Alternatives to Painful/Distressful Procedures: The Investigator "must" provide a written narrative description of the methods and sources used to consideration of alternatives to procedures that cause more than momentary or slight pain or distress to the animal(s). Reference AWA Sec. 13(a)(3)(B), 9 CFR, Part 2, Sec 2.31 (d)(1)(ii) and (e); Sec 2.32 (c)(2) and (5)(ii); see, www.aphis.usda.gov/ac/policy for Animal Welfare Act Policy 12 (12 June 2000) requirements.

USDA supports the performance of a database search to demonstrate compliance with the requirement, although other methods may be appropriate in some circumstances. One search source is the Animal Welfare Information Center (AWIC); e-mail awic@nal.usda.gov, see web site at <http://www.nal.usda.gov/awic>. A written narrative for federally-mandated animal testing needs only to include a citation of the controlling agency's regulation and guidance documents. When a database search is used the narrative must include:

1. name of the database(s) searched –
2. date of the search –
3. period covered by the search –
4. key words and/or the search strategy used –

4. Animal Research Protocol

Provide a concise description of the animal research plan in sequential order. Describe materials and procedures to be used. Include the dose, volume, route and frequency of agents administered. Describe the route, volume and frequency of tissue, blood or fluid collection. (Non-terminal blood collection volumes (ml) should not exceed guidelines; maximum blood collection will be determined on a case-by-case basis.) Describe procedures for preparing sites for injection or surgical procedures. Describe surgical procedures. Indicate any potential adverse effects on the animals well-being. Include the time schedule for observing animals during the study and post-procedure periods, and the steps which will be taken if any adverse reaction occurs. (Do not attach research publications or detailed procedures excerpted from grant applications or SOPs in lieu of a succinct description of the research protocol.)

Do not include proprietary information

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The drug might be administered (b)(4). Usually, a predose blood sample of 3-5 ml will be drawn and then 1ml aliquots of blood will be drawn at selected time points after dosing. These times will generally be 0, 15, 30, 45, 60, 90, 120, 150, and 180 min post-dose. Blood volumes collected will not exceed 1% of animal's body weight in kilograms. Some of the drugs will require that additional time points be taken out at (b)(4). Dosing and bleeds may be accomplished sedated or alert. If possible by delivery method, (b)(4)

(b)(4)

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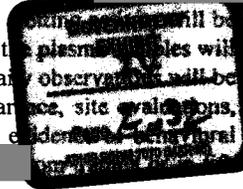
In studies designed to (b)(4) (b)(4) Then blood will be drawn to monitor (b)(4)

(b)(4)

Repeat dosing (b)(4) monkeys has been reported to (b)(4) as well as the (b)(4) this can potentially result in (b)(4) It is unknown at this time whether (b)(4) will have the same effects in monkeys or not although it is a clear possibility. Repeat dosing of (b)(4) does not appear to have the same hemophilic effect: while (b)(4)

(b)(4)

Therefore, (b)(4) will be (b)(4) and also the (b)(4) plasm (b)(4) will be (b)(4) also be collected and tested for the presence of (b)(4) Bidan (b)(4) observations will be (b)(4) conducted post d (b)(4) lay 0 until study completion for signs of adverse effect, activity, appetite, general appearance, site evaluations, petchiae, and external evidence of bleeding. Behavioral observations will be conducted at least once daily for evidence of abnormal behaviors and /or stereotypic behavior



5. What experimental requirements necessitate the use of this species?

The success of the experiments with (b)(4) is dependent on the presence of an (b)(4) the (b)(4) (b)(4) This receptor has been demonstrated to be expressed similarly in adult non-human primates

6. Has this research been conducted using other species of animals? YES NO
If YES, list these animal species and indicate any adverse reactions or toxicity observed.

(If this study proposes the use of a threatened species, provide specific toxicity data from studies conducted in lower species of animals including the species used, route and frequency of test material administration, dose concentration and vehicle description)

Similar experiments have been conducted in adult mice rats without evidence of toxicity

7. What experimental requirements necessitate use of the quantity of animals proposed? Provide an explanation and justification for the number of animals per study group, the number of groups per study, and the total number of animals projected for use.

Three animals per group is typically the lowest number of animals assessed to ensure that the reproducibility within the test is sufficient, although occasionally pilot studies will be run with two animals per group to be conservative on animals. The number of groups per study and the total number of animals is dictated by the need to (b)(4)

If the proposed number of animals per group is the minimum required to obtain statistically significant data, indicate if this is based on:

Supporting Historical Data _____ Published Literature _____ Biometric Analysis _____

Are the proposed numbers of animals per group dictated by regulatory requirements? YES _____ NO

(If it is necessary to exceed the total number of animals approved by the IACUC, an addendum justifying the need to increase animal use must be submitted to the IACUC Chairperson, prior to the conduct of the research.)

