

DAC Study Form 372 – Clinical Center Death Review Form

This form is completed by the Principal Investigator and submitted to the DCC within six weeks after the date of death. A Death Notification Report will be sent by e-mail with instructions concerning the Death Review Packet assembly. This form must be entered before the packet is sent to the DCC. A member of the SAE Committee will review the packet.

Part 1: To be completed by the Study Coordinator:

1. Patient Identification Number..... _ _ _ _ _
2. Patient Name Code _ _ _ _ _
3. Date of Death _ _ / _ _ / _ _ _ _ _
4. Date Death Review Packet submitted to DCC _ _ / _ _ / _ _ _ _ _
5. Where did the death occur? _
 1 = In a hospital, in the emergency room
 2 = In a hospital, not in the emergency room
 3 = In the dialysis unit
 4 = In a nursing home or other skilled care facility
 5 = In the patient's home
 6 = Other known location
 7 = Location unknown
6. Was an autopsy performed? (0=no, 1=yes, 9=unknown) _
 If YES, be sure to include the autopsy form in the Death Review Packet.

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- 1 = The team has been unblinded and knows it is placebo
- 2 = The team believes it is placebo
- 3 = The team does not know
- 4 = The team believes it is active drug
- 5 = The team has been unblinded and knows it is active drug
- 8 = N/A, patient is not randomized

b. If 1 or 5, date of unblinding ___ / ___ / _____

10. What is the current thought of the Principal Investigator regarding whether this death was related to the patient’s randomized study intervention?

- 0 = **Not related to the study drug.**
- 1 = **Unlikely to be related to the study drug.** This sort of event is not commonly associated with the study intervention, no temporal relationship with the study intervention exists, and other etiology does not seem possible.
- 2 = **Possibly related to the study drug.**
- 3 = **Probably related to the study drug.** This sort of event is commonly associated with the study intervention or a temporal relationship with the study intervention exists and no other etiology is apparent.
- 4 = **Definitely related to the study drug**
- 8 = N/A, patient is not randomized

11. If the event was definitely, probably or possibly related to the study medication (i.e. 10 = 2, 3 or 4), then what was the expectedness of it?.....

- 1 = Unexpected - not mentioned in the informed consent
- 2 = Expected, but of greater severity than mentioned in the informed consent.

201. Date this form completed..... ___ / ___ / _____

202. User ID of person completing this form

<i>Clinical Center Use Only</i>
Date Form Entered ___ / ___ / _____
Person Entering this Form _____

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DAC STUDY/CAUSES OF DEATH (FOR FORM 372)

CATEGORIES

Notation: A "2" indicates that the disease or condition could only be a secondary or other cause of death and not the primary cause.

An asterisk (*) indicates that the disease or condition is also classified as an infection outcome.

1. ISCHEMIC HEART DISEASE (IHD)

- 01DA Sudden death (due to IHD)
- 01DB Myocardial infarction (acute) (MI)
- 01DC Angina:2
- 01DD Atherosclerotic heart disease (CAD):2
- 01DE Other acute and subacute forms of ischemic heart disease
- 01DF Old myocardial infarction:2
- 01DG Other forms of chronic ischemic heart disease:2

2. CONGESTIVE HEART FAILURE (CHF)

- 02DA CHF
- 02DB CHF or pulmonary edema due to exogenous fluid (volume overload)
- 02DC Pulmonary edema (cardiogenic)
- 02DD Cardiogenic shock

3. ARRHYTHMIAS AND CONDUCTION PROBLEMS

- 03DA Sudden death (due to arrhythmia, not due to IHD)
- 03DB Atrioventricular conduction block
- 03DC Sick sinus syndrome
- 03DD Atrial fibrillation
- 03DE Ventricular tachycardia
- 03DF Other cardiac arrhythmia and conduction disorder
- 03DG Hyperkalemia

4. OTHER HEART DISEASES AND CONDITIONS (OHD)

- 04DA Sudden death (due to heart conditions other than IHD/arrhythmia)

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- 04DB Pericarditis
- 04DC Endocarditis *
- 04DD Myocarditis
- 04DE Pericardial effusion:2
- 04DF Cardiac tamponade
- 04DG Aortic valve stenosis or insufficiency:2
- 04DH Mitral valve stenosis, regurgitation, or prolapse:2
- 04DI Other valve defect:2
- 04DJ Prosthetic valve malfunction:2
- 04DK Cardiomyopathy (without IHD or CHF)

5. HYPERTENSION (HTN)

- 05DA Hypertensive crisis or accelerated HTN

6. CEREBRAL VASCULAR DISEASE (CVD)

- 06DA Cerebral vascular accident (CVA)
- 06DB Carotid artery stenosis:2
- 06DC Cerebral artery aneurysm:2
- 06DD Subarachnoid or cerebral hemorrhage
- 06DE Other cerebrovascular disease

