



MARINE BIOLOGICAL LABORATORY

DEA CONTROLLED SUBSTANCES POLICY

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APPROVAL:

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1 INTRODUCTION

Controlled Substances are subject to extensive licensing, registration, storage, security, use, disposal, and inventory requirements due to their potential for abuse. The purchase, use, storage, and disposal of Controlled Substances is regulated by the United States Department of Justice, Drug Enforcement Administration (DEA) Controlled Substances Act (21 CFR 1300), and the Massachusetts Department of Public Health regulation (105 CMR 700).

The Marine Biological Laboratory (MBL) Attending Veterinarian (AV) currently has a **PRACTITIONER** Federal DEA Registration and a Controlled Substances (Schedules II-VI) Registration issued by the Massachusetts Department of Public Health, Drug Control Program.

The MBL is ultimately responsible for ensuring proper acquisition, use, storage/security, disposal and accountability of all Controlled Substances purchased under the MBL's Federal and State registrations. Responsible Researchers and Authorized Individuals should be familiar with their responsibilities and obligations regarding procurement, storage and security, use and disposal of Controlled Substances.

Violations of the applicable Controlled Substances laws and regulations, even when unintentional, can lead to immediate loss of the privilege to use Controlled Substances in research at the MBL, civil penalties or revocation of the MBL Attending Veterinarian's Practitioner Federal DEA and Massachusetts registrations, and/or criminal prosecution by law enforcement agencies.

1.1 Policy

All authorized Responsible Researchers (Course Directors, Resident Faculty, Whitman Scientists, Visiting Scientists, and other Principal Investigators) and Authorized Individuals (laboratory personnel, postdoctoral researchers, research scientists, and graduate students working with or assisting in management of Controlled Substances at the MBL must comply with all applicable Federal DEA and Massachusetts Controlled Substances laws and regulations, and MBL Policy.

1.2 Purpose

This Policy provides guidance to the MBL research community regarding the management of Controlled Substances for research use, to ensure compliance with applicable Federal and State laws and regulations, and MBL Policy.

1.3 Scope

This Policy applies to all individuals involved with purchase, storage, use, and disposal of Controlled Substances (Schedules II-VI) at the MBL.

1.4 Updates to Policy

This Policy shall be reviewed periodically and updated, as necessary, to ensure accuracy and reflect any changes to the existing applicable laws and regulations.

2 ROLES AND RESPONSIBILITIES

2.1 Institutional Official (IO)

The Director of the Division of Research serves as the MBL's Institutional Official (IO). The IO is also responsible for providing oversight and support required to effectively implement the MBL's Controlled Substances Program.

2.2 MBL Attending Veterinarian

The MBL Attending Veterinarian (AV) holds a **Practitioner** DEA license, and Massachusetts Controlled Substances registration. The AV may use their licenses to purchase Controlled Substances for use in research animals for IACUC approved protocols. As the "**Registrant**", the AV is ultimately responsible for ensuring proper acquisition, use, storage/security, disposal, and accountability of **ALL** Controlled Substances purchased under their **Practitioner** DEA and State registrations.

- Approve and coordinate purchase and distribution of Controlled Substances.
- Keep track of all Responsible Researchers and Authorized Individuals who are authorized to have access to Controlled Substances and the storage locations.
- Maintain accurate and up-to-date records of purchase, receipt, storage, use, and disposal of Controlled Substances.
- Assume custody of and secure abandoned Controlled Substances.

2.3 Environmental Health & Safety Manager

The Environmental Health & Safety Manager is responsible for managing the use of Controlled Substances in research and teaching laboratories at the MBL.

- Develop and implement MBL's Controlled Substances Program.

- Create, implement, and update lab-specific policies and procedures.
- Assist Responsible Researchers and Authorized Individuals in complying with the Controlled Substances Program requirements.
- Provide training to Responsible Researchers and Authorized Individuals.
- Ensure security and access controls and procedures are implemented in each location where Controlled Substances are used or stored.
- Conduct annual inspections of research and teaching labs where Responsible Researchers store and use Controlled Substances. Assist Responsible Researchers in implementation of any corrective actions.
- Manage disposal of Controlled Substances at MBL.
- Conduct investigations of suspected theft or loss of Controlled Substances.
- Coordinate annual renewal of Federal DEA and State Controlled Substances registrations.
- Liaise with Federal DEA and Massachusetts Department of Public Health, Drug Control Program on all compliance issues.
- Maintain records of MBL's Controlled Substances Program.

