

**Application for Approval of Research Proposal**

Institutional Review Committee (IRC) Of B&B Hospital Pvt. Ltd. (B&B – IRC)

Gwarko, Lalitpur, Nepal

Tel: 9851300655, e-mail: bnbirc@gmail.com

#### Note: This format is created based on NHRC guidelines for IRC approval and modified to suit our local requirements.

Following papers are not considered for B&B IRC review hence has to be submitted to NHRC for IRB approval:

1. Randomized control trials. (However, a comparative study with random sampling technique can be submitted to B&B IRC for review)
2. Multicenter studies.
3. Any study involving foreign nationals.
4. Any study not involving an employee of B&B hospital or Hospital for Rehabilitation of Disabled Children (HRDC) will not be considered for B&B IRC review.
5. A study conducted outside B&B or HRDC and does not involve subjects from B&B Hospital will not be considered for review.

#### Review time: Since the proposal you have submitted has to be cleared by a statistician and should also be reviewed by two reviewers (1- research expert and 2- subject review experts), it might take 6–8-week time to achieve an approval letter. Hence please apply for IRC accordingly.

**Presentation in IRC board:** Sometimes, if the committee needs to call the principal author for more clarification, the primary author or representative has to make a proposal presentation.

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#### Review Charges: B&B IRC will charge Nepali rupees 5000 for each paper to be paid before the review process. This charge will cover, external reviewer’s charge, the Statistician’s expenses, and administrative expenses.

**Review charges waiver policies.**

#### Case reports do not need to pay the review charges; however, it needs to be approved from IRC.

#### Special situation – If a student is conducting the research, they can apply for funding explaining a waiver. The IRC executive committee will take an appropriate decision.

**Instruction:**

#### Carefully read and complete all the sections of this form. If you have any query write to B&B - IRC at bnbirc@gmail.com. This form is compulsory even if you have already developed a full proposal and have obtained approval from another authorized body.

#### Address all applications to the chairman B&B - IRC. Electronic submission is a must. Please download the ‘word’ version of the application form, complete (by inserting required information in the blank space, page number may increase), and submit via email (bnbirc@gmail.com ). Do not submit hard copies unless requested. You may attach a separate file for photos if you have difficulty putting the images in the required place. Use Times New Roman, font size 12.

1. Do not leave information blank; write Yes, No, or NA (not applicable). **Do not type in to or delete the shaded area.**

#### Do not modify the form. Use attachments (files) when required.

1. When replying, please use ‘review-track change mode’ of the word document, save in the same file name, **do not modify**.
2. **Use word track change mode during the review process, answer all the comments within the comment box, and incorporate relevant revisions in the main text.**
3. **Align title, objective, methods, and dummy table (results).**
4. Obtain approval for research from an authority above your position, e.g., faculty from the head of the department (HOD) and HOD from the hospital director (HD).
5. **Do not delete or type inside the box with the shaded area in this proposal form below.**
6. **Checklist, ensure that the following supporting information is included (Y=yes, N=no, NA=not applicable)**

|  |  |
| --- | --- |
| **Supplementary documents enclosed (when applicable, in a separate file)** | **Y/N/NA** |
|  | Approval letter from Head of Department/ Head of the institution.  |  |
|  | Consent form (as per B&B IRC format), plus assent form where applicable |  |
|  | Questionnaires/tools |  |
|  | Proforma |  |
|  | Timeline/work plan/Gantt Chart (submission, data collection, analysis, writing, publication) |  |
|  | Itemized detail budget breakdown, total budget, site budget  |  |
|  | Updated curriculum vitae with a photo of PI and co-PI’s/researcher co-researcher |  |
|  | cc email to all co-investigators and signatories |  |
|  | A declaration that you will submit raw data to ‘bnbirc@gmail.com’ for monitoring and verification |  |
|  | A declaration that you will submit a final thesis and approved proposal soft copy by email to B&B - IRC |  |
|  | Declaration of conflict of interest |  |
|  | A declaration that relevant fee will be paid before the proposal can be approved |  |

1. **For Office use only**

Submission Date: Record number:

Approved: Yes / No Date:

###### Applicant should provide all the details clearly

1. **Name and title of principal investigator responsible for the proposed research:**

Passport size photograph

Full name:

Title/designation/department:

Institute/organization:

Postal address organization:

Researcher mobile: Email:

1. **List of Co-Investigators responsible for the proposed research (add as needed)**

Electronic Signature

Full name:

Title/designation/department:

Institute/organization:

Mobile: Email:

 Full name:

Electronic Signature

Title/designation/department:

Institute/organization:

Mobile: Email:

Full name:

Electronic Signature

Title/designation/department:

Institute/organization:

Mobile: Email:

Full name:

Electronic Signature

Title/designation/department:

Institute/organization:

Mobile: Email:

Full name:

Electronic Signature

Title/designation/department:

Institute/organization:

Mobile: Email:

1. **Research Proposal**
2. **Title**
3. Short, no waste words, no abbreviation, should align and reflect the study's objective, method, and outcome—**do not type in shaded areas, do not delete!**

**(Delete this line and type or paste your title here)**

1. **Introduction (up to 250 words, citations up to 5-10 only, do not list out references here)**
* Write in ‘inverted triangle’ format ideally in 3-paragraphs- 1) ‘global, regional, local’ information about your study referring to the relevant literature; 2) What is known, controversies, and 3) Sum up with aim, rationale, and relevance of the study
* Citation in Vancouver format.
* Do not copy-paste the ‘abstract’ of a few randomly picked articles, avoid ‘**plagiarism**’—**do not type in the shaded areas, do not delete!**

**(Delete this line and type or paste introduction here)**

1. **Methods (details for reproducibility)**

Detail enough for reproducibility, validity, and further extension.

* Objectives- general, specific (number them, e.g., 1,2,3…) do not use abbreviations in the objective, use measurable action verb;
* Study design - the type of study, study site, study duration, sampling technique, sample size and sample size formula and calculation, study variables, inclusion and exclusion criteria, working definition,
* Procedure details-where, when, how, whom; data collection as per tools- proforma and questionnaire, dummy table as per specific objective (provide detail tools at the end), data processing software, analysis tools; data management have to be mentioned.
* Ethical consideration- Research participant safety, privacy, consideration for the vulnerable population, conflict of interest.
* Provide citation where applicable, e.g., sample calculation—**do not type in the shaded areas, do not delete!**

**(Delete this line and type or paste your methods here)**

1. **List of cited references (total max 15)**
* Please do not use references older than ten years. We encourage to use of local and regional papers to be used as reference. Use Vancouver style of referencing with superscript as citation symbol after the full stop. (e.g.- Joshi A, Singh N, Pradhan I, Basukala B, Banskota AK. A Definition of Significant Instability and a Scoring System for Predicting Meniscal Tear in ACL-Deficient Knees. Orthop J Sports Med. 2019;7(8):23-25. DOI: <https://doi.org/10.1177/2325967119866732>
* **do not type in shaded areas, do not delete!**

**(Delete this line and type or paste your references here)**

1. **Additional information - provide detail of all items a-j individually, write NA if not applicable**
	1. **Budget** (generic guideline, may modify as necessary)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| SN | Particulars | Qty | Unit cost NRs | Subtotal NRs |
|  |  |  |  |  |
| .. |  |  |  |  |
| .. |  |  |  |  |
| .. | Miscellaneous (unseen, justifiable, max. 10% of aggregate subtotal) |  |  |  |
| Total NRs |  |

* 1. **‘Work plan, Gantt chart** (generic guideline, may modify as necessary; Use AD)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| SN | Particulars | M Y | M Y | M Y | M Y |
| 1 | Proposal development |  |  |  |  |
| 2 | Data collection after ethical approval |  |  |  |  |
| 3 | Data analysis/ thesis/article writing |  |  |  |  |
| 4 | Final thesis/article submission |  |  |  |  |

* 1. **Data storage, sharing, dissemination details** (generic guideline, may modify as necessary)

During study- data will be stored in a password-protected computer of the researcher/department.

After study- data will be deposited in a password-protected computer in the department/organization for at least five years, with access to B&B - IRC when required.

1. **Declaration by the principal investigator**

I hereby certify that the statements mentioned above are factual. I/we will commence research after the approval from B&B-IRC (and NHRC- Nepal Health Research Council when suggested) and will comply fully. If the research is terminated for any reason, I will notify B&B-IRC of this decision and provide the reasons for such actions. I will provide a final summary of the research upon completion. For publication in a journal, I shall acknowledge the B&B-IRC approval and provide the committee copy of such publication.

Full name:

Electronic Signature

Date:

1. **Annex. Consent form**
2. **Consent form** (this is a generic consent form, add similar assent form where applicable)

Research title-

Researcher-

Research site-

I hereby give my voluntary consent for myself / Mr / Ms …………………………………………………………... to participate in the research. I have been fully informed about the nature, risks, and benefits of participation. I am aware that I have the right to accept/withdraw from participating in the research as mentioned above whenever I wish to do so.

Rt thumb Lt thumb

Signature..………………………..............

Participant (preferred) ………………..

Guardian………………………………………

Relation…………………………............... Contact number…………………..........

Date……………………………..................

Signature..………………………..............

Witness name ……….....………………..

Date……………………………..................

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(Note: Submit the same consent in the Nepali language as well)

1. **Proforma**