Hastings Deer Immunocontraception Study

Anesthetic Agent Custody Protocol

Hastings-on-Hudson

February 2014

Version 3.0

Contents

Introduction

This document describes the protocol around custody and possession of the anesthetic agents utilized during the Hastings-on-Hudson Immunocontraception experiment to begin in February 2014. Hastings-on-Hudson, in concert with The Humane Society of the United States, the Cummings School of Veterinary Medicine at Tufts University, and with support from In Defense of Animals, will engage in a five-year experiment involving controlling the white-tail deer population through the injection of the PZP (porcine zona pellucida) immunocontraceptive vaccine. The objective is to control and bring down the population of white-tailed deer by substantially lowering the birth rates of local does. If the experiment should provide evidence that the numbers of white-tailed deer are substantially reduced, we would move to a regular protocol where there would be no need to immobilize deer and the Village would dart the deer directly with the PZP agent.

During the first three years of the study deer within Hastings-on-Hudson will be captured with a combination of Xylazine HCl (at approximately 2.2 mg/kg) and Telazol HCl (at approximately 4.4 mg/kg). Telazol is supplied lyophilized and will be reconstituted with Xylazine to achieve a 200mg/ml dosage. Deer that do not become fully sedated may, when appropriate receive additional injections of the Xylazine/Telazol combination and/or Ketamine (at approximately 5 mg/kg) delivered in 1-3cc Pneu-Darts or by hand. Additional drugs that may be used during the course of capturing deer are the Xylazine antagonist Tolazoline at approximately 4mg/kg and the respiratory stimulant Dopram V (Dozapram HCl). All controlled substances and other drugs necessary for capturing and handling deer will handled and used under veterinary supervision.

Experiment Overview

Hastings-on-Hudson has examined a range of possible deer control approaches and decided to pursue immunocontraception. The New York State Department of Environmental Conservation issued a scientific Permit to Collect or Possess authorizing the study in December 2013. The protocol has also been reviewed and authorized by the Tufts University/Tufts Medical Center Institutional Animal Care and Use Committee (IACUC protocol #G2014-09). Under the approved protocols, during the winters of 2014 and 2015, up to 60 female deer (or more if accessible) will be captured via chemical immobilization delivered via darts, ear-tagged, blood-sampled for pregnancy testing, and administered an initial treatment of PZP/mFCA emulsion plus PZP/QA-21 in lactide-glycolide polymer pellets engineered to release at 1, 3, and 12 months. Treated deer will be monitored for fawns to determine whether observations are consistent with pregnancy test results, and monitoring procedures will be adjusted in

subsequent years if there are significant inconsistencies. To measure vaccine effectiveness and longevity, fawning of treated deer will be monitored for two to three years after initial treatment. The experiment will proceed for five years.

Beginning in late summer 2015 or 2016, all treated deer that can be relocated will receive dart-delivered boosters of PZP/FIA emulsion alone or PZP/FIA emulsion plus PZP/QA-21 in lactide-glycolide polymer pellets engineered to release at 1, 3, and 12 months. Fawning of boosted deer will be monitored for 2 to 3 additional years to determine whether the two treatments differ in effectiveness and longevity.

At the same time, we will use semi-annual camera-trap surveys, monitoring by resident volunteers, and other methods to examine trends in population fawning rates, population size, and to the extent practical, mortality/disappearance rates.

All deer captured with chemical immobilizing drugs and/or treated (injected) with immunocontraceptives will be fitted with two plastic ear-tags (one in each ear) marked with unique identifying numbers. Tags will be labeled on the back with "EXPERIMENTAL ANIMAL, DO NOT CONSUME" and a telephone number where information could be obtained in the event an animal is killed or found.

Experiment Locations

At the outset of the study, all capture and darting of deer will be carried out in Hillside Park, Andrus Nursing Home and the portion of Children's Village that is within Hastings (see Appendix A). We have also asked, but not yet received permission, for access to the portion of Andrus Children's home within Hastings. A police officer will be present during all darting that occurs on publicly accessible land. All access to these properties will be controlled either via volunteers posted at entrance ways to the park, by gates, or yellow-tape restrictive barriers.

