Mass General Brigham

RCO On-Demand Learning

Controlled Substance Disposition Log

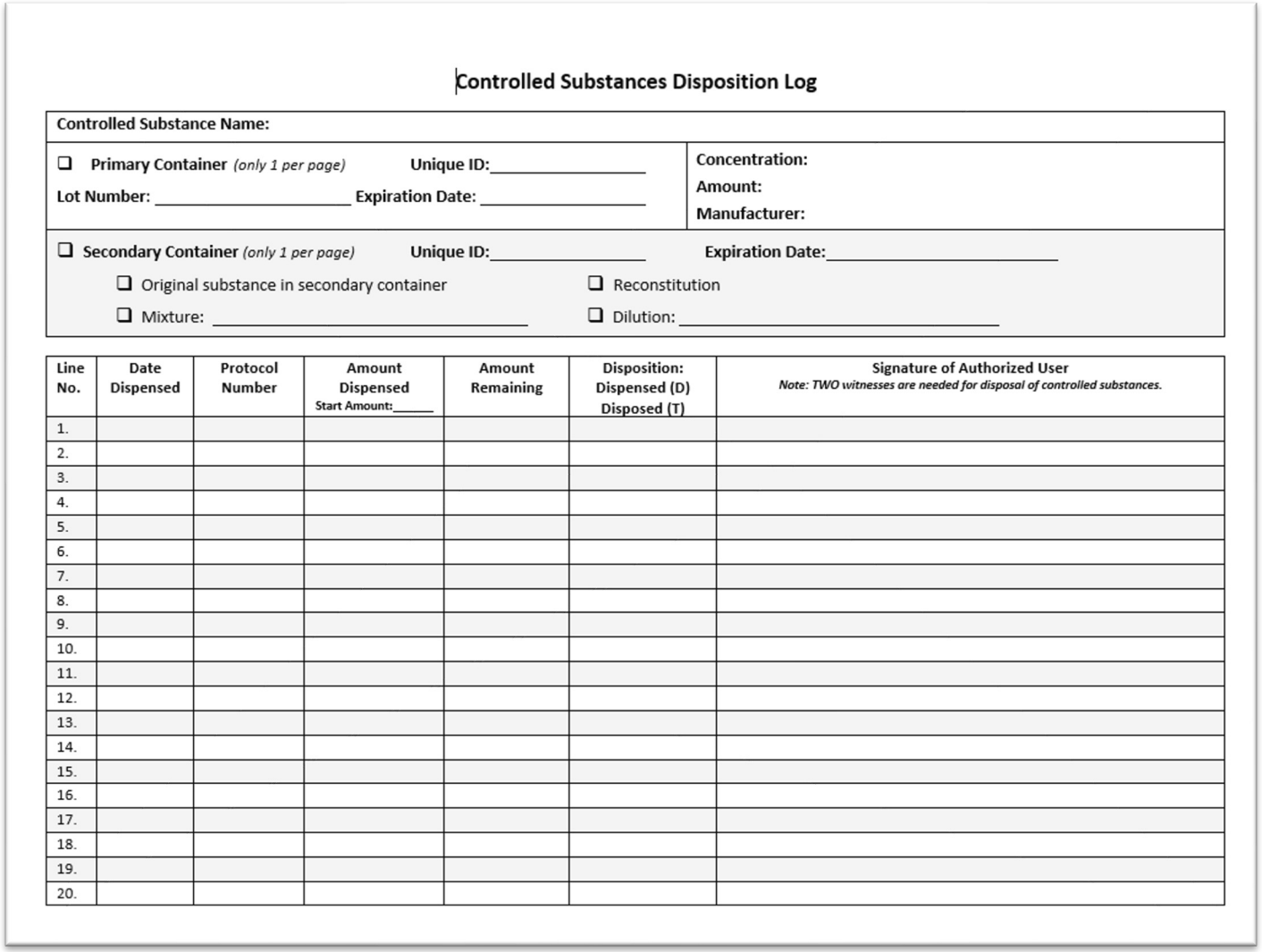
MGB Research Compliance

Record of Controlled Substance Usage

Controlled Substance Disposition Log is used to record all usage of controlled substances

