

GENERAL INSTRUCTIONS

This document provides general instructions and guidance for completing the GTE_x Informed Consent Verification Forms for Biospecimen Source Sites (BSS's) for the GTE_x 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.

Please use the following table to aid in completion of the Informed Consent Document (ICD) Verification.

TABLE 1. General Instruction Table for Completion of ICD Verification Form

FIELD	GUIDANCE	CONSISTENCY CHECK
Protocol Site and Number	Please verify the correct site and protocol is selected.	Check candidate 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 next person that has been approached for donation.	Form will be pre-populated with a BSS candidate number.
Person obtaining consent or approaching candidate	Provide first initial 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 initial 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.

FIELD	GUIDANCE	CONSISTENCY CHECK
Date of consent or date approached (mm/dd/yyyy)	Date of consent should be used unless consent is not received, then the date of approach.	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 seek donor consent 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 document or authorization form being used. The date represents the last date that the form can be used to seek donor consent or for authorization from next of kin.	Ensure date of IRB expiration matches what is on the form. If there is no date, type in the Institutional Version number of the ICD as above.
Is there a willingness to be contacted at a later date for the ELSI sub-study?	For individuals that have been approached by the requestor for participation in the GTEx study, determine if there is a willingness to be contacted at a future time to be given more information about another study (ELSI sub-study). This question applies to participants that have said yes to consenting/authorization and also individuals that have declined participation.	If individual was approached this should be a yes or no answer.
Tissue Specific check boxes	Check Yes or No in every box to indicate specific tissue types for donation.	Each box must be checked either Yes or No.
Specify limitations/additions, if any	In the last box, insert any and all limitations or additions for donation of specimens or tissue types.	Insert any limitations/additions to the list of tissues/fluids that were checked yes or no for collections. If no limitations/additions are requested, leave box empty.

Create Consent Verification For Candidate NDRI :

1. Protocol Site Number <input type="text"/>	2. Candidate ID <input type="text"/>	3. Person obtaining consent / approaching candidate <input type="text"/>
4. Relationship of consent signer to donor <input type="text"/>	5. Was consent obtained? <input type="radio"/> Yes <input type="radio"/> No	6. Date of consent or Date of approach (mm/dd/yyyy) <input type="text"/>
7. Institutional version number of ICD <input type="text"/>	8. IRB approval date (mm/dd/yyyy) <input type="text"/>	
9. IRB expiration date (mm/dd/yyyy) <input type="text"/>	10. Is there a willingness to be contacted at a later date for the ELSI sub-study? <input type="radio"/> Yes <input type="radio"/> No	
11. Comments to Consent Section <input type="text"/>		

Consent Verification - Postmortem continued on the next page...

To Be Completed for Consented Participants

- | | |
|-----------------------------|--------------------------------------|
| 12. Adipose | Yes <input type="button" value="v"/> |
| 13. Bladder | Yes <input type="button" value="v"/> |
| 14. Blood, urine, saliva | Yes <input type="button" value="v"/> |
| 15. Blood vessel | Yes <input type="button" value="v"/> |
| 16. Brain | Yes <input type="button" value="v"/> |
| 17. Mammary tissue (breast) | Yes <input type="button" value="v"/> |
| 18. Endocrine | Yes <input type="button" value="v"/> |
| 19. Esophagus | Yes <input type="button" value="v"/> |
| 20. Heart tissue | Yes <input type="button" value="v"/> |
| 21. Kidney | Yes <input type="button" value="v"/> |
| 22. Large intestine | Yes <input type="button" value="v"/> |
| 23. Liver | Yes <input type="button" value="v"/> |
| 24. Lung | Yes <input type="button" value="v"/> |
| 25. Lymph node | Yes <input type="button" value="v"/> |
| 26. Muscle | Yes <input type="button" value="v"/> |
| 27. Neurological tissue | Yes <input type="button" value="v"/> |
| 28. Pancreas | Yes <input type="button" value="v"/> |
| 29. Reproductive | Yes <input type="button" value="v"/> |
| 30. Small intestine | Yes <input type="button" value="v"/> |
| 31. Skin | Yes <input type="button" value="v"/> |
| 32. Spleen | Yes <input type="button" value="v"/> |
| 33. Stomach | Yes <input type="button" value="v"/> |
| 34. Minor Salivary | No <input type="button" value="v"/> |

35. Specify limitations / additions, if any