# **B&C Medical College Teaching Hospital and Research Center**

# **Institutional Review Committee**

# **(BNC-IRC)**

**Application for Ethical Approval of Research Proposal**

**(BNC-IRC)**



***Instructions to the Investigator:***

* *Please read the instructions in italics carefully and complete all the sections (that implies to your research). If a section is not applicable, mark NA.*
* *Type all the entries in English-* ***Times New Roman Font, size 12 without bold/ Italics****.*
* ***Please complete all (A, B, C, D) in plain English***
* *Submit the completed application at BNC-IRC office or in email ID (*irc@bncmedicalcollege.edu.np)
* ***As you are writing the protocol, remove all instructions in italics (including these) so that they are not contained in the final version.***

**A. Research Proposal Information**

### **Contact: B&C Medical College Teaching Hospital and Research Center**

**Birtamode-05, Jhapa, Nepal.**

##### Tel: 977-023-535566

##### Email: irc@bncmedicalcollege.edu.np

#### 1. Research Title:

**2. Principal investigator:**

* **Full Name:**
* **Nationality:**
* **Citizenship number:**
* **Passport number (for international citizens):**
* **Designation:**
* **Department:**
* **Institution:**
* **Contact number:**
* **Email id:**
* **Orchid id:**

**3. List name, affiliation and contact details of all investigator**

For faculty or Staff or other

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Position** | **Contact address** | **E-mail address** |
|  | Principal Investigator |  |  |
|  |  |  |  |
|  | Co-investigator |  |  |
|  | Co-investigator |  |  |
|  |  |  |  |

For Students

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Position** | **Contact address** | **E-mail address** |
|  | Principal Investigator (preceptor) |  |  |
|  | Principal Investigator(student) |  |  |
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**4. Contact detail**

*(Give name, title, address, and contact details of the responsible investigator, or person who is taking administrative responsibility for this study and can be contacted during the entire study.)*

**5. Nature of Study**

🞏 Clinical trial phase…/ Intervention study

🞏 Bioequivalence/ pharmacokinetic drug study

🞏 Epidemiological research

🞏 Laboratory study

🞏 Social/ behavioral research

🞏 Study using stored specimens/tissue

🞏 Study using stored medical records

🞏 Others………………………………………………………………………………....

**6. Is study single center or multicenter**

🞏 Single center

🞏 Multicenter (within Nepal)

Please specify the study sites ……………………………………………........

🞏 Multicenter (International)

Please specify the study sites …………………………………........................

***Note: NHRC Approval is compulsory for Ph. D/ International Study/ International Collaboration/ Multicenter & Clinical Trial Study*.**

#### 7. Summary of the proposed research protocol (within 200 words)

#### (The summary should be one paragraph and must include: A brief statement of the purpose, objective(s), research methodology including research design, participants and procedures, research setting, measurement tools and significance of the study)

**8. Source of Funding/Sponsor (if applicable):**

🞏 Funded by: ………………………………. *(Please also specify funded year)*

Budget amount: …………………………………...………………………...

🞏 Expecting fund from: …………………

*(State the name of the funding body and status of application)*

Budget amount: …………………………………...………….…………….

#### B. DETAIL OF THE STUDY

**9. BACKGROUND:**

*(Relevant to the topic, preferably recent evidences to drive the need of the study)*

**10. STATEMENT OF THE PROBLEM/ RATIONALE/ NEED OF THE STUDY:**

*(Rationale should demonstrate the literature gap and what is intended to do to address the gap. Describe why you are undertaking this study and why this study is needed, also include proper in-text citation)*

**11. RESEARCH HYPOTHESIS (IF APPLICABLE):**

**12. OBJECTIVES OF THE RESEARCH:**

***General objective (s):***

*(Describe general purpose / objective (s) of the project)*

***Specific objective(s):***

*(Outline very specific objective(s) that will be met with this specific project)*

**13. STUDY SITE AND JUSTIFICATION:**

*(Indicate where the sample (e.g., medical records or stored specimens) were obtained or the data collection will take place. Give reasons for selecting the site. Permission letter from study site is compulsory for proposal submission.))*

**14. METHODS/ METHODOLOGY:**

***14.1. Research* Methods** *(Cross in the appropriate box)*

*a) Qualitative Research b) Quantitative Research c) Mixed Research*

***14.2. Study design:***

*(Provide a description of type of study design. Experimental or observational: cohort, case control or a cross-sectional study)*

***14.3. Expected outcomes of the research*** *(Describe)*

***15.* STUDY POPULATION AND SAMPLE**

***15.1. Participants/ study population:***

*(Describe the participant characteristics whether healthy individuals, or patients from outpatient department or hospital wards or community)*

***15.2. Selection criteria:*** *(list out the criteria in bullets, provide reference if appropriate)*

***Inclusion criteria:***

*(Describe the specific criteria you will use to decide who will be included in your study from among interested or potential subjects. Define any technical terms in lay language).*

***Exclusion criteria:***

*(Describe the specific criteria you will use to decide who will be excluded from your study from subjects who meet the inclusion criteria listed above. Define any technical terms in lay language).*