8. Will animals be used in more than one study, or experiments within a blanket study?

YES NO

If YES, complete the following:

- a.) What is the duration of rest periods between studies? 6-8 weeks typically. However may be shortened to as little as 3 weeks, result driven dependent on sample analysis.
- b.) Will the animal be allowed to return to social housing during the rest period? Yes No If No, then please provide justification: _____
- c.) How many studies will be conducted on an individual animal? Maximum of 3-4.
- d.) Will study animals be active in any other research programs? YES _____ NO
If YES, EXPLAIN:

9. Can similar data be obtained by mathematical models, computer simulation, in vitro biological methods or other non-animal alternatives? YES _____ NO If YES, explain.

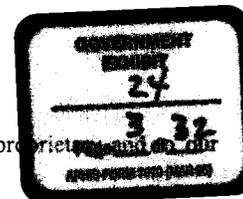
10. Do literature references or in vitro data support this experimental design and species selection (i.e., is this an established animal model)? YES NO EXPLAIN and/or PROVIDE LITERATURE REFERENCE:

NOT A FOIA DELETION

To date, non-human primates are the only species that we are aware of that express relatively high levels of _____ in adulthood in the appropriate (b)(4) In addition, non-human primates have been used in several studies in the literature demonstrating pharmacokinetics of (b)(4)

11. What measures are taken to assure that this work does not unnecessarily duplicate previous work?

We monitor the scientific literature for published reports. However, our technology is highly specialized and proprietary and as a result, we are the only company conducting studies of this type.



SECTION 4: OPPORTUNITY FOR NONHUMAN PRIMATE ENVIRONMENTAL ENRICHMENT PROGRAMS

If the research protocol proposes the use of nonhuman primates, please answer the following question. NOT APPLICABLE _____

FOIA10-568:000257

1. Will restrictions be placed on the study animals' participation in the facility's program for environmental enrichment? YES _____ NO

SECTION 5: ANESTHETICS, ANALGESICS, TRANQUILIZERS

1. List the pain relieving agents used (tranquilizers, analgesics, anesthetic) for each procedure.

Procedure	Drug	Dose	Route	Frequency
Dose Administration Sample Collection	Ketamine	10 mg/kg	IM	As required
Dose Administration	[REDACTED]	[REDACTED]	IM	As required

2. Will paralyzing agents be used? YES _____ NO X If YES, describe (include drug, dose, route and frequency).

NOTE: Paralyzing agents "must" be used with the benefit of anesthesia.

SECTION 6: PHYSICAL RESTRAINT

1. Will animals be confined for longer than one hour to an area less than the USDA or NIH standards for housing?
YES X NO _____ If YES, complete numbers 2 through 8, below.

2. Justify the use of restraint.

To facilitate dosing and sample collection, monkeys may be restrained for the [REDACTED] Animals will be returned to their cage and allowed to rest, then returned to the restraint chair for additional sample collection timepoints. The animals will not remain chaired for greater [REDACTED] This method will avoid a prolonged period of anesthesia that could be deleterious to the animals. The ability to alert dose and bleed will be dependent on delivery method of test article.

3. Describe the device, including dimensions.

Primate Products Restraint Chairs

4. State the duration of restraint (include length of intervals, number of intervals, rest periods between intervals).

Monkeys will be restrained for a maximum of [REDACTED] at a time. Rest periods will coincide with intervals between timepoints. Rest period between studies will be a minimum of 3 weeks.

5. Describe the preconditioning method(s) used.

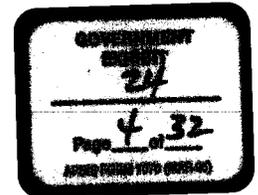
The monkeys used in this program will be actively conditioned to chair restraint for a minimum [REDACTED] prior to experimentation (during normal business hours). Any animal that does not acclimate to the chairing procedure will not be included in the study. Conditioning period may be shortened to one week if animals have been used on [REDACTED] studies previously.

6. List the procedures performed while the animal is confined.

Dosing and sample collections

7. List the criteria used to evaluate the animals well-being and the frequency of observations.

Posture, vocalization, hand and eye movements and temperament



8. Will pain-relieving agents be used while the animal is restrained? YES _____ NO X (If YES, list agent, dose, route and frequency in "Anesthetic, Analgesics, Tranquilizers" section).

SECTION 7: SURGICAL PROCEDURES (complete for survival surgery only) Check if NOT APPLICABLE X

1. Will sterile surgical techniques and equipment be used? YES _____ NO _____

2. Describe post-surgical care (include frequency of examinations, supportive therapy used, criteria used to assess pain, and long-term care).

3. Location of surgery-

5. Will pain-relieving agents be used pre- or post-operatively? YES _____ NO _____ (If YES, list agent, dose, route and frequency in "Anesthetics, Analgesics, Tranquilizers" section.)

