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#### **GUIDANCE INFORMATION**

The CRF is used to abstract requested death circumstances and medical/clinical history from the donor's medical record or next of kin.

All questions must be completed. "unknown" and "Not Applicable" are acceptable answers.

The form is divided into five sections. Special instructions, per section/question, are noted in italicized text.

### **Section A: Demographics**

Question	Response						
Gender							
(select one, specify if other)	Male	Female	Other (specify):				
Date of Birth							
(mm/dd/yyyy)							
Height							
(Enter total inches)							
Weight							
(Enter total lbs)							
Race	o Ame	rican Indian or Alaska Na	ative				
(select all that apply)	o Asiar	ı					
	o Black	or African American					
	o Nativ	e Hawaiian or other Pac	cific Islander				
	o Whit	e					
	o Unkr	lown					
Ethnicity	-	nic or Latino					
(select all that apply)		lispanic or Latino					
		eported					
	o Unkn						
Additional guidance for completing Race and Ethnicity can be found at the US Office of Management and							
Budget ( <u>http://www.whitehouse.gov</u>	<u>/omb/fedreg</u>	<u>race-ethnicity</u> ).					

### **Section B: Medical History**

Question	Response		
Primary source of history?	Medical Record	Family repo	ort:
(select all that apply, specify if other)		Self	Child
		Spou	se Sibling
		Parer	it
		Other	r, specify:
Is there a history of non-metastatic			
cancer?	yes	no	unknown
(select one)			

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### **Cancer History**

**INSTRUCTION:** If 'Yes' for history of non-metastatic cancer, fill in the below table. Include information from all known non-metastatic cancers.

Primary Cancer Type (Insert primary tumor site or type)	Month/year of first diagnosis (mm/yyyy)	Source of History (select one)	<b>History of Treatment</b> (select all that apply, specify if other)	Date of last radiation or chemotherapy treatment if applicable (mm/yyyy)	Is there medical record documentation of history of cancer and treatment? (select one)
		Medical Record Family Report Medical Record and Family Report	Surgery Radiation Chemotherapy None Unknown Other, specify:		yes no unknown
		Medical Record Family Report Medical Record and Family Report	Surgery Radiation Chemotherapy None Unknown Other, specify:		yes no unknown
		Medical Record Family Report Medical Record and Family Report	Surgery Radiation Chemotherapy None Unknown Other, specify:		yes no unknown
		Medical Record Family Report Medical Record and Family Report	Surgery Radiation Chemotherapy None Unknown Other, specify:		yes no unknown

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#### **General Medical History**

**INSTRUCTION**: Please mark all applicable medical conditions.

For medical conditions marked "yes", the "Year of Onset", "History of Treatment" and "Source of History" must be entered. Enter the year of onset or diagnosis or select "unknown" if the year is not known. Enter whether there is a documented history of treatment for the specified medical condition. The source of history will default to the primary source of history as selected in section B. Medical History above. Make changes as needed.

Medical Condition		<b>Option</b> (select one)		Year of Onset (yyyy) History of Treatment (select one)			Source of History (select one)	
	yes	no	unknown		yes	no	unknown	Medical Record Family Report
Alzheimer's OR Dementia	yes	110	unknown	unknown	yes	110	unknown	Medical Record and Family Report
Ischemic Heart Disease (coronary artery disease (CAD),	yes	no	unknown		yes	no	unknown	Medical Record Family Report
coronary heart disease, ischemic cardiomyopathy)	,			unknown	,			Medical Record and Family Report
Cerebrovascular Disease (stroke, TIA, embolism, aneurysm, other circulatory disorder affecting the brain)	yes	no	unknown	unknown	yes	no	unknown	Medical Record Family Report Medical Record and Family Report
Heart attack, acute myocardial infarction, acute coronary syndrome	yes	no	unknown	unknown	yes	no	unknown	Medical Record Family Report Medical Record and Family Report
Renal Failure	yes	no	unknown	unknown	yes	no	unknown	Medical Record Family Report Medical Record and Family Report
Nephritis, Nephrotic Syndrome and/or Nephrosis	yes	no	unknown	unknown	yes	no	unknown	Medical Record Family Report Medical Record and Family Report