***16. Sampling method/ technique:***

***17. Sample size determination:***

*(Mention appropriate number (neither too less nor too much) of participants (or participant units) required for your study. Provide reference if your prediction of number is based on previous studies. Include the calculation if you used formula to predict the sample size. Describe procedure and information provide necessary references. (if any software is used to calculate the sample size.)*

***18. Limitations of the study*** *(if any):*

**19. WORK PLAN** *(should include duration of study, tentative date of starting the project and work schedule)*

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| --- | --- | --- |
| **Work** | **Duration/ Date** | **Remarks** |
| *Protocol writing* |  |  |
| *Anticipated time of protocol approval* |  |  |
| *Clinical trial registry (in case of clinical trial)* |  |  |
| *Data collection and data entry* |  |  |
| *Data analysis* |  |  |
| *Manuscript/ thesis book preparation* |  |  |
| *Submission to journal/ dissemination* |  |  |

**19. BUDGET PLAN (if applicable):**

*(Include the details of anticipated budget for your research. Only few examples of the items are listed, you may add up items based on the nature of your research. Please note that the figures in the table are just examples)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **SN** | **Items** | **Unit** | **Unit cost (NRs)** | **Total**  **(NRs)** |
| 1 | Ethical clearance |  |  |  |
| 2 | Cost for printing/ photocopy |  |  |  |
| 3 | Allowance for participants |  |  |  |
| 4 | Laboratory cost |  |  |  |
| 5 | Payment to research assistant |  |  |  |
|  |  |  |  |  |
|  | Total |  |  |  |

**C. ETHICAL CONSIDERATION**

*(Ethical principles are based on Declaration of Helsinki. Please refer to explanations of the ethical consideration in the Declaration of Helsinki)*

**20. OBTAINING THE CONSENT (If applicable).**

***a. How will the informed consent be obtained from the research participants?***

***b. Who will obtain the consent from the study participants?***

***c. Is there anything being withheld from the research participants at the time the informed consent is being sought? Mention “YES” or “NO***

*If yes, explain*

**D. APPENDIX**

**1 REFERENCES**

*(Provide list of all references cited in the Submission Form using proper format, i.e. Vancouver style of referencing.)*

**2 COMMITMENT AND SIGNATURE**

**Commitment from PI and Co-investigators**

2.1 We, the principal investigator and co-investigators listed and signed below, certify that we will adhere strictly to the information provided in the research proposal

2.2. We will report to the Ethics Committee any changes or any serious adverse effects that may occur in this study.

2.3. We will notify research participants of any significant new findings developed during the course of the study that may affect them and influence their willingness to continue participation.

2.4. We will provide a progress report of the study annually, or as requested by the IRC.

2.5 We hereby certify that we will start our study only after the certification of approval by BNC- IRC.

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| --- | --- | --- | --- | --- |
| **3. Commitment from PI and Co-investigators** List the project team by filling in the table below. Add as many lines as needed. The percentage of time allocated to the project must also be calculated. For example, on a 40-hour work week, working two hours five days a week is equivalent to 25% full-time equivalent (FTE). | | | | |
| **First, Middle and Last Name** | **Institution Name** | **Expertise** | **Role in the Project** | **Signature** |
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**5.CONSENT FORM:**

Informed consent form (should be in English and also in the language of participants: eg. Nepali)

Informed consent form should contain, not limited to, below mentioned points

* *Clear* ***purpose of the research***
* **Procedure** of the study

*(Using lay language, explain what participants are supposed to do, time required, setting/location, participants’ active or passive role, preparation for the research participation etc., intervention or manipulation (if any), drug dosing information (if any))*

* ***Voluntary participation***
* ***Rights to withdraw*** *from the study:*

***(****A statement that the human participants can withdraw from the study at any time without giving reason and without fear)*

* *Statement to* ***assure confidentiality*** *of the participant’s details.*
* ***Risk and benefits of the participation***
* ***Payment / compensation to the participants or their community (if any):***

*(Describe any payment you will provide, including total amount/value, when you pay to them (at the beginning or end), describe if any non-monetary compensation eg: fuel for transportation, lodging during data collection, will be provided).*

* *A statement indicating that the participants has* ***understood*** *all the information in the consent form and is willing to volunteer / participate in the research.*
* ***Signature space*** *for the research participants, a witness and investigator with the date.*

### List of required documents:

• Personal covering letter addressing to Chairperson of IRC, BNC  
• Fully completed IRC application form (Please AVOID printing in the both side of page)  
• Properly written Consent form in both English and Nepali language wherever necessary  
• Fully completed Commitment form from PI and Co-investigators  
• Brief CV of Principal Investigator (not more than TWO pages)  
• Letter of support from Head or In-charge of the concerned department in which the proposed study is being conducted  
• Letter of support from the head of the institute if, research study is being conducted with the collaborators from outside the institution including foreign collaborators  
• A copy of Ethical clearance letter from the respective institution if, acquired from other institution

\*Submission of all the documents in email id (irc@bncmedicalcollege.edu.np) or directly to BNC-IRC office.

\*Approval letter and or comments shall be given by IRC-BNC with minimum time duration of 4 weeks after submission of proposal.