

**These are the sections in the system. Please go through it or start filling up in this template.**

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## About Your Research

\* indicates Mandatory

Help us understand the scope and purpose of your research. This summary information helps reviewers assess your protocol and supports national-level research analytic

### Scientific Title\*

Scientific title of the study as stated in the protocol submitted for funding and ethical review; Include the trial acronym if applicable. Provide a clear, self-explanatory title that is specific to the study and reflects its main objective.

.....

Scientific title must be at least 10 characters.

As appears in funding or ethics submissions. Acronyms encouraged for clinical trials. Must be between 10 to 300 characters.

### Public Title\*

Provide a clear, simple title in plain language that identifies the trial design, population, and interventions. Avoid technical jargon so the public can easily understand it, and keep it between 10 and 300 characters.

.....

Public title must be at least 10 characters.

Keep it simple and jargon-free. This is what the public will see. Must be between 10 to 300 characters.

## Proposal Summary

### Introduction\*

Briefly describe the context and rationale behind the research. What problem does it aim to address, and why is this study important?

.....

### Study Objectives \*

State the main aims or hypotheses of the study. What are the research questions or goals you intend to investigate?

.....

**Study Methods\***

Summarize the study design, population, key procedures, and how data will be collected and analyzed.

**Expected Outcomes\***

Describe the expected results of the research. What impact or value do you anticipate the findings will bring?

**Research Domain**

Main area(s) of research, based on five key domains: communicable diseases, non-communicable diseases, maternal/child/nutrition, health systems, and injuries.

- Communicable disease
- Health Systems
- Injuries
- Maternal, Neonatal, Child, Nutritional diseases/deficiencies
- Non-Communicable disease

Select as many as applicable

**Research Area\***

Specific topic(s) the study focuses on, chosen from a list of research areas such as communicable and non-communicable diseases, maternal and child health, mental health, environmental health, health systems, traditional medicine, and other specialized fields.

Select as many as applicable

- Adolescent Health
- Ayurveda and other traditional and complementary medicine
- Biomedical research (including antimicrobial resistance)
- Communicable disease, (infectious & tropical diseases including neglected tropical diseases)
- Dentistry
- Disabilities
- Drug and Vaccine trial
- Emergency, trauma and critical care (including injuries & accidents)
- Environmental and occupational health (including climate change, indoor air pollution)
- Essential Medical products including pharmaceutical products, pharmacovigilance and rational use of drugs
- Gender-based violence
- Geriatric health
- Health care delivery system (Health Services, including quality of care)
- Health Information Technology in health service and research
- Health workforce (human Resources for Health)
- Health economics and healthcare financing

- Health in altitude including mountain medicine (physiological changes in different altitude including mountain medicine)
- Human Genetics (including thalassemia, sickle cell disorder, hemophilia, autism)
- Maternal Health
- Mental health and substance abuse
- Miscellaneous
- Mountain Medicine (high-altitude)
- Neonatal and child health
- Non communicable disease
- Nutrition, Food Safety and security
- Population and population dynamics (fertility, mortality and migration)
- Sexual & Reproductive health
- Universal Health Coverage
- Urban Health
- Zoonotic diseases (including snake bite)

**Health Condition(s) Studied (Dropdown) Not applicable**

Does your research focus on particular diseases(es) or condition(s). This may include a procedure or a diagnosis which targets a particular disease(es). If your research doesn't focus on a particular disease or health condition, please make it applicable. For example, your research focuses on overall human resources, health financing, or infection control, which is not health condition specific. Please select this field as not applicable.

Search using ICD-10 codes or keywords

**Procedure Studied (Dropdown) Not applicable**

Does your research evaluate or study any specific health care procedure (surgery, screening procedure, anesthesia, etc.)? This may include a procedure or a diagnosis that targets a particular disease (es).

Search using ICD-10 codes or keywords

**Keywords \***

Add words or phrases that describe your study and make it easier for the public to find, such as key topics, health conditions, or target groups.