2.4 Responsible Researchers

Responsible Researchers include Course Directors, Resident Faculty, Whitman Scientists, Visiting Scientists, and other Principal Investigators who are authorized by the IO to purchase, possess, use and dispose of Controlled Substances under the MBL's Federal DEA and Massachusetts registrations.

It is the responsibility of each Responsible Researcher to familiarize themselves with the Federal DEA and Massachusetts laws and regulations referenced in this Policy. They must use the Controlled Substances they order exclusively for their own research. Controlled Substances must not be shared or transferred to others not supervised directly by the Responsible Researcher.

Responsible Researchers may authorize members of their research team (referred to as Authorized Individuals) to access Controlled Substances by listing those individuals on the MBL Form, "**CONTROLLED SUBSTANCES APPLICATION**".

Specific responsibilities of the Responsible Researchers include:

- Ensure that all applicable DEA and Massachusetts regulations and MBL Policy and procedures for acquisition, storage/security, use, disposal, and recordkeeping are followed by Authorized Individuals.
- Ensure Authorized Individuals are trained in Controlled Substances storage/security and record-keeping procedures
- Obtain prior approval for purchase of Controlled Substances from the MBL Attending Veterinarian.

- Keep Controlled Substances in an approved securely locked cabinet.
- Restrict access to Controlled Substances only to Authorized Individuals.
- Provide updated information regarding changes (additions/deletions) of Authorized Individuals to the Environmental Health & Safety Manager.
- Keep accurate records of receipt, use and disposal of Controlled Substances.
- Ensure that Controlled Substances Usage Logs and inventories are properly kept and transferred to the Attending Veterinarian.
- Supervise Authorized Individuals who assist them handling or using Controlled Substances in research.
- Actively monitor each Authorized Individual's use of Controlled Substances to ensure compliance with this Policy and applicable laws and regulations.
- Dispose of Controlled Substances only through the MBL Environmental Health and Safety (EHS) Office or the MBL Attending Veterinarian.
- Immediately report any theft or significant loss of Controlled Substances to the MBL Campus Security (x7-911), the MBL Attending Veterinarian (x7522 or vet@mbledu), and the Environmental Health & Safety Manager (x7424 or safety@mbledu).

2.5 Authorized Individuals

Authorized Individuals include laboratory staff (e.g. Postdoctoral Scientists, Research Assistants, and Graduate Students); Course Managers/Assistants and Students who access or manage Controlled Substances for approved research use.

- Participate in training prior to handling Controlled Substances.
- Comply with Federal DEA and State regulations and MBL Policy regarding Controlled Substances.
- Maintain strict access control and inventory of Controlled Substances.
- Immediately report any theft, suspected theft or loss of Controlled Substances to the Responsible Researcher and the Environmental Health & Safety Manager (x7424 or safety@mbledu).

3 AUTHORIZATION TO USE CONTROLLED SUBSTANCES

1. Controlled Substances may be used only for duly authorized, legitimate scientific research purposes.

2. The Federal DEA considers certain information vital to assessing the likelihood of an employee committing a drug security breach. The required information is critical for ensuring overall security of Controlled Substances.
3. All Responsible Researchers and Authorized Individuals planning to conduct research using Controlled Substances at MBL must complete and sign the form, "**CONTROLLED SUBSTANCES QUESTIONNAIRE**". The Form must be submitted to the MBL Attending Veterinarian (x7522) by emailing to vet@mbledu.
4. The MBL Attending Veterinarian is responsible for approving any controlled substance use.
5. Authorization to use or access Controlled Substances will be denied to any person who has been convicted of a felony relating to Controlled Substances or who, at any time, had an application for DEA registration denied or registration revoked (21 CFR 1301.90).
6. Responsible Researchers may authorize members of their research team ("Authorized Individuals") to access Controlled Substances by identifying those individuals on the MBL "**CONTROLLED SUBSTANCES PURCHASE REQUEST**" Form.
7. Only Responsible Researchers and Authorized Individuals are permitted to use, handle, or gain access to Controlled Substances.
8. All Responsible Researchers and Authorized Individuals must follow all procedures outlined in this Policy.

