



### Cancer History

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

<b>Primary Cancer Type</b> <i>(Insert primary tumor site or type)</i>	<b>Month/year of first diagnosis</b> <i>(mm/yyyy)</i>	<b>Source of History</b> <i>(select one)</i>	<b>History of Treatment</b> <i>(select all that apply, specify if other)</i>	<b>Date of last radiation or chemotherapy treatment if applicable</b> <i>(mm/yyyy)</i>	<b>Is there medical record documentation of history of cancer and treatment?</b> <i>(select one)</i>
		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

# GTEx Clinical Collection Case Report Form (CRF)

PM-0003-F6

VER. 03.03

Effective Date: mm/dd/yyyy

Page 3 of 15

## 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	Option (select one)	Year of Onset (yyyy)	History of Treatment (select one)	Source of History (select one)
Alzheimer's OR Dementia	yes    no    unknown	_____  unknown	yes    no    unknown	Medical Record Family Report  Medical Record and Family Report
Ischemic Heart Disease (coronary artery disease (CAD), coronary heart disease, ischemic cardiomyopathy)	yes    no    unknown	_____  unknown	yes    no    unknown	Medical Record Family Report  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

**General Medical History Continued**

Medical Condition	Option (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

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

**General Medical History Continued**

Medical Condition	Option (select 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

## GTEx Clinical Collection Case Report Form (CRF)

PM-0003-F6

VER. 03.03

Effective Date: mm/dd/yyyy

Page 7 of 15

		unknown		Medical Record and Family Report
Gastric Reflux Disease, reflux esophagitis, heartburn, GERD	yes no unknown	_____	yes no unknown	Medical Record Family Report
		unknown		Medical Record and Family Report

### General Medical History Continued

Medical Condition	Option <i>(select one)</i>	Year of Onset <i>(yyyy)</i>	History of Treatment <i>(select one)</i>	Source of History <i>(select one)</i>
Atrial Fibrillation	yes no unknown	_____	yes no unknown	Medical Record Family Report Medical Record and Family Report
Sjogren's Disease <i>(chronic dry mouth/dry eyes)</i>	yes no unknown	_____	yes no unknown	Medical Record Family Report Medical Record and Family Report
Diverticular Disease, diverticulitis	yes no unknown	_____	yes no unknown	Medical Record Family Report Medical Record and Family Report
Ulcerative Colitis	yes no unknown	_____	yes no unknown	Medical Record Family Report Medical Record and Family Report







## GTE<sub>x</sub> Clinical Collection Case Report Form (CRF)

PM-0003-F6

VER. 03.03

Effective Date: mm/dd/yyyy

Page 11 of 15

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

## 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<sub>2</sub>)). 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 one 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)

## GTEx Clinical Collection Case Report Form (CRF)

PM-0003-F6

VER. 03.03

Effective Date: mm/dd/yyyy

Page 13 of 15

Date and time last seen alive <i>(mm/dd/yyyy hr:min)</i>									
Place of death <i>(select one, if 'other' – specify)</i>	<table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Hospital inpatient</td> <td style="width: 50%;">Nursing home/Long-term care facility</td> </tr> <tr> <td>Emergency room</td> <td>Decedent's home</td> </tr> <tr> <td>Outpatient</td> <td>Dead on arrival at hospital</td> </tr> <tr> <td>Hospice</td> <td>Other (specify): _____</td> </tr> </table>	Hospital inpatient	Nursing home/Long-term care facility	Emergency room	Decedent's home	Outpatient	Dead on arrival at hospital	Hospice	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? <i>(select one, if 'other' – specify)</i>	<table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Physician</td> <td style="width: 50%;"></td> </tr> <tr> <td>Coroner/Medical Examiner (ME)</td> <td></td> </tr> <tr> <td>Other (specify): _____</td> <td></td> </tr> </table>	Physician		Coroner/Medical Examiner (ME)		Other (specify): _____			
Physician									
Coroner/Medical Examiner (ME)									
Other (specify): _____									
Manner of death <i>(select one)</i>	<table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Natural</td> <td style="width: 50%;">Homicide</td> </tr> <tr> <td>Accident</td> <td>Pending</td> </tr> <tr> <td>Suicide</td> <td>Undetermined</td> </tr> </table>	Natural	Homicide	Accident	Pending	Suicide	Undetermined		
Natural	Homicide								
Accident	Pending								
Suicide	Undetermined								
Death classification based on the 4-point Hardy Scale <i>(select one)</i>	<p>1) Violent and fast death <i>Deaths due to accident, blunt force trauma or suicide, terminal phase estimated at &lt; 10 min.</i></p> <p>2) Fast death of natural causes <i>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)</i></p> <p>3) Intermediate death <i>Death after a terminal phase of 1 to 24 hrs (not classifiable as 2 or 4); patients who were ill but death was unexpected</i></p> <p>4) Slow death <i>Death after a long illness, with a terminal phase longer than 1 day (commonly cancer or chronic pulmonary disease); deaths that are not unexpected</i></p> <p>5) Ventilator case <i>All cases on a ventilator immediately before death.</i></p>								
Did coroner / ME perform an autopsy? <i>(select one)</i>	<table style="width: 100%; border: none;"> <tr> <td style="width: 33%;">yes</td> <td style="width: 33%;">no</td> <td style="width: 33%;">unknown</td> </tr> </table>	yes	no	unknown					
yes	no	unknown							



## 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	