

All deaths are considered cardiac unless an unequivocal noncardiac cause can be established. Specifically, **any unexpected death even in patients with coexisting potentially fatal noncardiac disease** (e.g., cancer, infection) **should be classified as cardiac**.

This language is from the Protocol Appendix definition around Mortality.

Date of Death	____ / ____ / ____ (DD/MMM/YYYY)
Primary cause of death	<input type="checkbox"/> Cardiac death Any death due to proximate cardiac cause (e.g., MI, low output failure, fatal arrhythmia), unwitnessed death and death of unknown cause, AND all procedure-related deaths, including those related to concomitant treatment, should be classified as such.
	<input type="checkbox"/> Vascular death Any death caused by noncoronary vascular causes, such as cerebrovascular disease, pulmonary embolism, ruptured aortic, aneurysm, dissecting aneurysm, or other vascular diseases should be classified as such
	<input type="checkbox"/> Non-Cardiovascular death Any death not covered by Cardiovascular causes- such as death caused by infection, malignancy, sepsis, pulmonary causes, accident, suicide or trauma
	<input type="checkbox"/> Unknown/Not Available Should only be selected if death certificate, or autopsy is not available AND the investigator is not comfortable classifying as defined above given the information available at the time of death.
Was an autopsy performed?	<input type="checkbox"/> Yes, date of autopsy: ____ / ____ / ____ (DD/MMM/YYYY) <input type="checkbox"/> No <input type="checkbox"/> Unknown
Is subject autopsy available?	<input type="checkbox"/> No <input type="checkbox"/> Yes <i>Please provide source documents for this event to Safety including autopsy if available</i>

CONFORM Death

Source **Data Transfer Tool**

Site Number: _____ Subject ID: _____

If utilizing as source, (no autopsy/death certificate source) is available, form should be signed by Site Investigator

Site Personnel Signature

____/____/_____
Date (DD/MMM/YYYY)