**To be updated at every study contact when the participant/subject receives** **or returns study drug. This form is to be used in conjunction with the Study Drug Dosing Form.**

Table 1: Study Drug Dosing Form

| **Date Dispensed** | **Amount Dispensed** | **Dose Form** | **Date Returned** | **Actual Amount Returned** | **Expected Amount Taken** | **Expected Amount Returned** |
| --- | --- | --- | --- | --- | --- | --- |
| (mm/dd/yyyy) | (Please fill in the Amount Dispensed) | Please fill in the Dose Form | (mm/dd/yyyy) | (Please fill in the Amount Returned) | (Please fill in the Expected Amount Taken) | Please Fill in the Amount Returned |

*\* Examples of dose form: tablets, pills, bottles, vials, etc.*

## General Instructions

The Study Drug Compliance form tracks the actual use of the study drug/biologic by individual study participants/ subjects. The Study Drug Compliance form should be used in conjunction with the Study Drug Dosing form.

For drug treatment intervention studies, the study participants/subjects are usually asked to bring the bottle(s) with the unused treatment back at each visit. Study staff should count the number of remaining pills or vials. While the reliability of the count can be questioned, it provides an estimate of drug taken.

Important note: None of the data elements included on this CRF are considered Core (i.e., strongly recommended for all studies to collect). These data elements are supplemental and should be collected on clinical trials and only if the research team considers them appropriate for their study.

## Specific Instructions

*Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.*

* **Date Dispensed** – Record the date (and time) the study drug/biologic was dispensed to participant/subject. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in the format acceptable to the study database.
* **Amount Dispensed** – Record the amount of study drug/biologic that was dispensed to participant/subject.
* **Dose Form** – Record the dosage form for amount of study drug/biologic that was dispensed to participant/subject.The bottom of the form template includes examples of dose forms. Please refer to the US FDA CDER standard of drug dosage forms for additional examples.
* **Date Returned** – Record the date (and time) the participant/subject returned the study drug/biologic. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in the format acceptable to the study database.
* **Expected Amount Taken** – Record the amount of study drug/biologic the participant/subject was expected to take based on the prescribed dosing.
* **Actual Amount Returned** – Record the actual amount (versus reported amount) of study drug/biologic returned by the participant/subject.
* **Expected Amount Returned** – Record the amount of study drug/biologic the participant/subject was expected to return based on the prescribed dosing.