Maximum 5–6 keywords or short phrases, separated by commas (,)

**Secondary Identifying Numbers (optional) Not applicable**

Any identification number assigned to the study by external organizations, such as a Universal Trial Number (UTN), sponsor-issued ID, or registration numbers from other registries, funding bodies, or ethics review committees.

**Introduction**

**Background and Rationale\***

Provide an overview of the problem's relevance, summarize past studies and key findings, and clearly state the new aspect explored and its link to the methodology.

.....

**Study Objectives/Hypothesis\***

Assess if the main objective clearly captures the core focus of the study and specify the particular issues that will be measured or evaluated to achieve it.

**Provide dummy table for each of your study objectives right after the objective.**

.....

**Research Team & Contact Info**

Tell us who's involved in your research. If your team members are registered on the platform, most fields will auto-fill to save you time.

**What is your role in the proposed research? \* (Dropdown)**

Select your role in the proposed research from the dropdown list. If your role is not listed, choose "Others" and specify.

**Is this Student Research?**

Indicate whether this study is being conducted as part of a student research project

Yes / No

**Institution\***

Enter the name of the institution where you are pursuing the academic degree for which this research is being conducted.

.....

**Country of Institution: Nepal**

**Academic Degree (Dropdown)**

**Supervisors**

If the research team member is already registered on the platform, search and select them by name or email. If they are not registered, please enter their details manually to add them.

Email: .....

**CV of Supervisor (Upload CV)**

**Ethics Training (Upload Training Certificate)**

**Does this member has a conflict of interest?**

Yes / Not Sure / No

## Add Supervisor

### Principal Investigator (PI)

Enter the Principal Investigator's details. If you are not, you can add a maximum of two Principal Investigators only when a Non-National Principal Investigator is included. In that case, adding one National Principal Investigator is mandatory to proceed. If there is no Non-National Principal Investigator, include only one National Principal Investigator and then move forward with your submission.

### Co-Investigators (optional)

Enter the details of any Co-Investigator(s) involved in the study

## Add co-investigators

### Public Contact Person \*

Avoid the use of personal information as these details may be publicly published and cannot be removed later.

### Scientific Contact Person\*

Avoid the use of personal information as these details may be publicly published and cannot be removed later.

## Declaration

I confirm that I have obtained permission from each individual listed as a public or scientific contact in this submission — including myself, if selected — and I understand that their contact information may be published in a public research registry.

## Methodology

Describe your study design so that reviewers can assess its scientific rigor and ethical implications. Fields will adjust based on your study type.

### What type of study are you conducting? \*

Choose between observational (cross-sectional surveys, case-control, cohort studies, qualitative) and interventional study (clinical trials).

Observational / Interventional

## Study Design

### Choose the design that best describes your study type \*

Select the study design that best describes your research. Options depend on the study type (Interventional or Observational), and if "Other" is chosen, provide a brief description of the design used.

Cross-sectional  
Case-control  
Cohort Prospective

- Cohort Retrospective
- Retrospective Review
- Systematic Review
- Qualitative
- Mixed methods
- Any other (specify): .....

**Explain your Study Design**

Provide a brief description of your study design, including key methods, groups, and procedures used.

.....

**What is the primary purpose of the study?\***

The primary purpose can be treatment, prevention, diagnostic, screening, supportive care, health services research, basic science

- Basic Sciences
- Diagnostics
- Health Service Research
- Prevention
- Supportive Care
- Treatment
- Other: .....

Select as many as applicable

**Inclusion Criteria**

Specify the characteristics required for participants to join the study, including age, sex, clinical diagnosis, and co-morbid conditions. This information defines who is eligible to participate in the study.

**Sex of Participants \***

All/Male/Female/Other

**Minimum participant age (in years)\***

.....

**Maximum participant age (in years)\***

.....

**Who else will be included in the study? \***

.....

(at least 10 words)

**Exclusion Criteria**

Provide the characteristics or conditions that disqualify participants from the study.