Hillside Park is a heavily wooded, 100-acre park with an open understory (partly due to heavy deer browsing). Typical of Westchester County, Hillside Park is characterized by a series of north-south running ridges, with elevations ranging from approximately 170-430'. The site is bounded by the Saw Mill River Parkway on the east, by a forested facility (Children's Village) and other forest in the Village of Dobbs Ferry on the north, and by housing (mostly zoned for 0.5 acres) on the south and west.

A portion of The Children's Village site, based in Dobbs Ferry, is imbedded within this wooded site and shares all the same characteristics. The Village has received permission from Children's Village for access to this portion of their property within Hastings-on-Hudson. .

The Andrus Nursing home site is a private facility with 15 acres of wooded areas on the southern two-thirds of the private site. It is bounded on both sides by Broadway (southern-bound Broadway lanes on the west side of the property and northern-bound lanes on the East), and some private dwellings on the north end.

All sites within Hillside Park and elsewhere were chosen in consultation with the NYSDEC, village law enforcement, and affected private property owners so as to assure safety and compliance with all relevant laws and regulations.

Drug delivery protocol

Deer will be captured during March after New York deer hunting seasons have concluded and more than 60 days prior to the start of any deer hunting seasons and before the last two months of pregnancies in deer when fetus's may be susceptible to the effects of drugs. The listed drug combination will be loaded into self-injecting 1 cc Palmer Cap-Chur transmitter darts with 1" needles and single wire barbs or Pneu-Dart self-injecting 1cc transmitter darts with 1" needles and double or single wire barbs. Darts will be delivered intramuscularly in the hip from a Dan-Inject Model JM Standard CO_2 projectoror Dan-Inject CO_2 Bol-Jector. Dart transmitters have a tracking range of approximately 1 kilometer and will be tracked with a Telonics TR-4 receiver and Yagi antenna. Every effort will be made to recover darts. Drugs in darts failing to discharge will be disposed of according to American Veterinary Medical Association (AVMA) guidelines..

Custody and Safety Protocol

1. **Immobilizing Agent Purchase**
   The immobilizing and reversing agents ("agents", listed in Appendix B) will be purchased by veterinarians of record associated with this project. (Appendix C).

2. **Veterinarian Facility**
   The veterinarian of record works in a facility meets the standards of a secured facility as identified in DEA protocols covering requirements for the proper and secure storage of Class III controlled substances (Appendix D). The facility has locked access doors that can only be opened by key and an in-wall safe for storage of controlled substances.

3. **Agent custody secured in Veterinarian Facility**
   The darting professionals will have previously signed a signature sheet (Appendix E), which will include the signatures and names of the darting professionals authorized to retrieve the agent during the experiment. The date, substance, and quantity for the project will be registered, and the entries contra signed by the veterinarian. (All records will comply with BNE regulations as set in 10 NYCRR 80.37, listed in Appendix I) The agents will be in a labeled container with the name and schedule of the drug and

volume of the agent in the container. The agent(s) will be deposited in a marked manila envelope within the safe located within the facility

4. **Agent retrieval**
   When darting is to proceed on a given day, the designated darting professional (Appendix C) will present himself at the veterinarian facility and provide identification to verify his identity. He will retrieve the agents necessary for that days' study work. The type and quantity of drugs necessary for the day's study will be noted on the log sheet. The entries will be contra-signed by both the darting professional and the veterinarian. The dispensed drugs will then be used to immobilize the deer targeted as part of the DEC-approved immunocontraception study.

