**Participant Information Sheet**

*This document may contain some statements that you do not understand. Please ask the Principal Investigator or his/her representative to give you explanations until everything is clearly understood. To assist in your decision-making process for participation in this research, you may take this document home to read and consult your relatives, intimates, personal doctor, or other doctors.*

**Title of Research Project** ……………………………………………………………...………

**Name of Principal Investigator** ……………………………………………………………….

**Research Site(s)**………………………………………………………………………………...

**Source(s) of Funding** …………………………………………………………………………..

**Objective(s) of the Research Project:**

This research project aims to (briefly describe the research objectives in layman’s language), and expects the following benefits: ........................................................................

You are invited to participate in this research project because (indicate the important characteristics of the research participants that make them suitable research subjects and clarify that this research study is done to help diagnosis or offer new alternative disease treatment, and the advantages over the old method. Please inform the research participants that this research study is not a normal treatment procedure.)..............................................

There will be (number of) ........................ participants, and the research study will last for (months/years)……… You will be participate in the study for …………… (months/years)

**What you will be asked to do, if you agree to participate in the study**

If you agree to participate in this study, and sign the Informed Consent Form, the researcher will ask you to (For example: take medicines or undergo surgery, etc. Please indicate the details of diagnosis or treatment, such as how often blood draws will be taken, how much blood at each blood draw (indicate in teaspoons or tablespoons), how long food and water consumption should be suspended before blood draws, etc. If normal treatment procedures are not excluded, clearly inform which procedures are part of the research and which are part of normal treatment. If placebos are used, this implies that the research participant does not receive treatment. The research participant therefore needs to be informed that he/she may be given placebo(s). Indicate the proportion of placebo to the real medicine used in the research, and describe that how the placebo groups will be treated at the end of the study. If whole genome sequence (GWAS) information will be collected, specify clearly what it is collected for and what it will be used for. If it will be used beyond this project, permission the 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, permission must be obtained from the family. If this study is an interview, indicate that information clearly to the participant, with the option that they can stop answering questions at any time)

**Data/ Specimen sharing with other researcher(s)**

(If data/specimens are shared, please describe. For example: Your data/specimen may be used in research conducted by another researcher, who must submit the proprosal/protocol to the Ethics Committee for approval before use, and/or will be stored in a central database according to the funding source/publisher. However, the information shared will not be personally identifiable.)

**Risk and/or potential discomfort**

Risks that may occur during research participation (For example: drug allergies or other side effects, chance of disablement or death. Indicate the proportion of risk that may occur and the solutions the researcher can provide.)

**Participation in your research project must be voluntary**

If you do not participate in this research project, there will be no impact on you in the present or the future for……………..……………..… (Example: education/ medical treatment).

You will receive ……………………………….……………………………………… (For Example: a standard diagnosis and treatment, drug treatment instead of surgery, or other details that assist decision-making. Please explain in details how research participants will be assisted if adverse events occur in the course of the research study.)

**Name of the researcher who can be contacted**

If any concern arises and you wish to inquire about the research or if you are injured/ill due to the research study, you can contact………………..…….. (Indicate the name of the researcher whom the subject can contact, address and mobile phone number, ensuring contact is available 24 hours per day.)

**Compensation** ………………………………………………………………………………….

(Indicate the compensation given to the research participant, such as travel expenses, pharmaceutical costs, laboratory examination fees, etc.)

**Your own expense(s) (if any)**..................................................................................................(Indicate whether the participant will be responsible for any expense(s))

**Benefit(s) to the research participant and others**…………………….......……………………

**If relevant information arises** about benefits and risks related to the research project, the researcher will inform the subject immediately and without concealing any details.

**Assuring confidentiality** (Identify the system for assuring personal information and all other information is kept confidential, how to prevent the participant from being identified, and how to ask permission for disclosure of the participant’s face or name).

Your private information will be kept confidential, it will not be disclosed individually, but will be disseminated as part of the overall results. Individual information may be examined by groups of persons, e.g. the Ethics Committee, funding organizations.

**You have the right to withdraw from the project at any time** without prior notice, and refusal to participate or withdrawal from the research project will result in no consequences. .……………….…. (such as the appropriate services and treatment the participant will receive.)

**If you are not treated as indicated in this information sheet,** you can inform the at BNC–IRC office or email at irc@bncmedicalcollege.edu.np or contact at Tel: +977-023-535566.

Remarks

1. If the participant is a minor (< 18 years old) and this information sheet makes you the guardian/legal representative, please change the pronoun “you” to “children under your care” according to the appropriate relationship.

2. The researcher should provide a copy of Informed Consent Form together with Participant Information Sheet to the participant or guardian.