1. **Date and Time of Death**(m m /d d/ y y y y):

am

pm

24-hour clock

**Cause(s) of Death:**

Table 1: Cause(s) of Death

| **Cause of Death**  (List primary cause first) | **ICD-9-CM Code** |
| --- | --- |
| (Insert Cause of Death here) | (Please enter in the appropriate ICD-9-CM Code) |

*\**Element is classified as Core

## General Instructions

The Death Report Form should only be completed in the event of the participant’s/subject’s death while enrolled in the study. Enrollment is defined as the period of time after informed consent is signed and before follow-up is complete.

If this form is required, then the date, time and the medical reason to which death is attributed should be recorded.

Important note: None of the data elements included on this CRF are considered Core (i.e., strongly recommended for all studies to collect). The data elements are supplemental and should be collected 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 and Time of Death** – Record the date (and time) of death and verify with the death certificate if possible. 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. If uncertainty exists on the occurrence of death or date of death, confirm death and date of death using vital status search, such as the Social Security Death Index in the US.
* **Cause(s) of Death** – Record the cause or causes of death using explanatory text and the associated ICD-9-CM code. Include the primary cause of death first followed by any secondary causes.