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	General Medical History Continued								
Medical Condition	<b>Option</b> (select one)	Year of Onset (yyyy)	History of Treatment (select one)	Source of History (select one)					
Chronic Respiratory Disease (Chronic Obstructive Pulmonary Disease (COPD)	yes no unknown	unknown	yes no unknown	Medical Record Family Report Medical Record and Family Report					
Chronic Lower Respiratory Disease (CLRD-including chronic bronchitis, emphysema, asthma)	yes no unknown	unknown	yes no unknown	Medical Record Family Report Medical Record and Family Report					
Influenza (acute viral infection including avian influenza)	yes no unknown	unknown	yes no unknown	Medical Record Family Report Medical Record and Family Report					
Pneumonia (acute respiratory infection affecting the lungs)	yes no unknown	unknown	yes no unknown	Medical Record Family Report Medical Record and Family Report					
Diabetes mellitus type 1 (IDDM, formerly juvenile diabetes)	yes no unknown	unknown	yes no unknown	Medical Record Family Report Medical Record and Family Report					
Diabetes mellitus type II (NIDDM, adult onset diabetes)	yes no unknown	unknown	yes no unknown	Medical Record Family Report Medical Record and Family Report					
Uremia (Kidney Disorder)	yes no unknown	unknown	yes no unknown	Medical Record Family Report Medical Record and Family Report					

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Bacterial Infections								Medical Record
(including septicemia (bacteria								Family Report
in the blood), meningococcal	yes	no	unknown		yes	no	unknown	
disease, staphylococcal								Medical Record and
infection, streptococcus, sepsis)				unknown				Family Report

General Medical History Continued								
Medical Condition		-	tion t one)	Year of Onset (yyyy) History of Treatment (select one)			Source of History (select one)	
Liver Disease (liver abscess, failure, fatty liver syndrome, inherited liver insufficiency, acute/chronic hepatic insufficiency, necrobacillosis, rupture)	yes	no	unknown	unknown	yes	no	unknown	Medical Record Family Report Medical Record and Family Report
Arthritis	yes	no	unknown	unknown	yes	no	unknown	Medical Record Family Report Medical Record and Family Report
Major depression (unipolar depression, major depressive disorder)	yes	no	unknown	unknown	yes	no	unknown	Medical Record Family Report Medical Record and Family Report
Hypertension	yes	no	unknown	unknown	yes	no	unknown	Medical Record Family Report Medical Record and Family Report
Parkinson's Disease	yes	no	unknown	unknown	yes	no	unknown	Medical Record Family Report Medical Record and Family Report
Schizophrenia	yes	no	unknown	unknown	yes	no	unknown	Medical Record Family Report Medical Record and Family Report
Crohn's Disease	yes	no	unknown		yes	no	unknown	Medical Record Family Report

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		1			T				1
					unknown				Medical Record and
									Family Report
									Medical Record
									Family Report
Bastric Reflux Diseas		yes	no	unknown		yes	no	unknown	
sophagitis, heartbu	rn, GERD								Medical Record and
					unknown				Family Report

General Medical History Continued								
Medical Condition		-	t <b>ion</b> t one)	Year of Onset (yyyy)	Histo	-	Treatment t one)	Source of History (select one)
Atrial Fibrillation	yes	no	unknown	unknown	yes	no	unknown	Medical Record Family Report Medical Record and
Sjogren's Disease (chronic dry mouth/dry eyes)	yes	no	unknown	unknown	yes	no	unknown	Family Report Medical Record Family Report Medical Record and Family Report
Diverticular Disease, diverticulitis	yes	no	unknown	unknown	yes	no	unknown	Medical Record Family Report Medical Record and Family Report
Ulcerative Colitis	yes	no	unknown	unknown	yes	no	unknown	Medical Record Family Report Medical Record and Family Report

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### Medical Conditions (not specified in General Medical History medical conditions)

**INSTRUCTION**: Please list all other medical conditions not specified above. Examples include hearing loss, sinusitis, head injury, skin diseases, thyroid conditions, gallstones, TB, hernia, kidney stone, herpes, seizures, epilepsy, gout, anemia, etc. Please be as specific as possible when listing additional conditions.