6. Will the animal undergo multiple survival procedures? YES _____ NO _____ If YES, please justify.

SECTION 7: BIOHAZARDOUS AGENTS

1. Will potentially hazardous agents be used? YES _____ NO UNKNOWN _____

2. If YES or UNKNOWN, specify agent, hazard and quantity.

- Pathogen (Bacterial, Viral, Fungal) _____
- Cell or tumor line _____
- Recombinant DNA _____
- Viral Vector (attenuated or otherwise) _____
- Toxin _____
- Chemical carcinogen/mutagen _____
- Radioisotope _____
- Hazard unknown _____
- Other _____

3. If YES, list precautions to be used.

SECTION 8: EUTHANASIA (*A euthanasia agent MUST BE specified for all studies, even if death is not an intended endpoint.*)

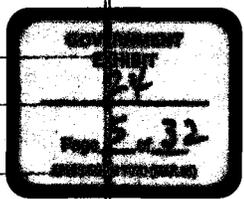
Agent	Dose	Route
Beuthanasia	1 ml/5-10 kg body weight to effect	IV

- Method of euthanasia, although unscheduled at this point, will occur as humane euthanasia using intravenous pentobarbital administration (SOP C-28.02) or equivalent. The Study Veterinarian has the authority and responsibility of reaching the decision and overseeing euthanasia. Alleviation of animal distress and suffering, in the absence of other suitable alternatives, would be non-experimental based criteria for euthanasia. Experimental based criteria for euthanasia is included in Animal Research Protocol section above.
- Tissue collection and sample collection will be determined by findings at the time of necropsy, as requested by the Study Veterinarian and upon sponsor request.

SECTION 9: PERSONNEL

List all personnel performing animal procedures: (include summer interns and temporary employees). If known NIRC personnel will be responsible for specific procedures, please identify them.

Name	Work Phone	Emergency Phone	Non-Surgical	Surgical	Post-Op Care	Euthanasia
[REDACTED]	[REDACTED]	[REDACTED]	X			X
[REDACTED]	[REDACTED]	[REDACTED]	X			X
[REDACTED]	[REDACTED]		X			X
[REDACTED] DVM	[REDACTED]		X	X	X	X
[REDACTED] DVM	[REDACTED]		X	X	X	
[REDACTED] DVM	[REDACTED]		X	X	X	X
[REDACTED] DVMS	[REDACTED]		X	X	X	X



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(A statement of experience and training must be on file at NIRC. Outside sponsors and technicians intending to perform animal procedures must provide a current curriculum vitae or other evidence of experience and training.)

SECTION 10: ASSURANCE STATEMENT

As the principal investigator, I acknowledge responsibility for the conduct of these procedures with animals. I hereby certify that the information provided is correct and reflects the procedures approved by the Committee and conform to NIRC standard operating procedures. I will submit a revised animal procedure statement and obtain IACUC approval prior to making changes in the procedures as approved by the IACUC. *[Note: Submission of the APS by the PI in the form of electronic mail is taken as evidence of this Assurance.]*

NOT A FOIA DELETION

[Redacted]

[Redacted] / [Redacted Signature]

27 Aug 08
Date

Study Director Typed Name

Study Director Signature

-END OF PROCEDURE STATEMENT-

This space may be used, if additional comments are necessary



The University of Louisiana at Lafayette
Institutional Animal Care and Use Committee

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Protocol Review Checklist

IACUC Number: [REDACTED]

Study Title: [REDACTED]

NOT A FOIA DELETION

Study Monitor/PI: [REDACTED]

Species

Number Of Animals

M. fascicularis (Cynomol [REDACTED])

ULL Study Director: [REDACTED]

NOT A FOIA DELETION

Funding Source: Private

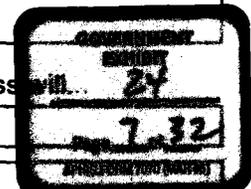
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Should you have questions concerning this application please contact [REDACTED]

You have been assigned the attached protocol to review. Use the following as a guide to evaluate the Animal Procedure Statement in accordance with the Animal Welfare Act and the Guide. If only minor revisions are needed, attach a signed note concerning the needed information. If you feel that the protocol should be reviewed by the full Committee, call the Chair to schedule a meeting. Please return the Review Checklist within five working days.

Check the Animal Procedure Statement (APS) for the following items.
Record your observations and any comments next to the item.

1. Y N N/A Rational and purpose are clear. Relevance to health issues or advancement of knowledge is present. [REDACTED]
2. Y N N/A Animal model identified; and the approximate number required stated. [REDACTED]
3. Y N N/A The APS adequately describes the proposed animal research protocol; and includes (if applicable) complete information on sample collection, dosing of experimental materials, aseptic technique, non-survival or survival surgical procedures, post-op care, adverse reactions, use of sedatives, analgesics or anesthetics, type and duration of restraint, animal housing, living conditions and non-medical care.
[REDACTED]
See below - Blanket
4. Y N N/A Pain and/or Distress Category Distribution is correctly represented.
[REDACTED]
May need re-assessment if adverse effects noted
5. Y N N/A The use of this animal species is adequately justified. [REDACTED]
6. Y N N/A The number of animals required for the study is adequately supported [REDACTED]
7. Y N N/A The APS supports the use of live animals in lieu of alternatives and the PI has provided assurance of such, along with assurance that activities do not unnecessarily duplicate previous studies [REDACTED]
8. Y N N/A Procedures that may cause more than momentary or slight pain or distress will... be performed with appropriate sedatives, analgesics or anesthetics, [REDACTED]
9. Y N N/A ...not include the use of paralytics without anesthesia. [REDACTED]
10. Y N N/A If pain relief is withheld for a justified scientific reason, has PI provided written justification of such, and assurance that withholding such agents will continue for only a necessary period of time? [REDACTED]