**Who will be excluded from the study? \***

.....

(at least 10 words)

**Sample Size**

Enter the number of participants planned for the study. Specify the sample size for Nepal. If your research involves multiple countries, also provide the total global sample size. If the study will be one only in Nepal, enter the same sample size as for Nepal in the global sample size also.

**Nepal Sample Size \***

**Global Sample Size (if multi-country)**

.....

.....

**Description of sample size and sampling technique\***

Provide the details of the planned number of participants for the study and explain how the sample size was determined, including the sampling unit, technique, key assumptions, and final calculation.

**Please add references. The list of references should contain all that has been cited in introduction and in methods.**

.....

**Sampling Units/Flow Chart. (Upload Document)**

Not applicable

**Primary Outcome**

**Name \***

Enter the full name of the primary outcome being measured.

.....

Avoid abbreviations. Be specific about what is measured and how.

**Metric/method of measurement \***

Describe how the primary outcome will be measured, including specific methods or metrics used.

.....

**Timepoint\***

Primary Outcome Specify the timing of measurement of outcome. In case of observational study --it can be "at the time of survey" " two years prior to survey" etc. In case of interventional study, it may be weeks/months after intervention or baseline (e.g. 12 weeks post-treatment).

.....

**Secondary Outcomes (optional)**

Not applicable

You can add up to 5 secondary outcomes

**+Add Secondary outcome**

**Data Collection\***

Upload Questionnaire document how study data will be gathered, including methods, tools, and sources, including any plans for pretesting, describe the validity or reliability of the tools used.

.....

**Add Questionnaire** (Upload Document) Not applicable

Upload Questionnaire(s) document how study data will be gathered, including methods, tools, and sources, including any plans for pretesting, and describe the validity or reliability of the tools used." If you have multiple data collection tools, please make a single PDF. file and then upload.

**Upload Document**

**Data Analysis\***

Explain the planned approach for analyzing the collected data, including statistical methods or qualitative techniques.

**Data Management**

Describe plans for data entry, coding, security, and storage, including processes to ensure data quality (e.g., double entry, range checks). Include references to detailed data management procedures if not in the protocol.

**Data Monitoring**

Does your study require a special data monitoring committee or board?

Yes / No

**Limitations or Biases in the study**

Describe any potential limitations or sources of bias in the study that could affect the validity, reliability, or generalizability of the results.

.....

**Ethical Consideration**

Provide information on human subject involvement, potential risks, safeguards, and ethical considerations. This ensures that your study complies with national and international research ethics standards and regulatory requirements of the relevant drug regulatory authority.

### **Study Risk due to nature of the 'Participants'**

#### **Does this study involve human subjects?**

Indicates whether the research directly involves human participants, either through interaction, observation, or collection of personal/medical data.

Yes / No

### **Study risk due to 'Study Procedures'**

#### **Is there use of new medical Treatment or Test? \***

Indicates whether the study introduces an untested or experimental medical intervention, diagnostic test, or therapeutic approach that may have unknown risks or benefits

Yes/ No

#### **Will any biological samples be collected during the study?**

Specifies if the study will gather human biological materials (e.g., blood, urine, tissue) for testing, analysis, or storage.

Yes / No

#### **Is there use of non ionizing radiation? \***

Indicates whether the study uses a radiation-emitting device or procedure (e.g., X-rays, CT scans, radiotherapy) that is not part of standard care.

Yes / No

#### **Is there involvement of pain or psychological distress? \***

Specifies whether study procedures could cause discomfort, pain, anxiety, or emotional harm to participants.

Yes / No

#### **Collection of sensitive/personal data \***

Refers to gathering identifiable or sensitive information, such as health records, sexual history, or financial status, which may require extra confidentiality safeguards.

Yes / No

#### **Use of assisted reproductive technology types \***

Identifies if the study involves fertility treatments such as in vitro fertilization (IVF), surrogacy, or gamete manipulation.