4 PURCHASING OF CONTROLLED SUBSTANCES

The MBL Attending Veterinarian will be responsible for coordinating all purchases, receipt and distribution of Controlled Substances.

1. The Responsible Researcher must complete the form, "**CONTROLLED SUBSTANCES PURCHASE REQUEST**". Submit the form to the MBL Attending Veterinarian (x7522; MRC Room 311 or E-mail: vet@mbledu).
2. All orders for Controlled Substances must be processed through the MBL Purchasing Department, using a Purchase Requisition Form. No orders may be placed directly with the vendors.
3. The MBL does not permit the use of MBL Corporate credit cards, personal credit cards, personal checks, or cash to purchase Controlled Substances.
4. Orders of Controlled Substances shall be limited to Schedules II-VI listed on the MBL Attending Veterinarian's DEA and Massachusetts registrations.
5. Schedule II Controlled Substances must be ordered on DEA Form 222 (www.deadiversion.usdoj.gov/faq/dea222.htm).

6. The MBL Attending Veterinarian's will review, approve, and submit the purchase order to the vendor.

5 RECEIPT OF CONTROLLED SUBSTANCES

1. All shipments of authorized Controlled Substances shall be delivered to the MBL Shipping & Receiving Department at the address listed on the DEA Registration Certificate (7 MBL Street, Woods Hole, MA 02543).
2. Upon receipt of the shipment, the MBL Shipping & Receiving Department personnel shall inform the MBL Attending Veterinarian (x7522; vet@mbi.edu).
3. The MBL Attending Veterinarian shall pick up the package and:
 - Verify the accuracy of the order and resolve any discrepancies with the vendor.
 - Enter the order in the Controlled Substance the form, "**CONTROLLED SUBSTANCES ORDER & RECEIPT LOG**".
 - Assign a unique Vial Identification Number to each vial. (First letter of drug, year, and vial number such as K-21-1)
 - Deliver the order to the Responsible Researcher. Only Responsible Researchers or Authorized Individuals with MBL ID Card will be allowed to receive and sign for the order.
4. The Responsible Researcher or Authorized Individual will sign the form, "**CONTROLLED SUBSTANCES USAGE LOG**" acknowledging receipt.
5. The MBL Attending Veterinarian will give the keys to storage cabinet and a copy of the form, "**CONTROLLED SUBSTANCE USAGE LOG**" to the Responsible Researcher or Authorized Individual.
6. The Responsible Researcher or Authorized Individual shall immediately secure the Controlled Substance(s) in the approved storage locked cabinet.

6 INVENTORY AND RECORDKEEPING

The MBL Attending Veterinarian shall maintain complete, accurate and current records (purchasing, receipt, inventory and disposal) of all Controlled Substances. Each Responsible Researcher is required to keep track of each Controlled Substance they receive.

6.1 Controlled Substance Usage Logs

- Each Responsible Researcher must maintain complete, accurate and current records for all Controlled Substances in their possession using the MBL's form, "**CONTROLLED SUBSTANCES USAGE LOG**".
- Each entry on the Usage Log must be signed by the Authorized Individual who dispensed or administered the Controlled Substance.
- A separate log must be kept for each vial or container of a Controlled Substance.
- Usage Log sheets shall be numbered and maintained at all times in the locked storage cabinet together with the Controlled Substances.
- Usage Log sheets must be maintained for a minimum of **3 years** after the complete use and disposal of Schedule II-VI Controlled Substances and be readily available for inspection by the DEA, the Federal DEA, Massachusetts Department of Public Safety, or MBL EHS personnel. Responsible Researchers are not required to maintain Usage Logs for Schedule VI Controlled Substances (prescription drugs).
- Records must be written, typewritten, or printed form. The use of codes, symbols, or foreign languages in identifying a Controlled Substance or person in the record is prohibited.

6.2 Laboratory Inspections

All laboratories that work with Controlled Substances (Schedule II-V) are required to conduct self-inspections annually. The purpose of the inspection is to verify if Usage Logs match the physical inventory. Research and teaching laboratories that are not operated by MBL Resident Faculty will be inspected prior to their end of stay at the MBL to ensure that all Controlled Substances records and inventory are compliant with the requirements of this Policy.