5. **Controlling Agent Compounding**

   Telazol is supplied lyophilized and is typically reconstituted to 100mg/ml with the addition of 5ml sterile water. When capturing deer Telazol is reconstituted to 200mg/ml. For capturing deer this combination is best done with 2.5ml of Xylazine at 100mg to provide a formulation of 200mg/ml Telazol/100mg/ml Xylazine. This combination produces 3 doses of drugs enough to capture 2-4 deer depending on weight. Reconstituted Telazol has a short shelf life (3 days room temperature, 10-14 days refrigerated) so to avoid waste the combination is typically done in the field as needed for capturing deer. The project leader and/or supervisor listed on the license will be responsible for handling and mixing drugs. When controlled substances are combined or diluted, it must be recorded on the Desk Log. When the drugs are combined, it should be listed in the "notes" section and tracked separately from that point in time. It is necessary to record the amount used from the stock bottle and to record the amount of the combined drugs ultimately used.

6. **Agent deployment**
   The agents will be transferred by the darting professional to a self-injecting 1 cc Palmer Cap-Chur transmitter darts or other appropriate darts. The quantity of darts filled and the amount of the drug transferred will be noted on the Field Log (Appendix G). The total volume used for the day will be tracked on the log.

7. **Agent utilization**
   As the darts are utilized in the field during the project (see "Field Safety Protocol" for additional information), the darting professional will log the deer capture data as presented in Appendix H, which is the Humane Society's standard capture form.

8. **Agent Return**

   At the end of the darting field work, the darting professional will return to the veterinarian office and turn over any remaining compounded agent, unutilized darts, and present his field logs displaying the use of the agents in the field. The employee will verify the quantities claimed in the log. The entries will be contra-signed by both the darting professional and the employee on duty at the desk at that time.