- 11. Y N N/A Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure.
- 12. Y N N/A If physical restraint or confined housing is proposed for longer than one hour, is it justified; and are conditions of confinement completely described and the well-being of the subject(s) adequately protected?
- 13. Y N N/A Specified the use of sterile techniques and equipment.
- 14. Y N N/A Described post-operative care.
- 15. Y N N/A Specified the location of surgery.
- 16. Y N N/A Described pain relieving agents and their use.
- 17. Y N N/A Justified multiple survival surgical procedures, if proposed.
- 18. Y N N/A If the use of a potentially hazardous agent is proposed, are proper precautions in place for the protection of personnel and inadvertent contamination of the facility available.
- 19. Y N N/A The method of euthanasia proposed is in accordance with the current Report of the AVMA Panel on Euthanasia.
- 20. Y N N/A Are personnel conducting procedures on the species to be used appropriately qualified and trained for the procedures assigned?

Additional Comments (You may present needed modifications, if appropriate, here or on an attached sheet of paper):

- Because this is a blanket protocol, individual specific study details should be submitted to IACUC prior to study evaluation.

- Any adverse effect (bleeding etc) should be reported to IACUC and distress/pain category re-evaluated.

Reviewer's Recommendation:

- Approve with no modification
- Approve with MINOR CHANGES indicated
- More information is required. I refer the APS to FULL COMMITTEE REVIEW.

(b)(6), (b)(7)c

9/9/08 phone conversation w/ [redacted]

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Reviewer's Signature

Date

Received by Chair on

16 Sep 08 Date/Initials

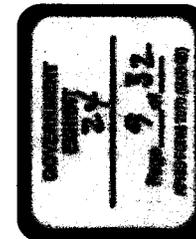
Action Taken:

Approved by receipt of response

NIRC # 8733-xxxx (November xx, 2008)

Confidential Information

Purpose: To determine pharmacokinetics and pharmacodynamics of [redacted]



Test Article and Vehicle:

Test Article:

Lot TBD

Stock = [redacted]

Storage conditions:

Vehicle:

TBD

Storage conditions: 2-8°C

Experimental Design/Dose Preparation

Animals will be given a single injection of [redacted] followed by blood sampling to determine pharmacokinetics and pharmacodynamics.

Group Number	Treatment	Route and Regimen	Monkey ID	Sex	Body Weight (kg)	[redacted]	Dose (mL/kg)	Dose (mL/animal)	Total mL needed
1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

looks very small

Animals:

Six cynomolgus monkeys (previously used; ~ 6-9 kg if possible) from [redacted]

Serum Chemistry and Hematology

Serum chemistry volume of 1.5 ml blood and hematology sample of 1 ml whole blood will be collected at the time of pre-study exams.

Dose Administration

Animals will receive a single subcutaneous dose of [redacted]. Dosing will be performed with appropriately sized Hamilton syringes..

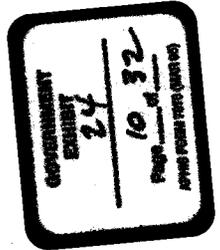
Sample Collection

Approximately 3.6 ml of blood will be drawn into 2 x 1.8 ml tubes for serum at time [REDACTED]. Approximately 1 mL of blood will be drawn into 1 x 1.8 ml tube for (b)(4). Samples will be divided into three approximately equal aliquots for pharmacokinetic and pharmacodynamic analysis. Plasma will be frozen at approximately -80°C until shipment to Sponsor.

Sample Shipment

Plasma samples will be shipped on dry ice after [REDACTED]. Samples will be shipped no later than Wednesday of the appropriate week.

Ship to: (b)(6), (b)(7)c
[REDACTED]



NIRC # 8733-090x (January xx, 2009)

Confidential Information

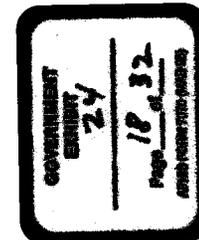
Purpose: To determine pharmacokinetics and pharmacodynamics of [redacted]

Test Article and Vehicle:

Test Article: [redacted]

Stock = [redacted]
 Storage conditions: 2-8°C
 PBS
 Storage conditions: 2-8°C

Vehicle:



Experimental Design/Dose Preparation

Animals will be given [redacted] once a week for two weeks. Following each dose, blood samples will be collected to determine pharmacokinetics and pharmacodynamics.

Group Number	Treatment	Route and Regimen	Monkey ID	Sex	Body Weight (kg)	Dose (mL/kg)	Dose (mL/animal)	Total mL needed
1	[redacted]	[redacted]				[redacted]		
2	[redacted]	[redacted]				[redacted]		
3	[redacted]	[redacted]				[redacted]		
4	[redacted]	[redacted]				[redacted]		
5	[redacted]	[redacted]				[redacted]		



Animals:

Fifteen cynomolgus monkeys from [redacted]

Serum Chemistry and Hematology

Serum chemistry volume of 1.5 ml blood and hematology sample of 1 ml whole blood will be collected at the time of pre-study exams.

