**CHAIN OF CUSTODY OF STUDY PRODUCT FOR PROTOCOL NUMBER: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

*SAMPLE FORM: To be used in the development of your site-specific chain of custody form. The sample contains the key elements to be included on the form. Footnotes are for instructional purposes and may be deleted on your site specific form, if needed.*

<Name of Pharmacy1>

<Address>

<Address>

Phone number: 2

Fax number:

**Study product sent by3:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Time:\_\_\_\_\_\_\_\_\_\_

**Name & Title/Signature**

**Study product destination4:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Location**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **No.** | **PID Number5** | **SID Number** | **Study Product Description6** | **Quantity**  # of Units Dispensed and Unit Description (e.g., bottles, syringes, etc.) | **Comments** |
| **1** |  |  |  |  |  |
| **2** |  |  |  |  |  |
| **3** |  |  |  |  |  |
| **4** |  |  |  |  |  |
| **5** |  |  |  |  |  |

**Study product delivered by7:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Time: \_\_\_\_\_\_\_\_\_\_

**Name & Title/Signature**

**Study product received by8:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Time: \_\_\_\_\_\_\_\_\_\_

**Name & Title/Signature**

Was study product received intact? Yes No Comments:

Temperature/Cold Chain Management During Transit (if applicable)9

Acceptable temperature range for study product: \_\_\_\_\_\_\_\_\_ to \_\_\_\_\_\_\_°C

Current temperature reading from min-max thermometer10 at origin: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_°C

Temperature of min-max thermometer at destination:

Current: \_\_\_\_\_\_\_\_\_\_ °C min: \_\_\_\_\_\_\_\_\_\_°C max: \_\_\_\_\_\_\_\_\_\_°C

Was temperature control acceptable during transport? Yes No Comments:

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1. Information for the recipient as to the origin of the study products.
2. Pharmacy telephone number in case there are questions from courier or clinic staff concerning delivery.
3. Pharmacist or technician that prepared package for delivery.
4. Documentation of the intended delivery site of the study products. Provides the courier with information as to where the study products should be delivered.
5. Specify the participant ID (PID) and / or Study Identification (SID) to be used at your site.
6. Describe the contents of package delivered (ex. drug name and strength, kit number, serial number from envelope tear off tab or prescription number). Limit to one study product per line.
7. Documentation of responsibility and custody of the study product by the courier or runner during delivery.
8. Documentation that the study products were received by a responsible party in the clinic, study product was received in good physical condition, and that the tamper resistant method of packaging was intact (if applicable).
9. Refer to Section 4, X. Transport/Cold Chain Management of the DAIDS Pharmacy Guidelines to assess the need for temperature monitoring during transit. The form customized by the site may also contain workflow instructions that may include the return of the min-max thermometer to the pharmacy, process to determine if the temperature during transport was acceptable, etc.
10. Study product should be transported in a carrying container that is monitored with a min-max thermometer. The study products and the min-max thermometer probe should be exposed to the same temperature conditions.