6.3 Annual Controlled Substances Inventory

The MBL Veterinarian shall perform an annual inventory. The inventory will be documented on the MBL's form, "**ANNUAL CONTROLLED SUBSTANCES INVENTORY FORM**". The MBL Veterinarian will maintain the inventory records.

6.4 Recordkeeping

The MBL shall keep a biennial inventory of Controlled Substances in possession, and the purchase order, receipt and shipping records for materials in inventory,

and any disposal records of the Controlled Substances for 3 years from the date record was created.

All records regarding the acquisition, use and disposal of Controlled Substances shall be made available to appropriate regulatory agencies and MBL officials for inspection. The Controlled Substance records are stored with the MBL Attending Veterinarian.

7 STORAGE AND SECURITY OF CONTROLLED SUBSTANCES

7.1 Storage and Security

The MBL Campus Security personnel routinely patrol the MBL premises (24/7). The MBL's laboratory buildings have swipe card key access control or key systems to lock buildings after hours.

- Controlled Substances (Schedule II-V) shall be stored in securely locked, substantially constructed drug cabinets in locations where access is limited. Standard file cabinets or drawers are not acceptable for the storage of Controlled Substances.
- Access to Controlled Substances within the laboratory must be limited to the minimum number of Authorized Individuals. Keys to the storage cabinets should be secure and under the control of a limited number of Authorized Individuals.
- Controlled Substances must not be left unattended. When they are not being used for research, Controlled Substances must be securely stored in a cabinet.
- All Schedule II-V Controlled Substances, including their diluted forms, must be kept locked in their storage location except for the actual time required for Responsible Researchers or Authorized Individuals to remove and legitimately work with them. They must be immediately returned to the securely storage cabinet after each use.
- Controlled Substances must not be transferred from their original containers for inventory purposes.
- Identifying labels must not be removed from the original containers. If the Controlled Substance is converted or diluted, the new container must be labeled properly.

7.2 Transfers to Secondary Containers

Controlled Substances transferred to another container for dilution or preparing drug mixtures must be clearly labeled to indicate the contents, concentration of each drug, and the expiry date. Secondary vials must be returned to double-locked cabinet at the end of each experiment.

7.3 Expired Controlled Substances

Controlled Substances must not be administered to research animals after the date of expiration, according to USDA Policy. Expired Controlled Substances should be clearly labeled as “**EXPIRED**” on the vial or box and kept separate from the non-expired drugs within the securely locked cabinet until they are disposed of properly.

8 TRANSFERRING CONTROLLED SUBSTANCES

8.1 Transfers of Controlled Substances within the MBL Campus

1. Possession of Controlled Substances may only be transferred to Responsible Researcher or Authorized Individual approved according to MBL’s Controlled Substances Policy procedures.
2. Intra-campus transfer may only occur with **written approval** granted by the MBL Attending Veterinarian (x7522 or vet@mbi.edu).
3. An intra-Campus transfer of a Controlled Substance will be approved only if the following criteria are met:
 - (a) The original Controlled Substances inventory must have been procured under the MBL’s Attending Veterinarian’s DEA and State registrations.
 - (b) The Responsible Researcher receiving the Controlled Substance(s) must submit the form, “**CONTROLLED SUBSTANCES PURCHASE REQUEST**” to the MBL Veterinarian and receive approval prior to the transfer.
 - (c) Both parties must maintain records of any approved transfer.

8.2 Prohibition of Transfers of Controlled Substances outside MBL

Under no circumstances can Controlled Substances procured under the MBL’s DEA and State registrations be transferred off MBL Campus. Responsible Researchers and Authorized Individuals are prohibited from taking or transferring Controlled Substances into or out of the MBL facility.

9 REPORTING THEFT OR LOSS OF CONTROLLED SUBSTANCES

Thefts, suspected thefts, unauthorized uses, or other losses of any Controlled Substance must be reported immediately to the MBL Campus Security, the MBL Attending Veterinarian or the Environmental Health & Safety Manager, upon discovery.

