1. Date and Time of Death:

am

pm

24-hour clock

1. Cause(s) of Death:

Table 1 Cause(s) of Death

| **Cause of Death**  (List primary cause first) | **ICD-10-CM Code** |
| --- | --- |
| (Insert Cause of Death here) | (Please enter in the appropriate ICD-10-CM Code) |
| Data to be filled in by site | Data to be filled in by site |
| Data to be filled in by site | Data to be filled in by site |

1. Was an autopsy performed?  No  Yes
2. Death Certificate:  Provided  Requested  Not Available  Status Unknown

Recorder Signature: Date:

## General Instructions

The Death Report Form should only be completed in the event of the participant’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 Module are classified as Core (i.e., strongly recommended for all clinical studies to collect). All of the data elements are classified as Supplemental and should only be collected if the research team considers them appropriate for their study.

Please see the Data Dictionary for element classifications.

## 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. Record the date/time according to the [ISO 8601](https://www.iso.org/home.html), the International Standard for the representation of dates and times. 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 an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](https://www.iso.org/iso-8601-date-and-time-format.html); YYYY-MM-DD T:hh:mm:ss. 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 what the death certificate lists as the official cause of death. Record the cause or causes of death using explanatory text and the associated ICD-10-CM code. Include the primary cause of death first followed by any secondary causes.