Dose Administration

Animals will receive a single intravenous or subcutaneous dose of [redacted]. Subcutaneous injection will be at two separate sites in the thigh. Injection sites will be shaved and monitored daily for reaction to dosing.

Sample Collection

Approximately 3.6 ml of blood will be drawn into 2 x 1.8 ml tubes for serum at time [redacted]. Approximately 1.8 mL of blood will be drawn into 1 x 1.8 ml tube for serum at [redacted] dosing. Samples will be divided into three approximately equal aliquots for analysis of [redacted] if an appropriately developed assay is available. Serum will be frozen at approximately -80°C until shipment to Sponsor.

Sample Shipment

Plasma samples will be shipped on dry ice after the [redacted] collection after each dose. Samples will be shipped no later than Wednesday of the appropriate week.

Ship to: (b)(6), (b)(7)c [redacted]

(November-December, 2008)
Information

Confidential

Purpose: To determine [redacted]

Test Article and Vehicle:

Test Article: [redacted]

Vehicle: Storage conditions:
TBD
Storage conditions: 2-8°C



Experimental Design/Dose Preparation

Animals will be given [redacted] followed by blood sampling to determine pharmacokinetics and pharmacodynamics.

Group Number	Treatment	Route and Regimen	Monkey ID	Sex	Body Weight (kg)	[redacted]	Dose (mL/kg)	Dose (mL/animal)	Total mL needed
1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	0.1	[redacted]
								0.1	
2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	0.03	[redacted]
								0.03	
3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	0.1	[redacted]
								0.1	

Animals:

Six cynomolgus monkeys (previously used; ~ 6-9 kg if possible) from [redacted] at NIRC

Serum Chemistry and Hematology

Serum chemistry volume of 1.5 ml blood and hematology sample of 1 ml whole blood will be collected at the time of pre-study exams.

Dose Administration

Animals will receive a single subcutaneous dose of [redacted] on Day 0, [redacted]
[redacted] Dosing will be performed with appropriately sized Hamilton syringes.

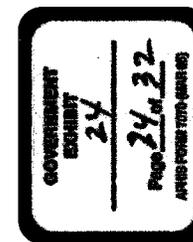
Sample Collection

Approximately 1.0 ml of blood will be drawn for serum at time [redacted]. Approximately 1 mL of blood will be drawn for serum at [redacted]. Samples will be divided into three approximately equal aliquots for pharmacokinetic and pharmacodynamic analysis. Plasma will be frozen at approximately -80°C until shipment to Sponsor.

Sample Shipment

Plasma samples will be shipped on dry ice after [redacted]. Samples will be shipped no later than Wednesday of the appropriate week.

Ship to [redacted] (b)(6), (b)(7)c



ANIMAL PROCEDURE STATEMENT
University of Louisiana at Lafayette - NEW IBERIA RESEARCH CENTER
Animal Welfare Assurance Identification No. A3029-01

DO NOT INCLUDE PROPRIETARY INFORMATION ON THIS FORM. PLEASE ANSWER ALL QUESTIONS.

SECTION 1: INVESTIGATOR and PROJECT INFORMATION

Principal Investigator [redacted] UL Lafayette NIRC

Organization and Department New Iberia Research Center Research Center - Research Resources

Office Phone [redacted] NOT A FOIA DELETION [redacted] Emergency (Home) Phone [redacted]

e-mail address [redacted]

Other Phone [redacted]

Project Title Immunogenicity of [redacted] in Rhesus monkeys

Study Title

Planned Start Date Jul 2008 End Date Jul 2009

SECTION 2: TYPE OF APPLICATION

CHECK A or B. If B, enter the most recent IACUC No. assigned to this study.

A. Is this a new application? YES NO X B. Is this an annual renewal? YES X NO
IACUC No.: 2007-042

Note: The Animal Procedure Statement must be resubmitted for IACUC review on an annual basis, if the research is to continue beyond the twelve-month IACUC approval period.

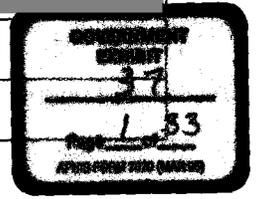
SECTION 3: EXPERIMENTAL DESIGN

1. State the purpose of the research - What are the objectives?

The objective of this study is to vaccinate Rhesus macaques to assess [redacted] of [redacted]

2. Animal Model

Table with 4 columns: Species (RHM), Sex, *Weight, *Age, *Study Length (in vivo portion only), *Number of Studies per Year, *Number of Animal per Study, *Number of Animals per Study Group, *Total Number of Animals per Year.



3. Pain and/or Distress Category Distribution

A painful procedure is any procedure that would reasonably be expected to cause more than slight or momentary pain or distress in a human being to which that procedure was applied, that is, pain in excess of that caused by injection or other minor procedures.