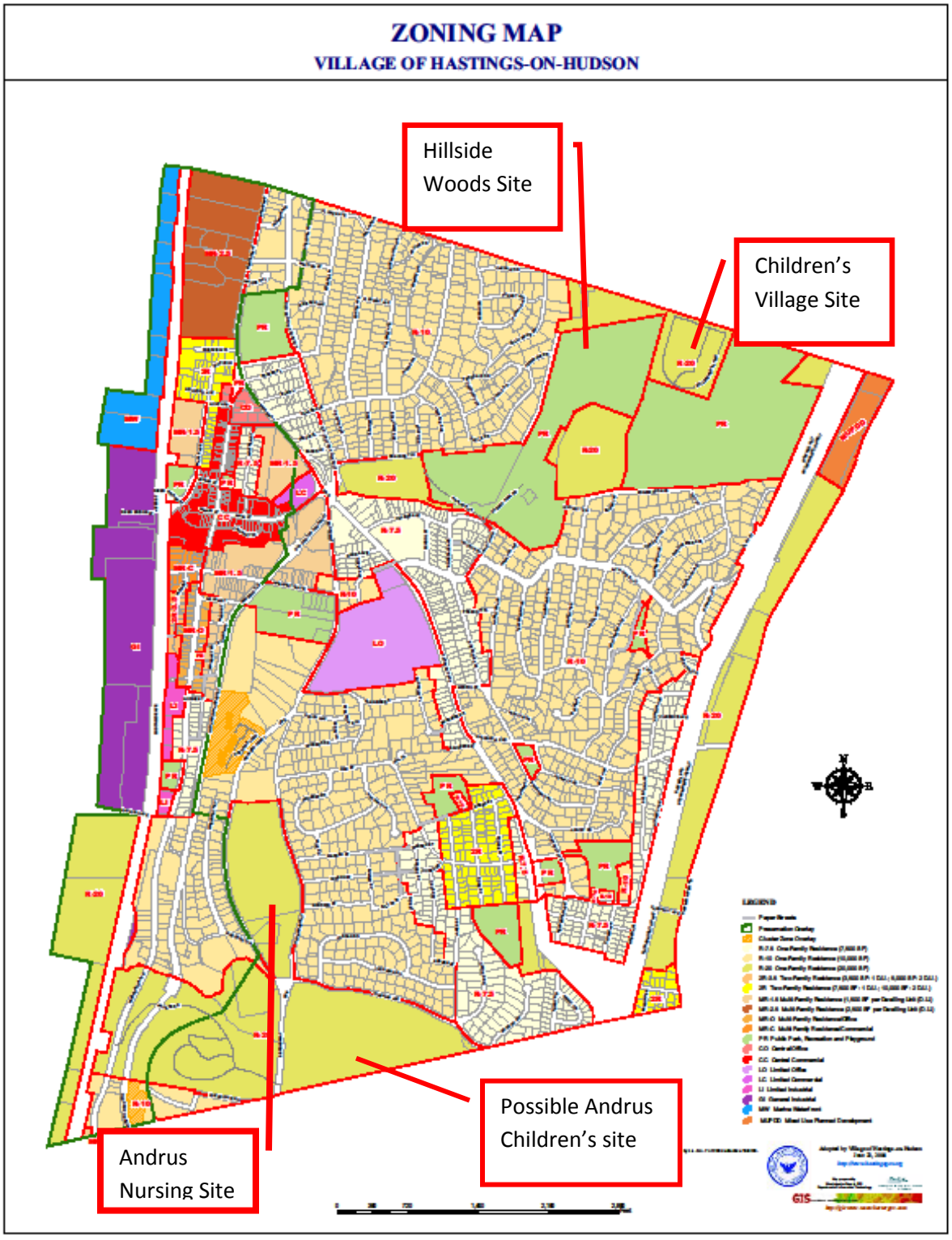
9. **Experiment conclusion**

   At the end of the experiment duration, originals of all logs will be retained by the Village and copies provided to the research team and the Humane Society's Office of General Counsel. Expired or excess controlled substances must be disposed of in the original bottle by marking the bottle "expired" and then disposed of in accordance with DEA directions and AVMA guidelines for proper disposal of controlled substances (expired controlled substances and any other drugs used will be kept locked in the veterinarian office for disposal at the completion of the years operations). All syringes, needles, darts, etc. used for mixing drugs, transferring drugs to darts, or injecting deer and containing drug residue will be disposed of in approved Sharps containers in the field and properly disposed of upon completion of each year's capture work.

10. **Handling Loss or Theft**

    If a theft or discrepancy is noted and verified, it should be reported to the DEA via the standard procedures and submission of a DEA Form 106. A loss should be reported on DEA Form 41.

Appendix A: Study Locations



Appendix B: Agents utilized

Telazol: A Schedule III substance under both the federal Controlled Substances Act and NY State Public Health Law (NYPBH section 3306).

Ketamine: A Schedule III substance under both the federal Controlled Substances Act and NY State Public Health Law (NYPBH section 3306).

Xylazine: Not considered a controlled substance under the CSA or New York State law.

Other agents utilized

1 Dopram V @ 20mg/ml (25ml)
1 Tolazoline @ 100mg/ml (100ml)
1 Antibiotic (liquamycin LA-200) (100ml)
1 Euthasol (100ml)

Appendix C: Designated Individuals

Authorized Project Veterinarians

Dr. Les Sills
Dr. Richard Joseph

Authorized Darting Professionals

Rick Naugle

Kayla Grams

Appendix D: DEA governing code for secured location

(from: http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_72.htm)

PART 1301 — REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

SECURITY REQUIREMENTS

§1301.72 Physical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; storage areas.

(a) Schedules I and II. Raw material, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedule I or II (except GHB that is manufactured or distributed in accordance with an exemption under section 505(i) of the FFDCA which shall be subject to the requirements of paragraph (b) of this section) shall be stored in one of the following secured areas:

(1) Where small quantities permit, a safe or steel cabinet;

(i) Which safe or steel cabinet shall have the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;

(ii) Which safe or steel cabinet, if it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way that it cannot be readily removed; and

(iii) Which safe or steel cabinet, if necessary, depending upon the quantities and type of controlled substances stored, is equipped with an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly to a central protection company or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve.