Yes / No

#### **Genetic or genomic research \***

Specifies if the study includes genetic testing, DNA sequencing, or genomic analysis to detect inherited conditions or predispositions.

Yes / No

**Stem cell research \***

Indicates whether the study uses human stem cells, including embryonic, adult, or induced pluripotent stem cells, for research purposes.

Yes / No

**Biosafety risk \***

Assesses whether the study involves hazardous biological agents, pathogens, or materials that could pose risks to researchers, participants, or the environment.

Yes / No

**Risk and Benefits**

**What is the anticipated risk involved in research? \***

Indicate the overall level of potential harm, discomfort, or inconvenience participants may face during the study (e.g., minimal, moderate, high).

Select risk level (Drop down): Minimal Risk

**What are the anticipated benefits of the research? \***

Select the expected positive outcomes of the study, such as improved knowledge, new treatments, or public health benefits.

**Select anticipated benefits (Drop down)**

Select as many as applicable

**Confidentiality and Data Protection Measures\***

Explain how data will be collected, who can access it, how it will be stored, and measures to ensure confidentiality before, during, and after the trial.

.....

**Plan for the Communication of Protocol Amendment\***

Describe the process for notifying investigators, ethics committees, sponsors, and other relevant parties of any protocol amendments post approval.

.....

**Implementation Plan**

Tell us where and when your research will be conducted, who's involved in implementation, and how it's being supported. This helps us assess site readiness and assign the appropriate ethics committee.

**Timeline**

The timeline fields can be updated after the approval of the proposal.

**Date of First Enrollment\*:** .....

When do you expect to enroll your first participant?

**Anticipated Date of Last Enrollment\*:** .....

When do you expect to complete data collection?

**Anticipated Study Completion Date\***

When do you expect to complete the final report?

**Recruitment Status**

Select the current stage of participant enrollment in the study.

- Complete: Participants are no longer being recruited or enrolled
- Pending: Participants are not yet being recruited or enrolled at any site
- Recruiting: Participants are currently being recruited and enrolled
- Suspended: There is a temporary halt in recruitment and enrolment
- Other: .....

The recruitment status field can be updated after the approval of the proposal.

**Countries of recruitment**

Indicate whether the study is conducted in multiple countries. If yes, select all countries where participants will be recruited from the dropdown list.

**Is this a multi-country research? \***

Yes / No

Countries: .....

**Research Sites (Geographical Area)**

**Is study nation-wide?**

Indicate whether the research will be conducted across the entire country.

Nationwide / Nation with randomly chosen provinces / Not Nationwide

**Province:** eg. Bagmati

Select the province(s) where the study sites are located.

**How is research being implemented?**

Through Research Institution(s) / As an Independent Researcher

**Where is research being done?**

Community/ Hospital/Institution

**Is the research multi-site?**

Specify if the study involves more than one research site (Research Institution/hospital).

Yes / No

**Implementing Institution/Site**

If you are not able to find your institution, you can type the name and add it.

Patan Academy of Health Sciences (PAHS)

**Institution Name**

Patan Academy of Health Sciences (PAHS)

**Site Contact Name**

PAHS-IRC

Number of Beds

Not applicable

**Existing IRCs of the Institution**

PAHS-IRC

**Sponsorship & Budget**

Provide details about the individuals or organizations funding the research and the total estimated budget. This information supports transparency, accountability, and helps determine review requirements.

**Is this protocol self-funded/sponsored?**

Select 'Yes' if the research is financially supported by the research team only, without any external funding source. Select "No" if the study is funded by an external sponsor, organization, or donor.

Yes / No

**Estimated Budget**

NPR: .....

**Total Budget Breakdown \***

Provide a detailed breakdown of the total project budget under the following categories: Human Resource Cost, Field Cost, Laboratory Cost, Data Management Cost, Dissemination Cost, Logistic Cost, Monitoring and Evaluation Cost, Report Writing, and Miscellaneous Cost.