(Categories are designated in accordance with USDA APHIS FORM 7023, Aug 91)

[A and B designations are not pain and distress categories. A are animals covered by the AWA; B are the number bred, conditioned are held for use in research, testing, experiments or surgery but not yet used for these purposes.]

Note: C + D + E = 100% % of

Animals

C: Percent of animals upon which teaching, research, experiments, or tests will be conducted involving no pain, distress, or use of pain-relieving drugs. (Animals will suffer no pain or distress greater than that produced by routine injection or venipuncture.) 100 vaccination phase %

D. Percent of animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to which appropriate anesthetic, analgesic, or tranquilizing drugs will be used. _____10

euthanasia phase (if applicable) _____%

(Only if high titer obtained in test subjects)

E. Percent of animals upon which teaching, research, surgery, or tests will be conducted involving accompanying pain or distress and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would adversely affect the procedures, results or interpretation of teaching, research, experiments, surgery, or tests.

_____ %

(An explanation of the procedures producing pain or distress in category E and the reasons drugs are to be withheld must be attached.)

Animal usage records must include accurate account of the number of animals assigned to the C, D, and/or E pain/distress categories. If, at any time during the conduct of the research, the pain/distress category distribution changes the IACUC must be notified. If the distribution changes from the C category to the D and/or E category, or from the D to the E category, the Animal Procedure Statement must be resubmitted for review.

Consideration of Alternatives to Painful/Distressful Procedures: The Investigator "must" provide a written narrative description of the methods and sources used to consideration of alternatives to procedures that cause more than momentary or slight pain or distress to the animal(s). Reference AWA Sec. 13(a)(3)(B), 9 CFR, Part 2, Sec 2.31 (d)(1)(ii) and (e); Sec 2.32 (c)(2) and (5)(ii); see, www.aphis.usda.gov/ac/policy for Animal Welfare Act Policy 12 (12 June 2000) requirements.

USDA supports the performance of a database search to demonstrate compliance with the requirement, although other methods may be appropriate in some circumstances. One search source is the Animal Welfare Information Center (AWIC); e-mail awic@nal.usda.gov, see web site at http://www.nal.usda.gov/awic. A written narrative for federally-mandated animal testing needs only to include a citation of the controlling agency's regulation and guidance documents. When a database search is used the narrative must include:

1. name of the database(s) searched - Pub Med
2. date of the search - 16 June 2008
3. period covered by the search - all inclusive dates
4. key words and/or the search strategy used - [redacted] antibody generation, Rhesus monkeys, alternatives



4. Animal Research Protocol

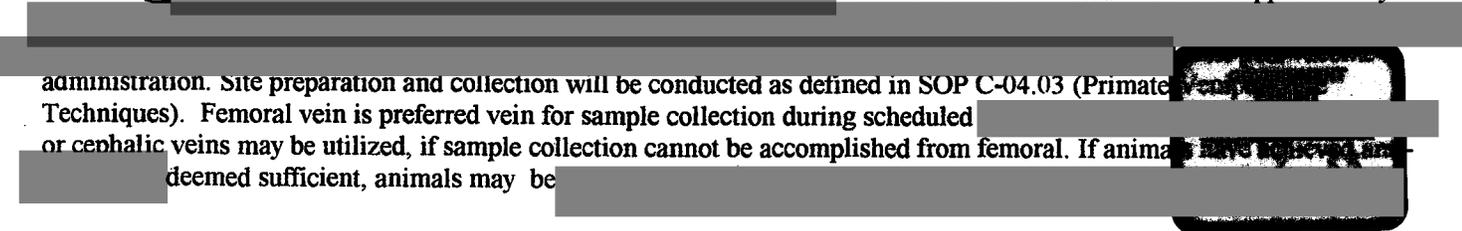
Provide a concise description of the animal research plan in sequential order. Describe materials and procedures to be used. Include

the dose, volume, route and frequency of agents administered. Describe the route, volume and frequency of tissue, blood or fluid collection. (Non-terminal blood collection volumes (ml) should not exceed guidelines; maximum blood collection will be determined on a case-by-case basis.) Describe procedures for preparing sites for injection or surgical procedures. Describe surgical procedures. Indicate any potential adverse effects on the animals well-being. Include the time schedule for observing animals during

the study and post-procedure periods, and the steps which will be taken if any adverse reaction occurs. (Do not attach research publications or detailed procedures excerpted from grant applications or SOPs in lieu of a succinct description of the research protocol.) Do not include proprietary information.

Groups of [redacted] each will be immunized with [redacted] although other constructs may be performed under this APS) at two to four separate vaccination timepoints anticipated as administered at no greater frequency than [redacted] Vaccines will be prepared from materials used in human clinical trials and will be administered by i.m. (deltoid) injection of anticipated volume not to exceed 1.0ml. Vaccination site preparation and administration will be conducted using SOP C-05.01 (Dose Administration for Non-Human Primates).