For all medical conditions listed, the "Year of Onset", "History of Treatment" and "Source of History" must be entered. Enter the name of the medical condition in the auto pick and select the correct term from the list provided. Enter the year of onset or diagnosis or select "unknown" if the year is not known. Enter whether there is a documented history of treatment for the specified medical condition. The source of history will default to the primary source of history as selected in section B. Medical History above. Make changes as needed.

Medical Condition	Year of Onset (YYYY)	History of Treatment (yes, no, unknown)	Source of History (Medical Record, Family Report, Medical Record and Family Report)
	unknown		
	unknown		
	unknown		
	unknown		
	unknown		
	unknown		

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unknown	
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unknown	
unknown	
unknown	
unknown	
unknown	
unknown	

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### **Section C: Current Medications**

**INSTRUCTION**: Document each medication, vitamin, or supplement taken in the last month (30 calendar days), or administered to the donor until the time of death.

Current medications include all drugs that the donor routinely took to treat, prevent or alleviate the symptoms of any disease or condition, as well as those given immediately preceding death. For each drug listed (generic name), enter the "Date of Last Administration" (if available) and the "Source of History". Enter the name of the medication in the auto pick and select the correct term from the list provided. Enter the date the medication was last administered or select "unknown" if the last date of administration of medication is not known. The source of history will default to the primary source of history as selected in section B. Medical History above. Make changes as needed.

Medication/Vitamin/Supplement (Insert generic name)	Date of Last Administration (mm/dd/yyyy)	Source of History (select one)
		Medical Record
		Family Report
		Medical Record and Family Report
	unknown	
		Medical Record
		Family Report
		Medical Record and Family Report
	unknown	
		Medical Record
		Family Report
		Medical Record and Family Report
	unknown	
		Medical Record
		Family Report
		Medical Record and Family Report
	unknown	
		Medical Record
		Family Report
		Medical Record and Family Report
	unknown	
		Medical Record
		Family Report
		Medical Record and Family Report
	unknown	
		Medical Record
		Family Report

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			Medical Record	and Family Report
		unknown		
			Medical Record	
			Family Report	
			Medical Record	and Family Report
		unknown		
			Medical Record	
			Family Report	
			Medical Record	and Family Report
		unknown		

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## Section D-1: Death Circumstances

**INSTRUCTION:** Complete for all postmortem and organ donor cases

Identifying the appropriate death classification using the 4-point Hardy Scale is a subjective determination. The following terminal phase explanations also include a working list of Cause of Death (COD) examples for reference and consistency. 1) Violent and fast death: Deaths with a terminal phase estimated at <10 min (including but not limited to multi vehicular accident (MVA) or blunt force trauma, gunshot, or suicide).

2) Fast death of natural causes: Sudden unexpected deaths of people who had been reasonably healthy, after a terminal phase estimated at <1 hr (with sudden death from a myocardial infarction and heart failure as model causes of death for this category).

3) Intermediate death: Death after a terminal phase of 1 to 24 hrs (not classifiable as 2 or 4); patients who were ill but death was unexpected (e.g., cerebrovascular accident (CVA)/stroke, intracranial hemorrhage, etc.)

4) Slow death: Death after a long illness (not unexpected), with a terminal phase longer than 1 day (commonly Amyotrophic Lateral Sclerosis (ALS), liver disease, heart disease, renal failure, dementia or chronic pulmonary disease, etc.)

5) Ventilator case: All cases on a ventilator immediately before death.

**Cardiac Cessation Time** is the warm ischemic time (cut off of oxygen ( $O_2$ ). It is recorded as **Clamp/Ligature Time** for Brain Death OPOs and **Time Pronounced Dead** for Donation after Cardiac OPOs. **Cardiac Cessation Time** is also known as cessation of blood flow.