How to:

- Complete the Disposition Log for:
  - Primary containers
  - Secondary Containers



Controlled Substances Disposition Log

Controlled Substance Name:

❑ **Primary Container** *(only 1 per page)* **Unique ID:**_____

Lot Number: _____ **Expiration Date:** _____

Concentration:
Amount:
Manufacturer:

❑ **Secondary Container** *(only 1 per page)* **Unique ID:**_____ **Expiration Date:**_____

❑ Original substance in secondary container ❑ Reconstitution

❑ Mixture: _____ ❑ Dilution: _____

Line No.	Date Dispensed	Protocol Number	Amount Dispensed Start Amount:_____	Amount Remaining	Disposition: Dispensed (D) Disposed (T)	Signature of Authorized User *Note: TWO witnesses are needed for disposal of controlled substances.*
1.						
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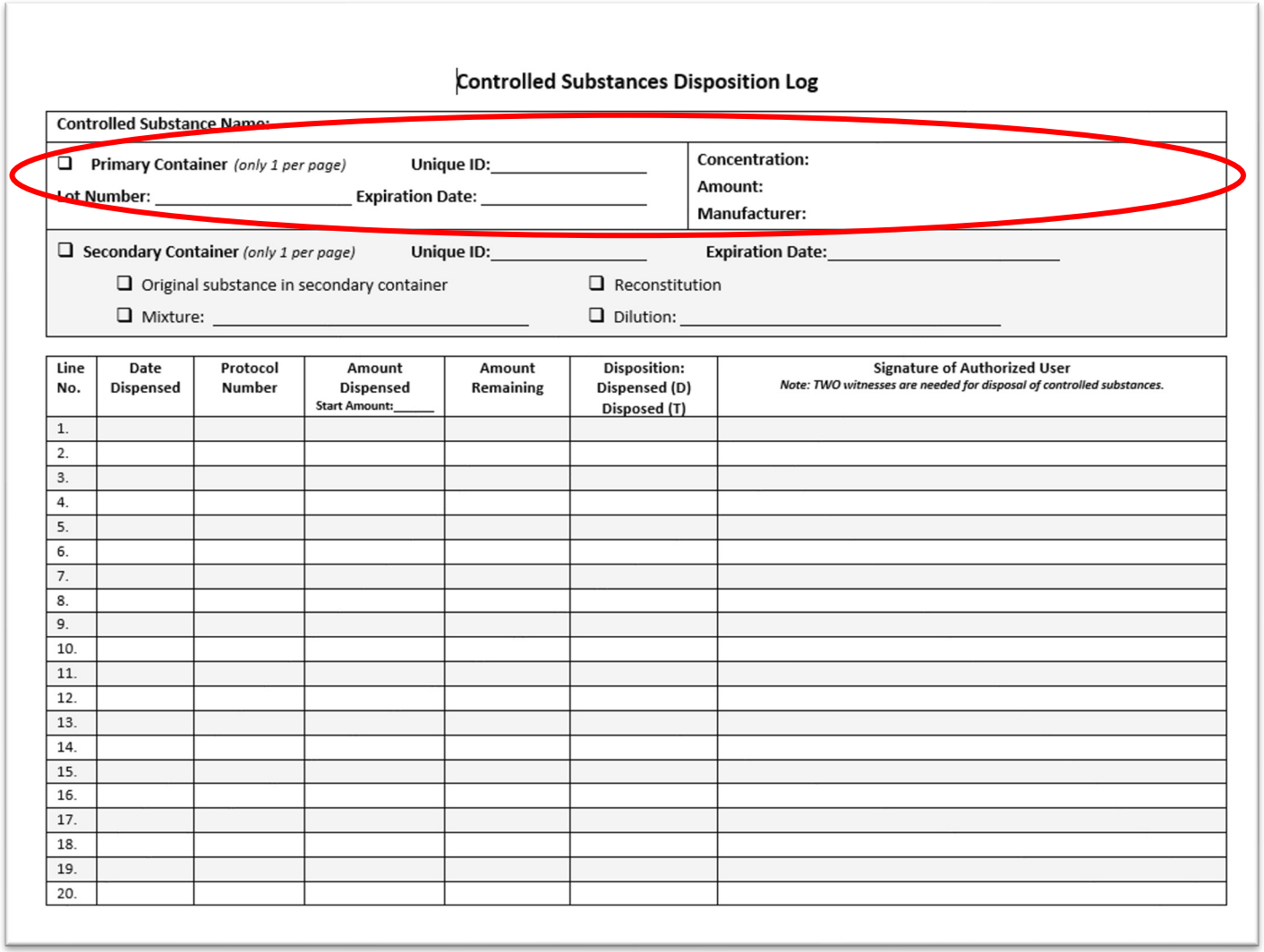
Completing the Disposition Log - Primary Container