Prior to each [redacted] blood will be collected from sedated animals by venipuncture. Blood sample collections (volume within guidelines defined in NIRC SOP C-32) to assess serological (antibody titer) status of monkeys will be collected at [redacted] Some studies conducted under this approval may



administration. Site preparation and collection will be conducted as defined in SOP C-04.03 (Primate [redacted] Techniques). Femoral vein is preferred vein for sample collection during scheduled [redacted] or cephalic veins may be utilized, if sample collection cannot be accomplished from femoral. If animal [redacted] deemed sufficient, animals may be [redacted]

immunological responses in future vaccine preclinical and clinical studies. Animals be returned to the colony upon study completion.

Daily observations will be conducted by research resources, behavioral sciences, and animal resources for signs of adverse effect, illness, or behavioral stereopathies. Abnormalities will be reported and treated by the attending veterinarian. Observations will also include site evaluation or vaccine induced adverse local effect such as redness, swelling, erythema, pain, guarding, etc.

Note: For both immunization and routine bleeding, sedation will be used as a chemical restraint. In the event that an animal becomes moribund during these studies it will be humanely euthanized.

5. What experimental requirements necessitate the use of this species?

Extensive published literature has shown that immune responses in humans cannot be predicted in rodent species, such as mice. Monkeys possess a functional intact immune system that closely resembles that of humans and is therefore predictive of the human immune response. Monkeys will be used to predict the potential human immune response to

in human clinical trials and cannot be altered.

The bleeding schedule is the minimum that can give complete and timely data. Sedation is used during and blood collection as a chemical restraint.

6. Has this research been conducted using other species of animals? YES NO

If YES, list these animal species and indicate any adverse reactions or toxicity observed.

(If this study proposes the use of a threatened species, provide specific toxicity data from studies conducted in lower species of animals including the species used, route and frequency of test material administration, dose concentration and vehicle description)

Prior Rodent studies may have been performed (at sponsor facility) using these same

Rodents, no adverse effect.

7. What experimental requirements necessitate use of the quantity of animals proposed? Provide an explanation and justification for the number of animals per study group, the number of groups per study, and the total number of animals projected for use.

If the proposed number of animals per group is the minimum required to obtain statistically significant data, indicate if this is based on:

Supporting Historical Data Published Literature Biometric Analysis

Are the proposed numbers of animals per group dictated by regulatory requirements? YES NO

(If it is necessary to exceed the total number of animals approved by the IACUC, an addendum justifying the need to increase animal use must be submitted to the IACUC Chairperson, prior to the conduct of the research.)

8. Will animals be used in more than one study, or experiments within a blanket study?

YES NO

If YES, complete the following:

a.) What is the duration of rest periods between studies? Rest period is defined as time

b.) Will the animal be allowed to return to social housing during the rest period? Yes No If No, then please provide justification:



c.) How many studies will be conducted on an individual animal? Dependent on sponsor needs (non responders only); N/A for high responders with endpoint of exsanguination. Typical use is limited to one study per sponsor antigenic line.

d.) Will study animals be active in any other research programs? YES _____ NO X
 If YES, EXPLAIN:

9. Can similar data be obtained by mathematical models, computer simulation, *in vitro* biological methods or other non-animal alternatives? YES _____ NO X If YES, explain.

10. Do literature references or *in vitro* data support this experimental design and species selection (i.e., is this an established animal model)? YES X NO _____ EXPLAIN and/or PROVIDE LITERATURE REFERENCE:

Literature references support this experimental model. Please provide references:

Kennedy, R.C., Shearer, M.H., Hildebrand, W. Nonhuman primate models to evaluate vaccine safety and immunogenicity. Vaccine (15):8 903-908. 1997

11. What measures are taken to assure that this work does not unnecessarily duplicate previous work?

These are previously untested [redacted] (however, some standard compounds may be used to validate the model for comparison to a new compound), these [redacted] in these studies have not previously existed, as they are being uniquely prepared by [redacted] scientists. Therefore, the [redacted] of these test molecules is not available in the literature [redacted] cannot be determined by use of computer modeling or comparison to other molecules in the literature. since each molecule is unique and each animal response is dependent on the animal's immune system. Therefore, to assess these [redacted] in a scientifically meaningful manner, immunization of monkeys is proposed.

SECTION 4: OPPORTUNITY FOR NONHUMAN PRIMATE ENVIRONMENTAL ENRICHMENT PROGRAMS

If the research protocol proposes the use of nonhuman primates, please answer the following question. NOT APPLICABLE _____

1. Will restrictions be placed on the study animals' participation in the facility's program for environmental enrichment? YES _____ NO X

SECTION 5: ANESTHETICS, ANALGESICS, TRANQUILIZERS

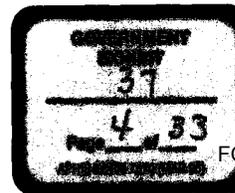
1. List the pain relieving agents used (tranquilizers, analgesics, anesthetic) for each procedure.

{PRIVATE } Procedure	Drug	Dose	Route	Frequency
[redacted]				As needed for veterinary attention
				As needed for procedure
				As needed for procedure
				Sedation prior to cardiac puncture-
				As needed per Vet recommendation, utilized for animals with ketamine reactions

2. Will paralyzing agents be used? YES _____ NO X If YES, describe (include drug, dose, route and frequency).

NOTE: Paralyzing agents "must" be used with the benefit of anesthesia.