7. PERIPHERAL VASCULAR DISEASE (PVD)

- 07DA Hemorrhage from ruptured vascular aneurysm
- 07DB Peripheral vascular disease:2
- 07DC Deep vein thrombosis (DVT):2
- 07DD Pulmonary embolism (PE)
- 07DE Abdominal aortic aneurysm (AAA):2
- 07DF Thoracic aortic aneurysm (TAA):2
- 07DG Aortic aneurysm (not specified as AAA or TAA):2
- 07DH Other aneurysm:2
- 07DI Arterial embolism and thrombosis
- 07DJ Mesenteric ischemia or infarction/ischemic bowel
- 07DK Gangrene with septicemia-shock due to PVD *
- 07DL Polyarteritis nodosa and other arteritides:2
- 07DM Other disorders of arteries:2

8. DIABETES MELLITUS (DM) AND ENDOCRINE DISORDERS

- 08DA Diabetes mellitus, Type I (insulin dependent):2
- 08DB Diabetes mellitus, Type II (non insulin dependent, could be insulin required):2
- 08DC Diabetes mellitus, type unclassified or unknown:2

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- 08DD Diabetes with ketoacidosis
- 08DE Diabetes with hyperosmolar state or coma (hyperglycemia)
- 08DF Diabetes with other coma
- 08DG Hypoglycemia coma
- 08DH Diabetic foot infection *
- 08DI Hypothyroidism:2
- 08DJ Disorders of the thyroid gland:2
- 08DK Other endocrine disorder:2

9. RESPIRATORY DISEASE

- 09DA Asthma
- 09DB COPD exacerbation
- 09DC Bronchitis (chronic):2
- 09DD COPD:2
- 09DE Pneumonia (community acquired)*
- 09DF Pneumonia (nosocomial)*
- 09DG Pneumonia-sepsis*
- 09DH Pneumonia (bacterial)*
- 09DI Pneumonia (fungal)*
- 09DJ Pneumonia (viral)*
- 09DK Pneumocystis pneumonia*
- 09DL Pneumonia (unspecified pathogen)*
- 09DM Empyema*
- 09DN Lung abscess*
- 09DO Pneumothorax
- 09DP Pulmonary hemorrhage
- 09DQ Cor pulmonale:2
- 09DR Pulmonary TB*
- 09DS Aspiration pneumonia
- 09DT Adult Respiratory Distress Syndrome (ARDS)
- 09DU Respiratory failure of unknown cause

10. MALIGNANCY

- 10DA Hematologic malignancy (AML, CML, ALL, CLL)
- 10DB Lymphoma (unspecified)
- 10DC Hodgkin's lymphoma
- 10DD Non-Hodgkin's lymphoma
- 10DE Multiple myeloma
- 10DF Colon cancer
- 10DG Breast cancer
- 10DH Prostatic cancer
- 10DI Ovarian cancer
- 10DJ Lung cancer

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- 10DK Gastric cancer
- 10DL Pancreatic cancer
- 10DM Thyroid cancer
- 10DN Cervical cancer
- 10DO Endometrial cancer
- 10DP Primary cancer of the liver
- 10DQ Head and neck squamous cell carcinoma
- 10DR Testicular cancer
- 10DS Renal cancer
- 10DT Bladder cancer
- 10DU Melanoma
- 10DV Other skin cancer
- 10DW Other malignancy or neoplasia
- 10DX Metastatic cancer with unknown primary
- 10DY Patient ever on immunosuppressive therapy

11. HEPATOBILIARY DISEASE

- 11DA Hepatitis B
- 11DB Hepatitis C
- 11DC Toxic/drug induced hepatitis
- 11DD Hepatitis (other unknown cause)
- 11DE Cirrhosis:2
- 11DF Ascites:2
- 11DG Portal hypertension or esophageal varices:2
- 11DH Hemorrhage from esophageal varices
- 11DI Hepatic (liver) failure/severe hepatic dysfunction
- 11DJ Polycystic liver disease:2
- 11DK Cholecystitis/cholangitis*
- 11DL Biliary sepsis*
- 11DM Other hepatobiliary disease

12. MUSCULOSKELETAL AND CONNECTIVE TISSUE DISEASES

- 12DA Wegener's granulomatosis
- 12DB Systemic vasculitis
- 12DC Rheumatoid arthritis:2
- 12DD SLE
- 12DE Osteomyelitis*
- 12DF Septic arthritis*
- 12DG Osteoporosis:2
- 12DH Bone fracture(s):2
- 12DI Renal osteodystrophy:2
- 12DJ Hyperparathyroidism:2
- 12DK Hypoparathyroidism:2

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12DL Other disorder of calcium and phosphorus metabolism
12DM Other musculoskeletal or connective tissue disease:2

