Consent document for varying a routine invasive procedure to obtain material for research

Institutional Technical and Ethical Review Board
University of Public Health, Yangon
Ministry of Health and Sports
Republic of the Union of Myanmar

Consent document for varying a routine invasive procedure to obtain material for research

This supplementary consent document is needed in case where a variation in a normal surgical technique is to be performed in order to obtain the research specimen and where the specimen would not normally be removed as part of the therapy.

1) Description of how the surgical technique will vary from the normal planned surgical procedure.
2) Description of the sample to be obtained
3) Description of any additional risks (even remote risks) those are extra to the normal risks of the planned surgical procedure.
4) Description of care to be provided in event of a side effect

I give permission for a sample of …….. to be collected for research purposes during the operation of……..

Signature of subject_____
Name of subject _____
Date (Day/month/year) _____

If illiterate *
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.
* 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 as well.

Name of witness_____ thumb print of participant
Signature of witness _____
Date (Day/month/year) _____

I have explained the variation in the normal surgical procedure required to collect the research sample. I have reviewed the additional risks of the variation in the normal procedure, over and above the normal risks of the planned surgery and the care to be provided if side effects occur. I have informed this patient that giving or withholding consent for obtaining the research sample will make no difference to the planned therapeutic surgery and subsequent follow up care and treatment.

Signature of Doctor _____
Name of Doctor _____
Date (Day/month/year) _____
(Doctor who will undertake the surgical procedure)

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.
Signature of researcher_____
Name of researcher _____
Date (Day/month/year) _____