

**Controlled Substance Renewal Checklist**

**Individual License Holder: .**

**Location (room/building): .**

**DEA registration #: . TXDPS License #: .**

**Schedule (I-V): .**

**Authorized User: Name: . Protocol # .**

 **Name: . Protocol # .**

**SECTION 1:**

|  |  |
| --- | --- |
| Select the correct response for each statement. | Yes, No, or N/A |
| Is the registrant listed in the approved protocol(s) (IRB, IBC, IACUC) where controlled substances are approved? And when listed, does the registrant have as a role of 'Providing anesthesia, analgesia, sedation, tranquilization, or euthanasia'? |  |
| Are the state and federal registrations current? |  |
| Does the IACUC-approved protocol contain the current DEA and TXDPS registration numbers? |  |
| Are the *current* DEA and TXDPS registrations maintained with the C.S. records? |  |

**SECTION 2: Authorized Users**

|  |  |
| --- | --- |
| Select the correct response for each statement. | Yes, No, or N/A |
| Have 'Authorized Users' (other than the registrant) been identified?*If the response is 'No' or 'Not Applicable,' then proceed to Section 3.* |  |
| Is an Authorized Users list being maintained inside the controlled substance file? |  |
| Have the Authorized Users signed and initialed the Authorized Users list?*Note: Initials are used for log-outs of C.S., purchases, receipts, transfers, administration, and audits.* |  |
| Has the registrant signed/dated the Authorized Users list? |  |
| Are all Authorized Users listed as approved personnel on the IACUC-approved protocol(s)? |  |
| Have all Authorized Users completed web training |  |
| Is access to controlled substances limited to only those persons on the ‘Authorized Users List’? |  |
| Has the registrant signed/dated the Authorized Users list? |  |
| Has the registrant signed/dated the Authorized Users list? |  |

**SECTION 3: Form 222 (only applies to Schedule 1 and Schedule II)**

|  |  |
| --- | --- |
| Select the correct response for each statement. | Yes, No, or N/A |
| Does this registration include Schedule I, Schedule II, or Schedule lIN substances?*If the response is 'No,' then proceed to Section* 4. |  |
| Are all Form 222s secured by the registrant?*Note: Form 222s are federal accountable forms, failure to secure the forms is a potential citation.* |  |
| Are all completed Form 222s signed by the registrant?*Note: Under federal regulation, ONLY the registrant may sign Form 222s.* |  |
| Are copies of all signed Form 222s maintained by the registrant?*Note: Any secure storage is acceptable, but every copy <even voided copies> are accountable. Do* *not destroy!* |  |

**SECTION 4: Receiving Controlled Substances (C.S.)**

|  |  |
| --- | --- |
| Select the correct response for each statement. | Yes, No, or N/A |
| Have C.S. been ordered and/or received during this period?If the response is 'No,' then proceed to Section 5. |  |
| Are C.S. counted and quantities verified upon receipt? |  |
| For Schedule I substances (if applicable): Are the receiving documents signed and dated by the Registrant? |  |
| For Schedules Ill, IV, & V (if applicable): Are receiving documents signed and dated by an Authorized User or Registrant? |  |
| Are receiving forms maintained as either a hard copy or a retrievable scanned copy? |  |
| Have discrepancies been identified during the receipt review? |  |
| Have discrepancies been documented on the receiving form and reported to the vendor/pharmacy providing the C.S.? |  |
| Are receipt documents being maintained for 3 years from the date of receipt? *Note: All receipt, discrepancies, or other documents must be maintained, but not necessarily in the same log book as other C.S. documentation.* |  |

**SECTION 5: Transfers of Controlled Substances (C.S.)**

|  |  |
| --- | --- |
| Select the correct response for each statement. | Yes, No, or N/A |
| Have transfers of C.S. between registrant occurred during this period?If the response is 'No,' then proceed to Section 6. |  |
| Was the transfer between two controlled substance registrants? |  |
| Are there appropriate transfer documents showing who received the C.S., volume received, bottle or container unique identifiers, and signatures from both receiver and provider?Note: 222 forms must be used for Schedule I/II;  |  |