If you suspect Controlled Substances has been lost or stolen from your lab:

- Notify MBL Campus Security immediately (x7-911).
- MBL Campus Security will notify the MBL Attending Veterinarian (x7522 or vet@mbi.edu) and the Environmental Health & Safety Manager (x7424; safety@mbi.edu.)
- The MBL Attending Veterinarian and Environmental Health & Safety Manager, together with the Responsible Researcher, will conduct an initial investigation to determine if the event is a suspected theft, a significant loss, or an insignificant loss.
- The MBL must report suspected thefts or significant losses of Controlled Substances (diversion) to the Federal DEA and the Massachusetts Department of Public Safety within one business day of discovery.
- DEA Form 106 should be submitted, after an initial investigation is made, within 60 days of the reported loss.
https://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html.

10 DISPOSAL OF CONTROLLED SUBSTANCES

The Environmental Health & Safety Manager is responsible for ensuring that all Controlled Substances are properly disposed of when the drugs expire; or when the Responsible Researcher no longer conducts research at MBL using Controlled Substances or leaves the MBL.

- All expired, unused, or unwanted Controlled Substances must be returned to the MBL Attending Veterinarian or Environmental Health & Safety Manager for proper disposal in accordance with applicable Federal DEA regulations.
- Controlled Substances must be disposed of through the use of a “*Reverse Distributor*” (i.e. DEA registered entity that is legally allowed to handle disposal of Controlled Substances). As appropriate, the MBL Attending Veterinarian has the discretion for inhouse deactivation and disposal.
- The MBL has contracted with Veolia Environmental Services, Inc. to collect and dispose of Controlled Substances in compliance with federal regulations.

- The Environmental Health & Safety Manager will coordinate disposal of Controlled Substances with the licensed vendor.
- Controlled Substances consumed in a reaction or converted into a hazardous waste mixture from which a Controlled Substance is not recoverable may be disposed of through routine Hazardous Waste disposal procedures. Contact Environmental Health & Safety Manager (x7424 or safety@mbi.edu).
- Animal carcasses that were injected with Controlled Substances must be disposed of through the MBL Animal Care Facility. Contact the Animal Care Coordinator (x7288 or djohnson@mbi.edu).
- All records regarding the transfer and disposal of Controlled Substances shall be kept for 3 years after disposal or transfer to a DEA registered Reverse Distributor.

11 SHIPPING PROCEDURES

Federal law prohibits the export of Controlled Substances unless certain requirements are met, including export permits. Violators of the law risk arrest or fines, both in the United States and the foreign country. Licensed brokers are available for transportation of Controlled Substances. Contact the Environmental Health & Safety Manager (x7424 or safety@mbi.edu) for assistance in arranging for any necessary transport of Controlled Substances.

12 CONTROLLED SUBSTANCES TRAINING

Training regarding use of Controlled Substances for research at MBL will be provided by the Environmental Health & Safety Manager or the MBL Attending Veterinarian. This training is mandated for all Responsible Researchers and Authorized Individuals who work for them on Controlled Substances in research involving animals.

13 REFERENCES AND RESOURCES

1. Massachusetts Department of Public Health, Drug Control Program
www.mass.gov/eohhs/gov/departments/dph/programs/hcq/drug-control/
2. United States Department of Justice, Drug Enforcement Administration. Diversion Control Division.
<https://www.deadiversion.usdoj.gov/index.html>

3. List of DEA Controlled Substances

<https://www.deadiversion.usdoj.gov/schedules/index.html#list>

4. DEA Controlled Substances Security Manual:

<http://www.deadiversion.usdoj.gov/pubs/manuals/sec/index.html>

14 APPENDICES



MARINE BIOLOGICAL LABORATORY

CONTROLLED SUBSTANCES QUESTIONNAIRE

The MBL requires that all individuals who have access to Controlled Substances used in research as a part of work-related duties/tasks complete the following questionnaire in order to ensure compliance with the federal regulations governing Controlled Substances (21 CFR 1301.90). The United States Drug Enforcement Agency (DEA) requires the collection of this information in order to “fairly assess the likelihood of an employee committing a drug security breach.” The information collected on this form will only be used by MBL to assess an individual’s security risk with respect to working with Controlled Substances.

Name of Authorized Individual:		DOB:
Title:	E-mail:	Phone:
Name of Responsible Researcher:		

BACKGROUND SCREENING QUESTIONS

- Within the past 5 years, have you been convicted of a felony, or within the past 2 years, of any misdemeanor or are you presently formally charged with committing a criminal offense?** (Do not include any traffic violations, juvenile offenses or military convictions, except by general court-martial).