- Primary containers must be logged in the Controlled Substances Disposition Log contained within the MGB Controlled Substance Accountability Logbook
- Only one container can be logged per page



Controlled Substances Disposition Log

Controlled Substance Name:

❑ **Primary Container** *(only 1 per page)* **Unique ID:**_____

Lot Number: _____ **Expiration Date:** _____

Concentration:
Amount:
Manufacturer:

❑ **Secondary Container** *(only 1 per page)* **Unique ID:**_____ **Expiration Date:**_____

❑ Original substance in secondary container ❑ Reconstitution

❑ Mixture: _____ ❑ Dilution: _____

Line No.	Date Dispensed	Protocol Number	Amount Dispensed Start Amount:_____	Amount Remaining	Disposition: Dispensed (D) Disposed (T)	Signature of Authorized User *Note: TWO witnesses are needed for disposal of controlled substances.*
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Completing the Disposition Log - Primary Container

Enter Primary Container information

- Enter the controlled substance name
- Enter the Unique ID – ID created for the Inventory Log
- Enter the Lot Number of the container
- Provide the Expiration Date of the container
- Enter the concentration of the controlled substance
- Enter the volume of controlled substance at the start of use
- Provide the Manufacturer of the controlled substance

Controlled Substance Name: *Ketamine*	
❑ **Primary Container** *(only 1 per page)* **Unique ID:** *KE1* **Lot Number:** *123456* **Expiration Date:** *12/31/2024*	**Concentration:** *100mg/ml* **Amount:** *10ml* **Manufacturer:** *NexGen*

Completing the Disposition Log - Primary Container

For the initial use of the controlled substance:

- Enter the date of usage
- Indicate the protocol number for the experiment being performed
- Indicate the start amount in the Amount Dispensed Column
- Enter the amount of drug dispensed from the container
- Calculate the amount remaining (Start Amount – Amount Dispensed)
- Indicate that the drug has been Dispensed with a “D”
- Sign the disposition record

Line No.	Date Dispensed	Protocol Number	Amount Dispensed Start Amount: 10ml	Amount Remaining	Disposition: Dispensed (D) Disposed (T)	Signature of Authorized User *Note: TWO witnesses are needed for disposal of controlled substances.*
1.	08/01/2024	2023P00234	1ml	9ml	D	
2.						
3.						

Completing the Disposition Log - Primary Container

For each consecutive use of the drug:

- Enter the date of usage
- Indicate the protocol number for the experiment being performed
- Enter the amount of drug dispensed from the container
- Calculate the amount remaining (Amount Remaining from the line above – Amount Dispensed)
- Indicate whether the drug has been Dispensed (D) or Disposed (T)
- Sign the disposition record (**two** signatures are required for disposal)

Line No.	Date Dispensed	Protocol Number	Amount Dispensed Start Amount: 10ml	Amount Remaining	Disposition: Dispensed (D) Disposed (T)	Signature of Authorized User *Note: TWO witnesses are needed for disposal of controlled substances.*
1.	*08/01/2024*	*2023P00234*	*1ml*	*9ml*	*D*	
2.	*08/03/2024*	*2023P00234*	*0.5ml*	*7.5ml*	*D*	
3.						