Provide budget table (Paste your budget table here)

**Supporting Documents**

Upload your supporting documents. Based on your study details, we'll route your proposal to the appropriate ethics committee for review.

Required Supplementary Documents

Dated Cover Letter (signed by PI)\*

Admin/HOD Approval

Add any extra Documents: (for thesis, provide thesis proposal signed by your guide and co-guide)

Consent form/Assent form where applicable

Patient Information Sheet

**Payment Details**

Provide details about your selected payment method and submit proof of payment. This information ensures proper processing of your submission and helps verify that all required fees have been settled.

Protocol Submission Fee            NPR 1,000 (where applicable/Waived for students and faculties/staff)

**Fee Calculation**

Condition: Nepali Student Nepal Under 2 Lac - Budget <= 2 Lakhs

**Payment Method**

Select payment method:

Bank Transfer/Manual Deposit/Yet to be Paid

**Payment Proof**

Upload a scanned or digital copy of your payment voucher.

**Deposited/Paid Amount**

NPR: .....

**Transaction Date:** Select Transaction Date

Payment remarks:

.....

### **Protocol Routing Summary**

Based on your responses, your protocol will be routed according to the national ethical guidelines of Nepal. Below is the Ethics Committee to which your submission will be assigned for review and approval.

#### **Assigned IRC for Review & Approval**

PAHS-IRC

Based on interventional study / multi-site study / international collaboration / budget threshold.

#### **Routing Reason**

**Routed based on site institution affiliation**

PAHS-IRC

#### **Submission Note (Optional)**

Add notes about your submission: .....

#### **Declaration**

I confirm that all information provided is accurate and complete to the best of my knowledge, and complies with national ethical guidelines. I agree to submit the final report within one year after the end date of the protocol, provide annual progress reports as required, and submit any proposal amendments for review before implementation.

This declaration is required in order to submit your protocol for ethics review.

## Proposal Submission format available in the system for reference

- About Your Research
- Research Team & Contact Info
- Methodology
- Ethical Consideration
- Implementation Plan
- Sponsorship & Budget
- Supporting Documents
- Payment Details
- Protocol Routing Summary

Submit Protocol
Save & Ex

**Scientific Title \***

Scientific title of the study as stated in the protocol submitted for funding and ethical review; Include the trial acronym if applicable. Provide a clear, self-explanatory title that is specific to the study and reflects its main objective.

e.g. Efficacy of Low-Dose Aspirin in Diabetic Patients (ELDAP Study)...

As appears in funding or ethics submissions. Acronyms encouraged for clinical trials. Must be between 10 to 300 characters.

**Public Title \***

Provide a clear, simple title in plain language that identifies the trial design, population, and interventions. Avoid technical jargon so the public can easily understand it, and keep it between 10 and 300 characters.

Evaluating the Benefits of Taking Low-Dose Aspirin for Diabetic Patients

Keep it simple and jargon-free. This is what the public will see. Must be between 10 to 300 characters.

**Proposal Summary**

**Introduction \***

Briefly describe the context and rationale behind the research. What problem does it aim to address, and why is this study important?

e.g., This study investigates the rising incidence of antibiotic resistance in urban Nepal and explores contributing behavioral and systemic factors.

Keep it under 50 words.

**Study Objectives \***

State the main aims or hypotheses of the study. What are the research questions or goals you intend to investigate?

e.g., To assess the effectiveness of community health interventions in reducing the misuse of antibiotics.

Keep it under 50 words.

**Study Methods \***

Summarize the study design, population, key procedures, and how data will be collected and analyzed.

e.g., A mixed-methods study using surveys, interviews, and clinical data from 5 urban health centers.

Keep it under 50 words.

**Expected Outcomes \***

Describe the expected results of the research. What impact or value do you anticipate the findings will bring?

e.g., We expect to identify key behavior change factors and develop evidence-based guidelines for improving antibiotic use.

