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MCL SOP: Controlled Substance Disposal (Pharmaceutical Waste)

Should a researcher be in possession of expired or expiring drug products or products that are otherwise no longer required, the opportunity will be available for them to submit the product(s) for destruction via Research Pharmacy.

- Any non-controlled product(s) will be destroyed or otherwise disposed of via approved pharmacy waste streams.
- Products identified as controlled substances (CI-CV) will be destroyed by way of RX Destroyer: All Purpose Solution, a method which renders the substance "non-retrievable" in accordance with 21 CFR 1317.90(a).

The process for submission and disposal is as follows:

- DEA license holders will schedule disposal through iLog system or contact Research Pharmacy to request disposal on an as-needed basis.
    - Research Pharmacy staff can be reached via email at phsmcleanrschpcy@partners.org
- At an agreed upon time, the licensee or authorized user will report to Research Pharmacy with the products to be disposed of.
    - For controlled substances, a copy of the applicable DEA Registration will be required.
- In the case of controlled substances (CI-CV), disposal will occur as follows:
    - Accountability will be performed to ensure that the quantity being disposed of matches the anticipated quantity as documented in the licensee's inventory.
        - Bulk powders will be weighed using an appropriately calibrated scale. Every effort will be made to scrape all residual product from the inside of the container.
        - Products in tablet and capsule form will be counted on a counting tray.
        - Liquid preparations will be measured using an appropriately sized syringe relative to the approximate volume to be measured.
    - If the quantity to be disposed of and the anticipated quantity do not match, appropriate action will be taken.
        - Licensee will make every attempt to identify where the discrepancy originated from and take appropriate action.
        - A note to file will be drafted explaining the reason behind the discrepancy and identifying any actions taken as applicable to the specific situation.
        - All unexplained losses will be reported to the DEA as required by law.
    - DEA Form 41 will be filled out by Research Pharmacy staff as disposal is completed to reflect the true quantity destroyed as witnessed by Research Pharmacy staff and licensee or authorized user. This will be signed by both parties.
        - The original will be kept accessible within the licensee's files and a copy will be scanned and electronically saved in the Research Pharmacy share drives.
- Non-controlled (CVI or OTC) substances will be disposed of via approved pharmacy waste streams in accordance with local regulations and no specific documentation will be required.