Secondary Containers

- The circumstances which would require that the Controlled Substance received from the manufacturer to be altered in some way for the purposes of the research are:
  - **Reconstitution:** the Controlled Substance is received in a powdered form and sterile saline is being added to return it to liquid form
    - Example: Telazol is reconstituted with sterile saline
  - **Mixture:** the Controlled Substance is mixed with another Controlled Substance or Schedule VI drug
    - Example: Ketamine is mixed with xylazine
  - **Dilution:** the Controlled Substance is too concentrated to dose due to the size of the animal so sterile saline is used to reduce the concentration
    - Example: Buprenorphine is diluted with sterile saline

Secondary Containers

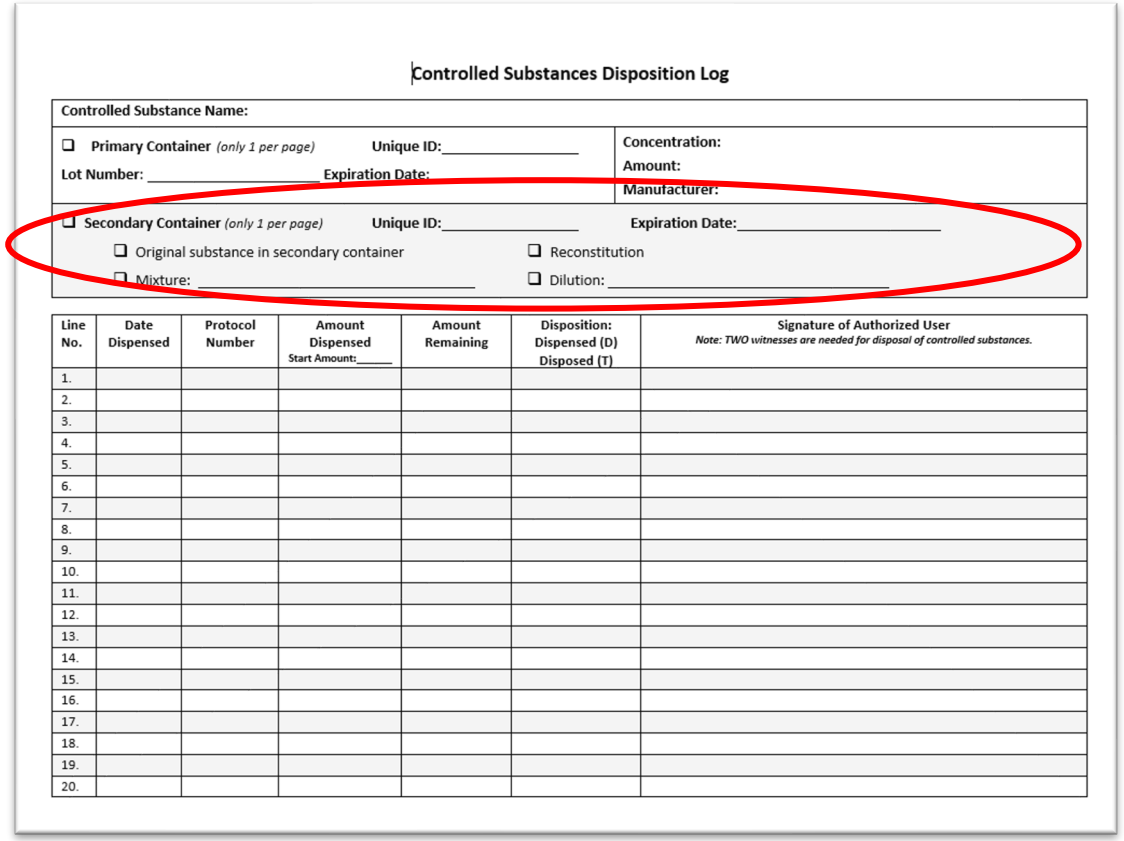
- If a Controlled Substance is removed from the primary container and placed in a secondary container to be altered, and the altered substance is not completely used
  - It must have a unique identifier (e.g. Ketamine/Xyalzine = KX1)
  - It must be tracked separately on a Controlled Substance Disposition Log page in the MGB Controlled Substance Accountability Logbook.