(2) A vault constructed before, or under construction on, September 1, 1971, which is of substantial construction with a steel door, combination or key lock, and an alarm system; or

(3) A vault constructed after September 1, 1971:

(i) The walls, floors, and ceilings of which vault are constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with \1/2\-inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings;

(ii) The door and frame unit of which vault shall conform to the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;

(iii) Which vault, if operations require it to remain open for frequent access, is equipped with a "day-gate" which is self-closing and self-locking, or the equivalent, for use during the hours of operation in which the vault door is open;

(iv) The walls or perimeter of which vault are equipped with an alarm, which upon unauthorized entry shall transmit a signal directly to a central station protection company, or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve, and, if necessary, holdup buttons at strategic points of entry to the perimeter area of the vault;

(v) The door of which vault is equipped with contact switches; and

(vi) Which vault has one of the following: Complete electrical lacing of the walls, floor and ceilings; sensitive ultrasonic equipment within the vault; a sensitive sound accumulator system; or such other device designed to detect illegal entry as may be approved by the Administration.

(b) Schedules III, IV and V. Raw material, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedules III, IV, and V, and GHB when it is manufactured or distributed in accordance with an exemption under section 505(i) of the FFDCA, shall be stored in the following secure storage areas:

(1) A safe or steel cabinet as described in **paragraph (a)(1)** of this section;

(2) A vault as described in **paragraph (a)(2)** or **(3)** of this section equipped with an alarm system as described in **paragraph (b)(4)(v)** of this section;

(3) A building used for storage of Schedules III through V controlled substances with perimeter security which limits access during working hours and provides security after working hours and meets the following specifications:

(i) Has an electronic alarm system as described in **paragraph (b)(4)(v)** of this section,

(ii) Is equipped with self-closing, self-locking doors constructed of substantial material commensurate with the type of building construction, provided, however, a door which is kept closed and locked at all times when not in use and when in use is kept under direct observation of a responsible employee or agent of the registrant is permitted in lieu of a self-closing, self-locking door. Doors may be sliding or hinged. Regarding hinged doors, where hinges are mounted on the outside, such hinges shall be sealed, welded or otherwise constructed to inhibit removal. Locking devices for such doors shall be either of the multiple-position combination or key lock type and:

(a) In the case of key locks, shall require key control which limits access to a limited number of employees, or;

(b) In the case of combination locks, the combination shall be limited to a minimum number of employees and can be changed upon termination of employment of an employee having knowledge of the combination;

(4) A cage, located within a building on the premises, meeting the following specifications:

(i) Having walls constructed of not less than No. 10 gauge steel fabric mounted on steel posts, which posts are:

(a) At least one inch in diameter;

(b) Set in concrete or installed with lag bolts that are pinned or brazed; and

(c) Which are placed no more than ten feet apart with horizontal one and one-half inch reinforcements every sixty inches;

(ii) Having a mesh construction with openings of not more than two and one-half inches across the square,

(iii) Having a ceiling constructed of the same material, or in the alternative, a cage shall be erected which reaches and is securely attached to the structural ceiling of the building. A lighter gauge mesh may be used for the ceilings of large enclosed areas if walls are at least 14 feet in height,

(iv) Is equipped with a door constructed of No. 10 gauge steel fabric on a metal door frame in a metal door flange, and in all other respects conforms to all the requirements of **21 CFR 1301.72(b)(3)(ii)**, and

(v) Is equipped with an alarm system which upon unauthorized entry shall transmit a signal directly to a central station protection agency or a local or state police agency, each having a legal duty to respond, or to a 24-hour control station operated by the registrant, or to such other source of protection as the Administrator may approve;

(5) An enclosure of masonry or other material, approved in writing by the Administrator as providing security comparable to a cage;

(6) A building or enclosure within a building which has been inspected and approved by DEA or its predecessor agency, BND, and continues to provide adequate security against the diversion of Schedule III through V controlled substances, of which fact written acknowledgment has been made by the Special Agent in Charge of DEA for the area in which such building or enclosure is situated;

(7) Such other secure storage areas as may be approved by the Administrator after considering the factors listed in **§1301.71**(b);