**Please fill up this section**

- About Your Research
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**Submit Protocol** Save & E

**Research Domain**

Main area(s) of research, based on five key domains: communicable diseases, non-communicable diseases, maternal/child/nutrition, health systems, and injuries.

e.g. Non-Communicable Diseases, Health Systems

Select as many as applicable

**Research Area \***

Specific topic(s) the study focuses on, chosen from a list of research areas such as communicable and non-communicable diseases, maternal and child health, mental health, environmental health, health systems, traditional medicine, and other specialized fields.

Start typing to find a relevant area...

Select as many as applicable

**Health Condition(s) Studied**  Not applicable

Does your research focus on particular disease(es) or condition(s). This may include a procedure or a diagnosis which targets a particular disease(es). If your research doesn't focus on a particular disease or health condition, please make it applicable. For example, your research focuses on overall human resources, health financing, or infection control, which is not health condition specific. Please select this field as not applicable.

Search using ICD-11 codes or keywords

**Procedure Studied**  Not applicable

Does your research evaluate or study any specific health care procedure(surgery, screening procedure, anesthesia, etc.)? This may include a procedure or a diagnosis that targets a particular disease (es).

Search using ICD-10 codes or keywords

**Keywords \***

Add words or phrases that describe your study and make it easier for the public to find, such as key topics, health conditions, or target groups.

type...

Maximum 5-6 keywords or short phrases, separated by commas(,)

**Secondary Identifying Numbers** (optional)  Not applicable

Any identification number assigned to the study by external organizations, such as a Universal Trial Number (UTN), sponsor-issued ID, or registration numbers from other registries, funding bodies, or ethics review committees.

+ Add secondary ID number

These section has drop down menu, select the one that is suitable. Please click not applicable if there is no secondary identifying number

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**Submit Protocol** Save & Ex

**Introduction**

**Background and Rationale \***

Provide an overview of the problem's relevance, summarize past studies and key findings, and clearly state the new aspect explored and its link to the methodology.

B I U S T L H<sub>1</sub> H<sub>2</sub> H<sub>3</sub> H<sub>4</sub>  $x_2$   $x^2$   $\frac{1}{x}$   $\frac{1}{x^2}$   $\frac{1}{x^3}$   $\frac{1}{x^4}$   $\frac{1}{x^5}$   $\frac{1}{x^6}$   $\frac{1}{x^7}$   $\frac{1}{x^8}$   $\frac{1}{x^9}$   $\frac{1}{x^{10}}$   $\frac{1}{x^{11}}$   $\frac{1}{x^{12}}$   $\frac{1}{x^{13}}$   $\frac{1}{x^{14}}$   $\frac{1}{x^{15}}$   $\frac{1}{x^{16}}$   $\frac{1}{x^{17}}$   $\frac{1}{x^{18}}$   $\frac{1}{x^{19}}$   $\frac{1}{x^{20}}$   $\frac{1}{x^{21}}$   $\frac{1}{x^{22}}$   $\frac{1}{x^{23}}$   $\frac{1}{x^{24}}$   $\frac{1}{x^{25}}$   $\frac{1}{x^{26}}$   $\frac{1}{x^{27}}$   $\frac{1}{x^{28}}$   $\frac{1}{x^{29}}$   $\frac{1}{x^{30}}$   $\frac{1}{x^{31}}$   $\frac{1}{x^{32}}$   $\frac{1}{x^{33}}$   $\frac{1}{x^{34}}$   $\frac{1}{x^{35}}$   $\frac{1}{x^{36}}$   $\frac{1}{x^{37}}$   $\frac{1}{x^{38}}$   $\frac{1}{x^{39}}$   $\frac{1}{x^{40}}$   $\frac{1}{x^{41}}$   $\frac{1}{x^{42}}$   $\frac{1}{x^{43}}$   $\frac{1}{x^{44}}$   $\frac{1}{x^{45}}$   $\frac{1}{x^{46}}$   $\frac{1}{x^{47}}$   $\frac{1}{x^{48}}$   $\frac{1}{x^{49}}$   $\frac{1}{x^{50}}$   $\frac{1}{x^{51}}$   $\frac{1}{x^{52}}$   $\frac{1}{x^{53}}$   $\frac{1}{x^{54}}$   $\frac{1}{x^{55}}$   $\frac{1}{x^{56}}$   $\frac{1}{x^{57}}$   $\frac{1}{x^{58}}$   $\frac{1}{x^{59}}$   $\frac{1}{x^{60}}$   $\frac{1}{x^{61}}$   $\frac{1}{x^{62}}$   $\frac{1}{x^{63}}$   $\frac{1}{x^{64}}$   $\frac{1}{x^{65}}$   $\frac{1}{x^{66}}$   $\frac{1}{x^{67}}$   $\frac{1}{x^{68}}$   $\frac{1}{x^{69}}$   $\frac{1}{x^{70}}$   $\frac{1}{x^{71}}$   $\frac{1}{x^{72}}$   $\frac{1}{x^{73}}$   $\frac{1}{x^{74}}$   $\frac{1}{x^{75}}$   $\frac{1}{x^{76}}$   $\frac{1}{x^{77}}$   $\frac{1}{x^{78}}$   $\frac{1}{x^{79}}$   $\frac{1}{x^{80}}$   $\frac{1}{x^{81}}$   $\frac{1}{x^{82}}$   $\frac{1}{x^{83}}$   $\frac{1}{x^{84}}$   $\frac{1}{x^{85}}$   $\frac{1}{x^{86}}$   $\frac{1}{x^{87}}$   $\frac{1}{x^{88}}$   $\frac{1}{x^{89}}$   $\frac{1}{x^{90}}$   $\frac{1}{x^{91}}$   $\frac{1}{x^{92}}$   $\frac{1}{x^{93}}$   $\frac{1}{x^{94}}$   $\frac{1}{x^{95}}$   $\frac{1}{x^{96}}$   $\frac{1}{x^{97}}$   $\frac{1}{x^{98}}$   $\frac{1}{x^{99}}$   $\frac{1}{x^{100}}$