YES NO

If the answer is yes, furnish details of conviction, offense, location, date and sentence.

- In the past 3 years, have you ever knowingly used any narcotics, amphetamines or barbiturates, other than those prescribed to you by a physician?**

YES NO

If the answer is yes, furnish details.

STATEMENT OF INDIVIDUAL

I certify the accuracy of the above information and that I have read, understood, and agree with the above statements. I authorize MBL to make inquiries with the Federal Drug Enforcement Agency’s local field office for possible pending charges or convictions I may have.

Signature of Authorized Individual: _____ Date: _____

CONTROLLED SUBSTANCES PURCHASE REQUEST FORM

INSTRUCTIONS: *The Responsible Researcher completes this Form and submits it to the MBL Attending Veterinarian (x7522; MRC Room 311; E-mail: vet@mbl.edu).*

1. APPLICANT (Responsible Researcher):

Name: _____ Title: _____

Department/Course: _____ Phone: _____

E-mail Address: _____ MBL Cost Center Account: _____

2. CONTROLLED SUBSTANCE(S) REQUESTED:

CONTROLLED SUBSTANCE	SCHEDULE (II-V)	MANUFACTURER OR PRODUCT NUMBER	QUANTITY	
			Unit Size	No. of Units

3. ADDITIONAL USERS

Authorized Individual	Email	Phone Number
1.		
2.		
3.		
4.		

4. STORAGE AND USE LOCATION:

Building	Room	Security Measures
		<input type="checkbox"/> Securely locked, substantially constructed cabinet <input type="checkbox"/> Other:

I certify that the information provided above is accurate, and that I understand and will abide by the use requirements of the MBL Controlled Substances Program.

Signature Responsible Researcher: _____ **Date:** _____



CONTROLLED SUBSTANCES ORDER AND RECEIPT LOG

Name of Responsible Researcher	PO Number	Name of Supplier	Catalog Number	Product Description	Date Order Placed	Amount Ordered	Date Shipment Received	Name of Person who Received Shipment	Amount Received	Date Delivered to Responsible Researcher	Controlled Substance Storage Location	Responsible Researcher Signature

Signature (MBL Attending Veterinarian): _____ Date: _____



MARINE BIOLOGICAL LABORATORY

CONTROLLED SUBSTANCES USAGE LOG

INSTRUCTIONS

1. Due to their potential for abuse, Controlled Substances are subject to extensive licensing, registration, storage, security, use, disposal, and inventory requirements.

Purchase Order Number:		Date:
Name of Responsible Researcher:		
Location Where Drugs Are Stored	Building :	Room:
Name of Controlled Substance:	Lot/Serial Number:	Amount in Container:
Expiration Date:	Strength:	FORM: <input type="checkbox"/> Powder <input type="checkbox"/> Tablet <input type="checkbox"/> Injectable <input type="checkbox"/> Elixir
Unique Vial # Assigned by Authorized Individual:		Date Disposed/Empty:

2. **FILL OUT THIS FORM UPON RECEIPT OF THE CONTROLLED SUBSTANCE.**
3. One Usage Log sheet must be completed for each container/vial of Controlled Substance.
4. **Controlled Substance usage MUST BE TRACKED on a per dose (use) basis and only by the Responsible Researcher or an Authorized Individual.**
5. All Schedule II-V Controlled Substances, including their diluted forms, must be kept locked in the storage cabinet except for the actual time required for Responsible Researcher or Authorized Individual to remove, legitimately work with and return the Controlled Substances.
6. Controlled Substances Usage Logs must be maintained at all times in the locked cabinet together with the Controlled Substances.
7. The Responsible Researcher must surrender any unused, unwanted or expired Controlled Substance(s), including diluted forms, to the MBL Attending Veterinarian (x7522; MRC Room 311; E-mail: vet@mbl.edu).for proper disposal.
8. **Failure to follow these guidelines is a serious violation of the US Drug Enforcement Administration (DEA) Controlled Substances Act (21 CFR 1300) and the Massachusetts Department of Public Health, Drug Control Program regulations (105 CMR 700.000).**

Signature of Responsible Researcher: _____ Date: _____

MBL Attending Veterinarian: _____ Date: _____

