
	<p><u>Informed Consent Form Template for Storage and Future Use of Unused Samples</u></p>	Document No.	IITB/IEC/ICF-B/2023
		Revision No.	1
		Page No.	Page 1 of 5

Please delete the instructions marked in BLUE before submitting the proposal for review

Notes to Researchers:

1. Please note that this is a template developed by the WHO ERC to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study.
2. The informed consent form consists of two parts: the information sheet and the consent certificate.
3. This template includes examples of key questions that may be asked at the end of each section that could ensure the understanding of the information being provided, especially if the research study is complex. These are just examples, and suggestions, and the investigators will have to modify the questions depending upon their study.
4. Please do not delete any sections. If any portion is not relevant to your study, please mark it as NA.
5. ICF should be drafted in simple language (language used throughout form should be at the level of a local student of class 6th/8th) – English, Hindi and other vernacular languages as applicable

TEMPLATE ON FOLLOWING PAGE...

	<u>Informed Consent Form Template for Storage and Future Use of Unused Samples</u>	Document No.	IITB/IEC/ICF-B/2023
		Revision No.	1
		Page No.	Page 2 of 5

Additional Consent to [Study Title]

Please delete the instructions marked in BLUE before submitting the proposal for review

This Statement of Consent consists of two parts:

- **Information Sheet (to share information about unused samples with you)**
- **Certificate of Consent (to record your agreement)**

You will be given a copy of the full Statement of Consent

PART I: Information Sheet

Explain that you are seeking permission to store their unused samples for possible future use in either your own research or someone else's research

Inform the participant that at present, the researchers can trace which blood/tissue/sperm/sputum sample belongs to the participant. In most cases, the participant must decide whether they want to let the researchers keep the sample but get rid of all identifying information, or whether they are comfortable with the researchers knowing whose sample it is. Explain the risks and benefits of each of these options. Inform the participant of researcher obligations in cases where the sample remains linked. These obligations include informing the participant of results which have immediate clinical relevance.


Inform participants that their sample will not be sold for profit and that any research which uses their sample will have been approved.

Right to Refuse and Withdraw

Explain that the participant may refuse to allow samples to be kept or put restrictions on those samples with no loss of benefits and that the current research study will not be affected in any way. Inform the participant that they may withdraw permission at anytime and provide them with the name, address, and number of the person and sponsoring institution to contact.

Confidentiality

Briefly explain how confidentiality will be maintained including any limitations.

	<p><u>Informed Consent Form Template for Storage and Future Use of Unused Samples</u></p>	Document No.	IITB/IEC/ICF-B/2023
		Revision No.	1
		Page No.	Page 3 of 5

Part II. Certificate of Consent

If any of the (TYPE OF SAMPLE i.e. blood, tissue) I have provided for this research project is unused or leftover when the project is completed

(Note: Tick one choice from each of the following boxes)

<input type="checkbox"/> I wish my [TYPE OF SAMPLE] sample to be destroyed immediately. <input type="checkbox"/> I want my [TYPE OF SAMPLE] sample to be destroyed after ____ years. <input type="checkbox"/> I give permission for my [TYPE OF SAMPLE] sample to be stored indefinitely
--

AND (if the sample is to be stored)

<p>I give permission for my [TYPE OF SAMPLE] sample to be stored and used in future research but only on the same subject as the current research project : [give name of current research] I give my permission for my [TYPE OF SAMPLE] sample to be stored and used in future research of any type which has been properly approved I give permission for my [TYPE OF SAMPLE] sample to be stored and used in future research except for research about [NAME TYPE OF RESEARCH]</p>

AND


<p>I want my identity to be removed from my [TYPE OF SAMPLE] sample. I want my identity to be kept with my [TYPE OF SAMPLE] sample.</p>
--

I have read the information, or it has been read to me. I have had the opportunity to ask questions about it and my questions have been answered to my satisfaction. I consent voluntarily to have my samples stored in the manner and for the purpose indicated above.

Print Name of Participant _____

Signature of Participant _____

Date _____

	<u>Informed Consent Form Template for Storage and Future Use of Unused Samples</u>	Document No.	IITB/IEC/ICF-B/2023
		Revision No.	1
		Page No.	Page 4 of 5

Day/month/year

If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness _____


AND Thumb print of participant

Signature of witness _____

Date _____

Day/month/year

[Note: This document should be signed by the PI / Researchers at the time of taking consent of participants]

	<u>Informed Consent Form Template for Storage and Future Use of Unused Samples</u>	Document No.	IITB/IEC/ICF-B/2023
		Revision No.	1
		Page No.	Page 5 of 5

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the requirements of the study as outlined in the Information Sheet.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the parent or guardian of the participant _____

Print Name of Researcher/person taking the consent _____

Signature of Researcher /person taking the consent _____

Date _____
Day/month/year

Print Name of Principal Investigator _____

Signature of Principal Investigator _____

Date _____
Day/month/year