Type here...

This section must have following contents  
 Background of the study  
 What are the gaps identified in this area?  
 What component of gap does this study address?

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- ✓ About Your Research
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**Study Objectives/Hypothesis \***

Assess if the main objective clearly captures the core focus of the study and specify the particular issues that will be measured or evaluated to achieve it.

B I U S T H<sub>1</sub> H<sub>2</sub> H<sub>3</sub> H<sub>4</sub> ... x<sub>2</sub> x<sup>2</sup>

Type here...

Please list objectives in following format

General Objective

Specific Objective number 1

Dummy Table Number 1

Specific Objective Number 2

Dummy Table Number 2

\*In some cases dummy table may not be applicable

**Research Team & Contact Info**

Tell us who's involved in your research. If your team members are registered on the platform, most fields will auto-fill to save you time.

---

**What is your role in the proposed research? \***

Select your role in the proposed research from the dropdown list. If your role is not listed, choose "Others" and specify.

Principal Investigator / PI

**Is this Student Research?**

Indicate whether this study is being conducted as part of a student research project

Yes ✓

No

**Institution \***

Enter the name of the institution where you are pursuing the academic degree for which this research is being conducted.

Insight Genomics Research Group

**Institution \***

Enter the name of the institution where you are pursuing the academic degree for which this research is being conducted.

Insight Genomics Research Group

**Country of Institution \***

Select country

**Academic Degree \***

Select degree program name...

**Supervisors**

If the research team member is already registered on the platform, search and select them by name or email. If they are not registered, please enter their details manually to add them.


✕

**Email**

Type here to search user...

If the research team member is registered on the platform, search and select them by name or email.


**CV of Supervisor**  
Upload a scanned or digital copy of your cv.



Drag and drop or click to upload  
PDF, DOCX. Max size: 5 MB

[Upload CV](#)

**Ethics Training**  
Upload a scanned or digital copy of your ethics training.



Drag and drop or click to upload  
PDF, DOCX. Max size: 5 MB

[Upload Ethics Training Certificate](#)

Does this member has a conflict of interest?