The following methods and information source types can be used to obtain the immediate COD, first underlying COD and last underlying COD. Death certificate Donor source site records Next of Kin medical/social records

Instruction: A response to EACH question is required.						
Note "unknown" if not known						
Is death certificate available?						
(select one)	yes	no	unknown			
Date and time pronounced dead						
(mm/dd/yyyy hr:min)						
INSTRUCTION: Capture on	e of the next two	highlighted	sections			
Date and time of actual (witnessed) death as						
defined by Cardiac Cessation						
(mm/dd/yyyy hr:min)						
or						
Date and time of presumed Cardiac Cessation						
(mm/dd/yyyy hr:min)						

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Date and time last seen alive (mm/dd/yyyy hr:min)			
Place of death			
(select one, if 'other' – specify)	Hospital inpatient	Nursing home/Long-term care facility	
	Emergency room	Decedent's home	
	Outpatient	Dead on arrival at hospital	
	Hospice	Other (specify):	
If death occurred outside of hospital, who determined date/time of death? (select one, if 'other' – specify)	Physician		
	Coroner/Medical Examiner (ME)		
	Other (specify):		
Manner of death			
(select one)	Natural	Homicide	
	Accident	Pending	
	Suicide	Undetermined	
Death classification based on the 4-point Hardy Scale (select one)	<ul> <li>1) Violent and fast death Deaths due to accident, blunt force trauma or suicide, terminal phase estimated at &lt; 10 min.</li> <li>2) Fast death of natural causes Sudden unexpected deaths of people who had been reasonably healthy, after a terminal phase estimated at &lt; 1 hr (with sudden death from a myocardial infarction as a model cause of death for this category)</li> </ul>		
	3) Intermediate death Death after a terminal phase of 1 to 24 hrs (not classifiable as 2 or 4); patients who were ill but death was unexpected		
	4) Slow death Death after a long illness, with a terminal phase longer than 1 day (a cancer or chronic pulmonary disease); deaths that are not unexpected		
	5) Ventilator case All cases on a ventilator immediately before death.		
Did coroner / ME perform an autopsy?			
(select one)	yes no	unknown	

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Was donor on a ventilator immediately prior to	yes: hours on ve	ntilator=
death?		
(if yes – enter number of hours)	no	unknown
Death Certificate COD		
(Enter COD as noted on the donor's death		
certificate.)		
Immediate COD		
(Enter final disease, injury or complication directly		
causing death. Select the correct term from the auto		
pick.)		
Approximate interval: onset to death (hours)		
(Enter interval of time from the immediate cause of		
death to death.)		
First underlying COD		
(Enter disease or injury leading to the COD listed in		
the immediate COD. Select the correct term from the		
auto pick.)		
Approximate interval: onset to death (hours)		
(Enter interval of time from the first underlying		
cause of death to death.)		
Last underlying COD		
(Enter disease or injury that initiated the chain of		
events that lead directly and inevitably to the COD		
listed as the immediate COD. Select the correct term		
from the auto pick.)		
Was the body refrigerated at any time before	yes: hours refri	gerated=
procurement?		
(if yes, enter approximate number of hours)	no	unknown
Organ Donor (OPO) Type	Brain Death (BD)	
(select one)	Donation After Car	diac Death (DCD)

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### Section E: Serology Results

**INSTRUCTION:** Select one for each test. If the test result is "positive" or "indeterminate", please provide verification for the result.

Test	Result			Verified if "Positive" or "Indeterminate" (yes, no)	
HIV I/II Ab	Not Performed	Positive	Negative	Indeterminate	
HIV I/II Plus O Antibody	Not Performed	Positive	Negative	Indeterminate	
HBsAg	Not Performed	Positive	Negative	Indeterminate	
HBsAb	Not Performed	Positive	Negative	Indeterminate	
HBcAb (Total; IgG+IgM)	Not Performed	Positive	Negative	Indeterminate	
HBcAb-IgM	Not Performed	Positive	Negative	Indeterminate	
HCV Ab	Not Performed	Positive	Negative	Indeterminate	
EBV IgG Ab	Not Performed	Positive	Negative	Indeterminate	
EBV IgM Ab	Not Performed	Positive	Negative	Indeterminate	
RPR	Not Performed	Positive	Negative	Indeterminate	
CMV Total Ab	Not Performed	Positive	Negative	Indeterminate	
HIV-1 NAT	Not Performed	Positive	Negative	Indeterminate	
HCV-1 NAT	Not Performed	Positive	Negative	Indeterminate	
PRR/VDRL	Not Performed	Positive	Negative	Indeterminate	