Informed Consent Form Template for Consent for Storage and Future Use of Unused Human Biological Material (HBM)

Notes to Applicants:

1. Please note that this is a template developed by the WHO ERC.
   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. In this template:
   - square brackets indicate where specific information is to be inserted
   - bold lettering indicates sections or wording which should be included
   - standard lettering is used for explanations to researchers only and must not be included in your consent forms. The explanation is provided in black, and examples are provided in red in italics. Suggested questions to elucidate understanding are given in black in italics.

Include the following section if the research protocol calls for storage and future use of samples

Insert: Title, Date and Version number

PARTICIPANT INFORMATION SHEET
Additional Consent to [Title of the project]

1. Explain that you are seeking permission to store unused biological samples for possible future use.
2. Explain the research possibilities of the stored HBM using lay terms.
3. If genetic research is a possibility, explain what this is and any implications for them.
4. Inform the participants that at present, HBM are identifiable and they must decide whether they want the samples to be anonymised. Explain the risks and benefits of each of these options.
5. Inform the participant of researcher obligations in cases where the sample are not anonymised. These obligations include informing the participant of results which have immediate clinical relevance.
6. Inform participants that stored HBM will be used only for approved research studies and there will not be any commercial use.
7. 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.
8. Briefly explain how confidentiality will be maintained including any limitations.
9. Contact details of the investigator and the ERC
   ERC Office Address: Ethics review committee, Faculty of Medicine, University of Kelaniya.
   Telephone no: 0112961267 Email: ercmed@kln.ac.lk

Insert: Title, Date and Version number

INFORMED CONSENT FORM

(Title of the project)

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 (Tick **one** choice from each of the following boxes)

- ☐ I wish my [TYPE OF SAMPLE] sample to be destroyed immediately.
- ☐ I want my [TYPE OF SAMPLE] sample to be destroyed after [NUMBER] years.
- ☐ I give permission for my [TYPE OF SAMPLE] sample to be stored indefinitely

AND (if the sample is to be stored)

- ☐ 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]

AND

- ☐ 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.

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 :

(BLOCK CAPITALS)

Signature of Participant :……..

Date :……..