SECTION 6: PHYSICAL RESTRAINT



1. Will animals be confined for longer than one hour to an area less than the USDA/NIH standards for housing?
YES _____ NO X If YES, complete numbers 2 through 8, below.

2. Justify the use of restraint.

3. Describe the device, including dimensions.

4. State the duration of restraint (include length of intervals, number of intervals, rest periods between intervals).

5. Describe the preconditioning method(s) used.

6. List the procedures performed while the animal is confined.

7. List the criteria used to evaluate the animals well-being and the frequency of observations.

8. Will pain-relieving agents be used while the animal is restrained? YES _____ NO _____ (If YES, list agent, dose, route and frequency in "Anesthetic, Analgesics, Tranquilizers" section).

SECTION 7: SURGICAL PROCEDURES (complete for survival surgery only) Check if NOT APPLICABLE X

1. Will sterile surgical techniques and equipment be used? YES _____ NO _____

2. Describe post-surgical care (include frequency of examinations, supportive therapy used, criteria used to assess pain, and long-term care).

3. Location of surgery-

4. Location of post-surgical recovery-

5. Will pain-relieving agents be used pre- or post-operatively? YES _____ NO _____ (If YES, list agent, dose, route and frequency in "Anesthetics, Analgesics, Tranquilizers" section.)

6. Will the animal undergo multiple survival procedures? YES _____ NO _____ If YES, please justify.

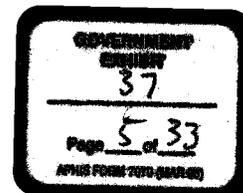
SECTION 7: BIOHAZARDOUS AGENTS

1. Will potentially hazardous agents be used? YES _____ NO X UNKNOWN _____

2. If YES or UNKNOWN, specify agent, hazard and quantity.

- Pathogen (Bacterial, Viral, Fungal) _____
- Cell or tumor line _____
- Recombinant DNA _____
- Viral Vector (attenuated or otherwise) _____
- Toxin _____
- Chemical carcinogen/mutagen _____
- Radioisotope _____
- Hazard unknown _____
- Other _____

3. If YES, list precautions to be used.



SECTION 8: EUTHANASIA (A euthanasia agent MUST BE specified for all studies, even if death is not an intended endpoint.)

(b)(4)

pinch, stimulus to pain, withdrawal touch and standard SST tubes. Maximum blood volume will be collected (until sample flow is unattainable).

ethanasia is required after blood sample collection. Euthanasia will be administered as below. Should an animal become moribund during the study, the test subject will be euthanised by

sponsor colony.

{PRIVATE} Agent	Dose	Route
[REDACTED]	1ml/5-10 kg body weight (to effect)	IV

SECTION 9: PERSONNEL

List all personnel performing animal procedures: (include summer interns and temporary employees). If known NIRC personnel will be responsible for specific procedures, please identify them.

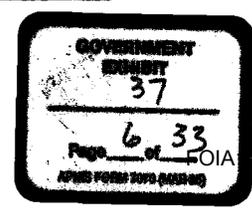
{PRIVATE} Name	Work Phone	Emergency Phone	Non-Surgical	Surgical	Post-Op Care	Euthanasia
[REDACTED]	3[REDACTED]	[REDACTED]	X			X
[REDACTED]	3[REDACTED]	[REDACTED]	X			X
[REDACTED]	3[REDACTED]		X			X
[REDACTED]	3[REDACTED]		X			X
[REDACTED]	3[REDACTED]		X			X
[REDACTED]	[REDACTED]		X			X

Do all personnel have the experience or training necessary to perform the procedures? YES NO
 (A statement of experience and training must be on file at NIRC. Outside sponsors and technicians intending to perform animal procedures must provide a current curriculum vitae or other evidence of experience and training.)

SECTION 10: ASSURANCE STATEMENT

As the principal investigator, I acknowledge responsibility for the conduct of these procedures with animals. I hereby certify that the information provided is correct and reflects the procedures approved by the Committee and conform to NIRC standard operating procedures. I will submit a revised animal procedure statement and obtain IACUC approval prior to making changes in the procedures as approved by the IACUC. [Note: Submission of the APS by the PI in the form of electronic mail is taken as evidence of this Assurance.]

Principal Investigator's Typed Name: [REDACTED] Principal Investigator's Signature: [REDACTED] Date: 6/18/2007

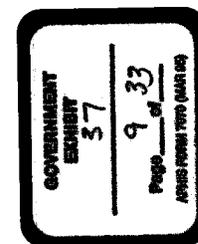


-END OF PROCEDURE STATEMENT-

This space may be used, if additional comments are necessary



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[REDACTED]

[REDACTED]

[REDACTED]

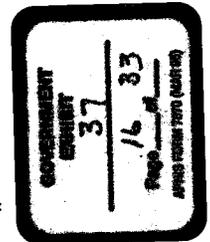
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