(8)(i) Schedule III through V controlled substances may be stored with Schedules I and II controlled substances under security measures provided by **21 CFR 1301.72(a)**;

(ii) Non-controlled drugs, substances and other materials may be stored with Schedule III through V controlled substances in any of the secure storage areas required by **21 CFR 1301.72(b)**, provided that permission for such storage of non-controlled items is obtained in advance, in writing, from the Special Agent in Charge of DEA for the area in which such storage area is situated. Any such permission tendered must be upon the Special Agent in Charge's written determination that such non-segregated storage does not diminish security effectiveness for Schedules III through V controlled substances

Appendix E: Signature Sheet

AUTHORIZED USERS SIGNATURE LOG

Location: Police Headquarters, 7 Maple Avenue, Hastings-on-Hudson, NY 10706

Date Signed	Name (Please Print)	Job Title	Signature	Initials

Appendix F: Log Sheet

LOG SHEET

Location: Veterinarian office

Date	Drug	Concen-tration	Volume	Quantity delivered to location	Quantity released	Signature of authorized person	Employee Signature	Notes

Appendix G: Field Controlled Substance Log

THE HUMANE SOCIETY OF THE UNITED STATES CONTROLLED SUBSTANCE LOG

Project:_____

Date	Drug	Concentration	Volume	Loss	Animal Number	Handler

HANDLERS SIGNATURE:_____ DATE:_____/_____/___

Appendix H: Deer Capture Data Form

THE HUMANE SOCIETY OF THE UNITED STATES CHEMICAL IMMOBILIZATION DEER CAPTURE DATA FORM

Animal Number_____

Date (mm/dd/yy)____/____/____ Capture Location:_____

Weather:_____ Temperature:_____

Recorder:_____ Gunner:_____ Spotter:_____ Monitor:_____

Time Darted:_____ Time Recumbent:_____ Time Released:_____ Down Time:_____

Tag Numbers: Left ear #_____ Right ear #_____

Sex: (circle one) M F Estimated Age:_____

Physical Condition:____ (1-4)(1=excellent, fat, 2= good, not fat, 3=fair, bony, 4= poor, emaciated)

Pregnant/Lactating: (circle one) Yes No Unknown

Hind-foot Length:_____ Girth:_____ Body Length:_____ Weight:_____

Blood Collected: Yes No Reason:_____ Fecal Collected: Yes No Reason:_____

PZP Treated: Yes No Dose:_____ Adjuvant:_____ Hip Injected:_____

Antibiotic Administered:_____

Chemical Immobilizer Drug Log

Drug	Concentration	Dose/Volume	Route	Purpose	Effect	Time

Vitals Monitoring

Time						
Temp (°F)						
HR						
Respiration						
Pulse Oximeter						

Injuries, Problems, Comments:

_____

_____

_____

Signature:_____ Date:____/____/____

Appendix I: BNE Reporting Requirements

10 NYCRR 80.37

Title: Section 80.37 - Records; researchers

80.37 Records; researchers. (a) Researchers, licensed and authorized to possess and use controlled substances, shall keep a record of all such substances received and used by them.

(1) A record of all such controlled substances received shall include date of receipt, name and address of vendor, type and quantity of drug received. A duplicate invoice or separate itemized list furnished by the vendor will be sufficient to meet this record requirement providing it contains all the information required and is maintained in a separate file.

(2) A record of all controlled substances used shall include the name of the person authorized to control and use such drugs, the date, type and quantity of drug and signature of the user.

(b) In addition, such records shall contain the following information for each controlled substance:

(1) Name of substance.

(2) Each finished form (such as 10 mg. tablet, or 10 mg. concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container.

(3) The number of commercial containers of such finished form received from other persons, including the date of and number of containers in each receipt, and the name, address, and registration number of the person from whom the containers were received.

(4) The amount of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, and the written or typewritten name or initials of the individual who dispensed or administered the substance.

(5) The number of units or volume of the finished form and/or commercial containers disposed of in any other manner by the researcher, including the date and manner of disposal.