- This secondary container must be stored in the Controlled Substance cabinet and labeled with the following:
  - A unique identifier
  - Formulary of drugs in the container
  - Date the solution was prepared (substance altered)
  - Expiration date
  - Initials of individual that prepared solution

KX1
10ml = Ketamine 90mg/kg and xylazine 10mg/kg
Prep: 9/1/24 Exp: 10/1/24 Initials: AB

Completing the Disposition Log - Secondary Container

- The formulation details of the altered controlled substance must be provided on the Controlled Substances Disposition Log for the secondary container
- Secondary containers **must be sterile** to consider storing for later use
- **The expiration dates will change when the controlled substances are altered**. Use packaging instructions to determine the expiration dates when possible, including storage requirements
  - If there are no packaging instructions, reach out to your IACUC or animal facility for guidance



Controlled Substances Disposition Log

Controlled Substance Name:

❑ **Primary Container** *(only 1 per page)* **Unique ID:**_____
Lot Number: _____ **Expiration Date:**
Concentration:
Amount:
Manufacturer:

❑ **Secondary Container** *(only 1 per page)* **Unique ID:**_____ **Expiration Date:**_____
❑ Original substance in secondary container ❑ Reconstitution
❑ Mixture: _____ ❑ Dilution: _____

Line No.	Date Dispensed	Protocol Number	Amount Dispensed Start Amount:____	Amount Remaining	Disposition: Dispensed (D) Disposed (T)	Signature of Authorized User *Note: TWO witnesses are needed for disposal of controlled substances.*
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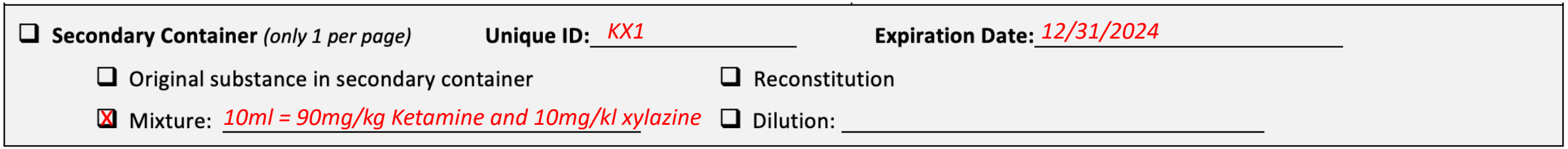
Completing the Disposition Log - Secondary Container

Enter Secondary Container information

- Enter the unique ID created for the secondary container
- Enter the expiration date of the secondary container
- Enter the formulary of the drugs in the secondary container



Completing the Disposition Log - Secondary Container

For each use of the drug:

- Indicate the start amount in the Amount Dispensed Column
- Enter the date of usage
- Indicate the protocol number for the experiment being performed
- Enter the amount of drug dispensed from the container
- Calculate the amount remaining
- Indicate whether the drug has been dispensed or disposed of.
- Sign the disposition record (**two** signatures are required for disposal)

Line No.	Date Dispensed	Protocol Number	Amount Dispensed Start Amount: *10ml*	Amount Remaining	Disposition: Dispensed (D) Disposed (T)	Signature of Authorized User *Note: TWO witnesses are needed for disposal of controlled substances.*
1.	*08/01/2024*	*2023P00234*	*1ml*	*9ml*	*D*	
2.	*08/03/2024*	*2023P00234*	*9ml*	*0ml*	*T*	
3.						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