**Informed Consent/Assent Form**

This form is to be used for the following groups:

(1) Research participants aged 18 years and more

(2) Children aged 13-18 years and their parents (should sign assent or consent separately)

(3) Parents of children aged less than 13 years

Please change the pronoun and information according to the appropriate project.

Remark: This form is just an example. You can change the content appropriately, according to the project.

Date/Month/Year

 *(Where the participant is aged ≥ 18 years or 13- < 18 years)*

My name is …………………………………………, aged……….years, address…………..…… I hereby express my consent to participate in the research project entitled………………………..

*Or (In case being a parent/LAR of a participant aged < 18 years)*

My name is ……………………………………………, aged……….years, address…………..… I am the Father/ Mother/ Guardian of child named……………………………….aged……..years I hereby express my consent to permit the child under my care to participate in the research project entitled…………………………………………………………………………….……….

I have read the information in the Participant Information Sheet and/or was given an explanation by…..……..…….. (specify the information provider), and was informed about the details of the research project, including the objective, research duration, procedures and methods that I (or child(ren) under my care) will be performing, benefit that I (or child(ren) under my care) will receive, side effects or harmful consequences that may occur from participating in the research study (describe appropriately according to the nature of the research study), as well as compensation and individual expenses.

I (or child(ren) under my care) consent to the researchers’ use of my (or child(ren) under my care) personal information (Will whole genome sequence (GWAS) information be collected? Specify clearly what it is collected for and what it will be used for. If it will be used beyond this project, the permission of the volunteer, who is the owner of the sample, must be re-consented. Also explain whether this will affect their family, or not. However, in the event that the volunteer has died, the permission of the family must be obtained) and research data obtained in the research study, which may be presented as part of a comprehensive report, but will not be published separately. I (or child(ren) under my care) can withdraw or refrain from participating in the research study at any time without any consequences for the service or healthcare that I (or child(ren) under my care) will receive in future.

If I (or child(ren) under my care) have any questions about the research procedures, or suffer from an undesirable side effect from this research, I (or child(ren) under my care) can contact……………………….. (Indicate the name of the person in charge who is available for contact by phone and the address, at any time during a 24-hour period).

 If I am (or child(ren) under my care) not treated as indicated in the Participant Information Sheet, I can inform the at BNC–IRC or email at irc@bncmedicalcollge.edu.np, Tel: +977-023-535566.

I thoroughly understand the statements in the Participant Information Sheet and Informed Consent Form, and I hereby give my signature.

Participant Signature........................................

(...................................................................)

Day/Month/Year ………………………..

Legal Representative Signature........................................

(...................................................................)

Day/Month/Year ………………………..

Informant/ Consent Obtainer’s Signature.....................................

(...................................................................)

Day/Month/Year ………………………..

Where a participant is illiterate/ a fingerprint is required.

I cannot read, but the researcher has read the statement in this consent form for me, such that I clearly understand it. Therefore, I willingly stamp my fingerprint on this form in front of my witness.

 Signature of the person who explained/ read the statement

……………………………………..

 (………………………..…………..)

Stamp the fingerprint of the participant ……. Date/ Month/Year………

Witness’ Signature (Not Explainer)

 ….………………………………….

 (…..….…………………………….)

 ……. Date/ Month/Year………

Remarks

1. If the participant is between 12 - < 18 years old, they can make their own decisions but however, they have not attend legal age to make consent. The participant should sign assent and their parent/LAR will sign the consent form.
2. If the participant is between 7 - 12 years old, verbal/oral assent must be obtained in the presence of the parents/LAR and should be recorded.
3. Witness must not be a physician or a researcher.
4. The informant or statement reader must not be the patient’s treating physician, to prevent obligated participation.
5. Please replace all information in blue ink with appropriate information

(The researcher should provide a copy of this Informed Consent Form to the participant/ guardian)