GENERAL INSTRUCTIONS

This document provides general instructions and guidance for completing the GTEx Informed Consent Verification Forms for Biospecimen Source Sites (BSS's) for the GTEx project. The Informed Consent Verification Form is completed for donors that have consented to the project **AND** for donors that have not consented to the project.

Table 1. General Instruction Table for Completion of Informed Consent Document (ICD) Verification Form

FIELD	GUIDANCE	CONSISTENCY CHECK
Protocol Site and Number	Please verify the correct site and protocol is selected.	Check candidate Informed Consent Document (ICD) for site name and protocol number.
Candidate ID	This number will automatically be generated and the field will be pre-populated on the form to randomly identify the next person that has been approached for donation.	Form will be pre-populated with a BSS candidate number.
Person obtaining consent or approaching candidate	First and last name of person that is requesting donation from the candidate or the person who is approaching the candidate for donation.	Field must be completed with both first and last name.
Relationship of consent signer to donor	This is the person actually providing signature on the form.	Please verify that the signer is the one checked in the answer box.
Was consent obtained?	If consent was obtained, check Yes. If consent was not obtained, check No.	Verify that the signer provided their signature on the ICD.
Date of consent or date approached (mm/dd/yyyy)	Date that the candidate was approached for consenting.	Check the ICD or authorization forms for date recorded if candidate was consented. Verify the Date entered.
Institutional version number of ICD	Informed consent or authorization form version number assigned to the form that is being used. This can be a version number, a date, a revision date or any other number or unique identifier used to control the version of the form.	Check on the bottom or top of the page for an identifier or version number. If not found use date of form (not date created unless this is unique to this form) with any other unique identifier to correctly document the form version**.**
IRB approval date (mm/dd/yyyy)	This is the date of approval for the current protocol/project and version for the informed consent document or authorization form being used. The date represents the date from which that form can be used to consent donors or for authorization from next of kin.	Ensure date of IRB approval matches what is on the form. If there is no date, type in the Institutional Version number of the ICD as above.
IRB expiration date (mm/dd/yyyy)	This is the date of expiration for the current version for the informed consent	Ensure date of IRB expiration matches what is on the form. If there is no date,

FIELD	GUIDANCE	CONSISTENCY CHECK
	document or authorization form being used. The date represents the last date that the form can be used to consent donors or for authorization from next of kin.	type in the Institutional Version number of the ICD as above.
Authorization Addendum check box	Check Yes or No for GTEx Authorization Addendum research agreement.	Box must be checked Yes.
I make this gift, if medically acceptable for the purpose of:	Check one or more of the options available.	Verify that the answers checked on the ICD are correct on the verification form here.
Specify limitation/additions, if any:	Insert any and all limitations or additions for donation from the list of specimens or tissue types on the informed consent form or authorization document. Enter Brain if consent is given.	Insert any limitations/additions to the list of tissues/fluids that were checked yes or no for collections. Enter Brain here, if consent is given. If no limitations/additions are requested, leave box empty.

Create Consent Information

1. Protocol site and number

2. BSS Candidate ID

3. Person obtaining consent/approaching candidate

4. Relationship of consent signer to donor

1 - Spouse
2 - Child

5. Was consent obtained?

☐ 1- Yes ☐ 2- No

6. Date of consent or Date of approach *(mm/dd/yyyy)*

7. Institutional version number of ICD

8. IRB approval date *(mm/dd/yyyy)*

9. IRB expiration date *(mm/dd/yyyy)*

10. Comments

To Be Completed for Consented Participants

11. GTEx Authorization Addendum

I agree to the research addendum as it has been read or presented to me.

☐ 1- Yes ☐ 2- No

12. Research Sample as needed:

☐ 1- Yes ☐ 2- No

13. I make this anatomical gift, if medically acceptable, for the purpose of:

☐ **Transplantation to another person or persons only.**

☐ **Transplantation, research, education and the advancement of science.**

☐ **Additional organs, tissues, and samples may be recovered for research only purposes.**

14. Specify additions (such as brain consent)/ limitations, if any: