

## GENERAL INSTRUCTIONS

This Standard Operating Procedure (SOP) is intended to provide instructions and guidance for completing the GTEx Donor Eligibility Criteria Form (PM-0003-F4) which is used to determine acceptability of a potential donor into the GTEx study.

At the top of the form you will notice the following *Note: Complete all questions for documentation of screening and eligibility of donor. Please submit for ALL screened AND enrolled subjects. Donor is ineligible if any box is checked in the ineligible column.* When proceeding through the form, you will notice that most questions have answers that either lead to the next question or inform you that the answer you chose has disqualified the potential donor for inclusion into GTEx. Please read these questions and answers carefully as sometimes answers appear similar.

Please note: Documenting additional information or comments in the *General Comments* field (question 59) is not required. Examples of information that can be documented in the General Comments field include: explanation of information otherwise specified on another form, explanation of an *Informational Purposes Only* section question or other information the site deems pertinent to the participant's history as it relates to eligibility questions.

Here are the screening questions for donor eligibility:

1. Does the consent form allow for the minimum number of organs/tissue types (skeletal muscle, tibial nerve, tibial artery, skin and adipose tissue) to be collected?
2. Donor is  $\geq 21$  and  $\leq 70$  years of age
3. Donor BMI is  $\geq 18.50$  and  $\leq 35.00$  (BMI =  $703 \times \text{weight in \#} / \text{height in inches squared}$ )

4a. Is it likely that tissue collection can be started AND the first tissue can be placed in fixative within 8.0 hours of cardiac cessation or recorded time of death (observed or presumed) for a non-brain donor?

**Or**

4b. Is it likely that all tissues can be collected and placed into fixative within 24.0 hours of cardiac cessation (observed or presumed) for a brain donor?

5. Did donor receive a whole blood transfusion within the previous 48 hours?
6. Has the donor ever been diagnosed with metastatic cancer (cancer that spread beyond the initial site, such as to other organs like brain, bone, or liver)
7. Has the donor received chemotherapy or radiation therapy for cancer or any other condition within the past 2 years?
8. Does the donor have a history of intravenous drug abuse in the last 5 years?
9. Does the donor have a history of sex with someone who has been diagnosed or at risk for HIV/AIDS, and/or HCV, and/or HBV or someone who has used intravenous drugs in the last 5 years?

10. Has the donor been exposed to HIV/AIDS, and/or HCV, and/or HBV through needle sticks, and/or contact with non-intact skin and/or contact with open wounds, and/or contact with mucous membranes?
11. Does the donor have a history of repeatedly reactive screening assays for HIV-1 or HIV-2 antibody regardless of the results of supplemental assays?
12. **History of any of the following at the time of death:**
  - Documented Sepsis
  - Pneumonia
  - Open Wounds
  - High Unexplained Fever
  - Positive Blood Cultures
  - Abnormal WBC
  - Infected Lines
  - Fungal Infections
  - Ascites
  - Cellulites
13. Has blood donation been denied in the past, specify below: If Yes, Reason:
14. Blood transfusion received in another country
15. Received a human and/or animal tissue and/or organ transplant or xenotransplant. If yes, specify in comments below:
- Comments:
16. Recent smallpox vaccination
17. Contact with someone who has recently had smallpox
18. Dialysis treatment (long term greater than 1 month @ 3 times per week)
19. Current diagnosis of cancer (regardless of treatment and location)
20. Cancer diagnosis within the preceding 5 years (regardless of treatment and location)
21. TB History
22. Active meningitis
23. Active encephalitis
24. Long term steroid use

25. Osteomyelitis
26. Unexplained seizures
27. Unexplained weakness and fatigue described as flu-like symptoms
28. Exposure to toxic substances that may have led to chronic conditions
29. No physical activity defined as bed bound for greater than 4 weeks
30. Resided on a Northern European military base for 6 months from 1980-1990 or elsewhere in Europe from 1980-1996
31. Bite from an animal suspected to have rabies in the last 12 months
32. Heroin use - EVER - by any route
33. Cocaine use in the past 5 years
34. Men who have sex with men
35. Drug injection(s) (intravenous, intramuscular, and subcutaneous) for non-medical use in the last 5 years
36. Hemophilia and/or clotting disorders requiring treatment with human-derived clotting factors
37. Performed sexual acts in exchange for money or drugs
38. **Sexual activity with another person who has a history of:**
  - Men who have sex with men
  - Utilized drug injections (intravenous and/or intramuscular and/or subcutaneous) for non-medical use in the last 5 years
  - Hemophilia and/or clotting disorders requiring treatment with human-derived clotting factors
  - Performed sexual acts in exchange for money or drugs
39. Was not able to be tested for HIV infection because of hemodilution where no pre-transfused specimen is available
40. **History, physical examination, medical records, or autopsy reports reveal other evidence of HIV infection or high-risk behavior such as:**
  - Unexplained weight loss
  - Night sweats
  - Blue or purple spots on the skin or mucus membranes (typical of Kaposi's sarcoma)
  - Unexplained lymphadenopathy lasting more than one month
  - Unexplained temperature  $\geq 100.5$  F (38.6 C) for more than 10 days

- Unexplained persistent cough and/or shortness of breath
- Opportunistic infections
- Sexually transmitted diseases
- Needle tracks and/or other signs of drug abuse

41. Diagnosis of SARS or recent contact with someone who has it

42. History of West Nile Virus (WNV)

43. History of contact with someone who has West Nile Virus (WNV) (including animals)

44. Unexplained weight loss

45. Spending >72 hours in a correction/detention center in the last 12 months

46. Tattoos done in the last 12 months (professionally) if done in a state that does not regulate tattoo parlors

47. Received human growth hormone

48. Prescription pill use that are not prescribed to the donor

49. Intravenous Drug Abuse (IVDA) in the past 5 years

50. Current infection or treatment in the last 12 months for syphilis

51. Current infection or treatment in the last 12 months for gonorrhea

**52. Living or close physical contact with someone in the last 12 months who has been diagnosed with:**

- Hepatitis B
- Hepatitis C
- HIV

53. Three or more months cumulatively spent in the UK any time from 1980-1996

54. Non-professional piercing

55. Non-professional tattoos

56. A resident of a state run group home at time of death

57. Living in Europe for 5 or more years cumulatively since 1980

**58. History of any of the following autoimmune or degenerative neurological disease:**

- Systemic Lupus
- Sarcoidosis
- Scleroderma

- Reyes Syndrome
- Rheumatoid Arthritis
- Heart Disease (Idiopathic)
- Alzheimer's Disease
- Dementia with unknown cause (not from a previous CVA, infection, head trauma, or brain tumor)
- MS Multiple Sclerosis
- ALS Amyotrophic Lateral Sclerosis (Lou Gehrig's Disease)
- Creutzfeldt-Jakob or risk factors/blood relatives being diagnosed

**59. General Comments**