13. GASTROINTESTINAL CONDITIONS (GI)

13DA Upper GI bleed
13DB Lower GI bleed
13DC GI bleeding, site unknown
13DD Peptic ulcer disease:2
13DE Gastritis:2
13DF Diverticulosis:2
13DG Ulcerative colitis (UC):2
13DH Enteritis (Crohn's disease):2
13DI Perforation of peptic ulcer
13DJ Perforation of bowel
13DK Diverticulitis*
13DL Necrotizing enterocolitis*
13DM *C. difficile* associated enterocolitis*
13DN Peritonitis*
13DO Appendicitis*
13DP Septicemia due to peritonitis*
13DQ Fungal peritonitis*
13DR Pancreatitis
13DS Intra-abdominal abscess*
13DT Arteriovenous malformation (AVM)
13DU Other GI condition:2

14. NONVASCULAR NERVOUS SYSTEM DISEASES

14DA Dementia (Alzheimer's):2
14DB Dementia (other, unknown, including dialysis dementia):2
14DC Seizure disorder (chronic):2
14DD Seizure episode
14DE Depression:2
14DF Suicide (not due to withdrawal from dialysis, which is code 23DA)
14DG Drug overdose (alcohol/drug abuse--street drugs or other non-accidental chemical abuse)
14DH Subdural or epidural hematoma (spontaneous or traumatic)
14DI Meningitis (non viral, bacterial, or fungal or TB)*
14DJ Brain abscess*
14DK Other CNS infection*
14DL Head trauma (brain injury)
14DM Ischemic brain damage, anoxic encephalopathy
14DN Other psychiatric or mental disorder:2
14DO Parkinson's disease:2

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- 14DP Multiple sclerosis (MS):2
- 14DQ Other demyelinating diseases of CNS:2
- 14DR Cranial or peripheral nerve disorder:2
- 14DS Other nonvascular nervous system condition

15. URINARY TRACT CONDITIONS

- 15DA Urinary tract infection (chronic UTIs):2
- 15DB UTI-septicemia*
- 15DC Nephrolithiasis:2
- 15DD Prostatitis*
- 15DE Benign prostatic hypertrophy:2
- 15DF Orchitis*
- 15DG Cystic kidney disease (PKD or acquired):2
- 15DH Cyst-related hemorrhage
- 15DI Cyst-related infection*
- 15DJ Urinary tract hemorrhage
- 15DK Hemorrhage from renal transplant site
- 15DL Other renal and urologic condition (excluding ESRD)

16. HIV/AIDS

- 16DA HIV positive (not AIDS)
- 16DB AIDS
- 16DC AIDS-related infection
- 16DD Other AIDS-related condition (not infection)

17. OPHTHALMOLOGIC CONDITIONS

- 17DA Endophthalmitis*
- 17DB Legally blind:2

18. INFECTIONS (NOT ACCESS RELATED)

- 18DA Abscess (not recorded in previous category)*
- 18DB Other infection (not recorded in previous category)*
- 18DC Septic shock*
- 18DD Septicemia (bacteremia) (known source, not access related)*
- 18DE Septicemia (bacteremia) (unknown source, not access related)*
- 18DF Extrapulmonary TB*
- 18DG Miliary TB*
- 18DH Disseminated candida infection*
- 18DI Other fungal infection*
- 18DJ Viral infection (CMV)*
- 18DK Other viral infection (not hepatitis)*

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18DL Protozoan or parasitic infection (not PCP)*

19. NON-MALIGNANT HEMATOLOGIC CONDITIONS

19DA Anemia:2

19DB Bone marrow depression:2

19DC Leukocytopenia:2

19DD Coagulation disorder:2

19DE Thrombocytopenia:2

19DF Disseminated intravascular coagulation

19DG Other consumption coagulopathy:2

19DH Thrombotic thrombocytopenic purpura (TTP) and hemolytic uremic syndrome (HUS)

19DI Other non-malignant hematologic condition

20. HEMODIALYSIS VASCULAR ACCESS COMPLICATIONS

20DA Septicemia (bacteremia) access related*

20DB Hemorrhage from vascular access

20DC Venous thrombosis access related:2

20DD Arterial thrombosis or embolism access related

20DE Other access infection

20DF Other complication of temporary access placement

21. OTHER HEMODIALYSIS COMPLICATIONS

21DA Hemorrhage from dialysis circuit

21DB Air embolism

21DC Anaphylaxis, treatment related

21DD Hemolysis, treatment related

21DE Electrolyte and acid-base disorder, treatment related (other than hyperkalemia)

21DF Dialysis-induced hypotension

21DG Other accident related to treatment

22. OTHER SURGICAL COMPLICATIONS

22DA Hemorrhage from surgery

22DB Complications from surgery

22DC Complications from anesthesia

23. OTHER

23DA Withdrawal from dialysis::2

23DB Other hemorrhage

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- 23DC Cachexia
- 23DD Other trauma
- 23DE Drug overdose (accidental)
- 23DF Accident unrelated to treatment
- 23DG Drug reaction, anaphylaxis
- 23DH Drug reaction, not anaphylaxis, not overdose
- 23DI Other electrolyte and acid-base disorder (not related to hemodialysis treatment)
- 23DJ Homicide
- 23DK Refusal of lifesaving therapy

24. UNKNOWN

- 24DA Sudden death, unknown cause
- 24DB Other death, unknown cause