**SECTION 6: Dispensing Recordkeeping Controlled Substances (C.S.)**

|  |  |
| --- | --- |
| Select the correct response for each statement. | Yes, No, or N/A |
| Are the templates being used?*Note: If templates are not used, then confirm all necessary information is captured*  |  |
| Are the dispensing records complete?*Note: Complete C.S. records will show the agent(s) used, beginning volume or weight, the amount left after each withdrawal, having no empty lines, and signed or initialed where appropriate.* |  |
| Are the records stored in a secure manner?*Note: Primary security may be a folder, binder, or heavy clip holding all records. Secondary security is the C.S. cabinet, locked file drawer, locked room, etc.* |  |
| Do the records indicate any usage by individuals not on the 'Authorized User's list? |  |
| Are Schedule I records maintained in a bound notebook? *Note: If you do not have any Schedule I agents, then select 'Not Applicable’.*  |  |
| Are records completed in pen and contain no 'white out’.*Note: Errors should be single-lined through, with an initial and date of the person making the correction.* |  |
| Are prior internal audits maintained? Were prior discrepancies or deficiencies corrected?*Note: The Procedures Plan recommends a QUARTERLY internal audit.*  |  |
| Are mixtures created? If so, are expiration dates, volumes, dispensing recorded? *If the response is 'No,' then proceed to Section 7.* |  |
| If mixtures are created, then is a separate Mixture Log and Source Log maintained and tracked? |  |
| If mixtures are created, are expiration dates based on the most limited date used, volumes & dispensing recorded? |  |

**SECTION 7: Labeling of Controlled Substances**

|  |  |
| --- | --- |
| Select the correct response for each statement. | Yes, No, or N/A |
| Is each bottle (or other primary container) individually identified by a unique (not re-used) number? *Note: The unique identifier may be assigned by the vendor or the registrant.* |  |
| Is the original packaging being used showing the product information?*Note: If not specified information must be transferred to the new container.*  |  |
| If syringes are filled and stored, is each syringe labeled and tracked on the log sheet?*Note: If syringes are used, then syringe labels should include: Name, Lot Number, Date combined/**mixed, final concentration, expiration/discard date, and initials of who created the syringe mixture..* |  |

**SECTION 8: Storage**

|  |  |
| --- | --- |
| Select the correct response for each statement. | Yes, No, or N/A |
| Have C.S. been stored during this period?If the response is 'NO,' then proceed to Section 10. |  |
| Are C.S. behind two (2) locks?*Note: Individuals who are not on the 'Authorized User' list and the C.S. should be separated by a minimum of two locks.* |  |
| Are keys (if used) kept on separate rings, secured, and out of plain in sight? |  |
| Does anyone other than the 'Authorized Users' have access to the keys or access codes? |  |
| Are the C.S. stored at the address on the registration? |  |
| Are there primary and secondary storage or use locations?Note: A secondary location is a location geographically distant from the storage (primary) location. |  |
| Are any C.S. removed from the C.S. cabinet returned to the C.S. cabinet within 24 hours (or the end of the work day – whichever is first)? |  |

**SECTION 9: Disposal**

|  |  |
| --- | --- |
| Select the correct response for each statement. | Yes, No, or N/A |
| Have any products required disposal during this period?*If the response is 'No,' then proceed to Section 10.* |  |
| Did you use a 'Reverse Distributor' vendor for disposal? |  |
| Are records maintained (either as scanned document or signed hard copy) for three (3) years after disposal? |  |

**SECTION 10: Losses**

|  |  |
| --- | --- |
| Select the correct response for each statement. | Yes, No, or N/A |
| Have there been any losses of C.S. during this period?*If the response is 'No,' then proceed to Section 11.* |  |
| Were the losses documented? |  |
| Were the losses reported to Office of Research and Compliance and the DEA?*Note: Losses should be reported to ORC at* *ar-ehs@wtamu.edu.* *Losses of a significant nature must also be reported to the federal agents by the on-line reporting system within 24 hours of documenting the loss.* |  |

**SECTION 11: Terminating a Registration:**

|  |
| --- |
| *Note: If the registrant no longer needs the controlled substances registration, they should communicate a ' termination request' to the following agencies/activities and document the request with their other records:**\* Texas DPS.**\*The federal DEA.**\*The IACUC (to modify the protocol's association with the controlled substances registration).* |