Yes  Not Sure  No

There are two interface, for student and other researchers. If you click student, you are required to submit detail of your supervisors (Guide and Co Guide).

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**Submit Protocol** [Save & Exit](#)

**Is this Student Research?**

Indicate whether this study is being conducted as part of a student research project

Yes  No

**Principal Investigator (PI)**  
Enter the Principal Investigator's details. If you are not, you can add a maximum of two Principal Investigators only when a Non-National Principal Investigator is included. In that case, adding one National Principal Investigator is mandatory to proceed. If there is no Non-National Principal Investigator, include only one National Principal Investigator and then move forward with your submission.

**Principal Investigator 1** ×

**Email**

If the research team member is registered on the platform, search and select them by name or email.

[+ Add Another Principal Investigator](#)

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**Co-Investigators** (optional)

Enter the details of any Co-Investigator(s) involved in the study

+ Add Co-Investigators

**Public Contact Person \***

Avoid the use of personal information as these details may be publicly published and cannot be removed later.

Enter different contact

**Scientific Contact Person \***

Avoid the use of personal information as these details may be publicly published and cannot be removed later.

Enter different contact

I confirm that I have obtained permission from each individual listed as a public or scientific contact in this submission — including myself, if selected — and I understand that their contact information may be published in a public research registry.

However, if you do not select “student” you need to put investigator and co investigator, public and scientific contact person.

**Methodology**

Describe your study design so that reviewers can assess its scientific rigor and ethical implications. Fields will adjust based on your study type.

**What type of study are you conducting? \***

Choose between observational (cross-sectional surveys, case-control, cohort studies, qualitative) and interventional study (clinical trials).

Observational  Interventional

**Study Design**

**Choose the design that best describes your study type \***

Select the study design that best describes your research. Options depend on the study type (Interventional or Observational), and if “Other” is chosen, provide a brief description of the design used.

...

**Explain your Study Design**

Provide a brief description of your study design, including key methods, groups, and procedures used.

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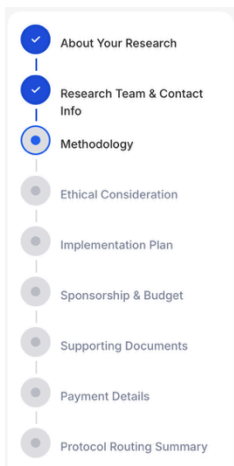
type here...

**What is the primary purpose of the study? \***

The primary purpose can be treatment, prevention, diagnostic, screening, supportive care, health services research, basic science

...

Select as many as applicable



### Inclusion Criteria

Specify the characteristics required for participants to join the study, including age, sex, clinical diagnosis, and co-morbid conditions. This information defines who is eligible to participate in the study.

**Sex of Participants \***

All  Male  Female  Other

**Minimum participant age (in years) \***

**Maximum participant age (in years) \***

**Who else will be included in the study? \***

If your study includes both gender, please select “ALL”. Mention minimum and maximum age of participants

### Exclusion Criteria

Provide the characteristics or conditions that disqualify participants from the study.

**Who will be excluded from the study? \***

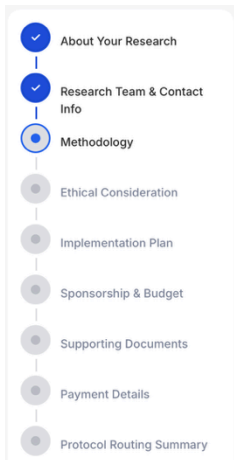
**Sample Size**

Enter the number of participants planned for the study. Specify the sample size for Nepal. If your research involves multiple countries, also provide the total global sample size. If the study will be one only in Nepal, enter the same sample size as for Nepal in the global sample size also.

**Nepal Sample Size \***

**Global Sample Size (if multi-country)**

In sample size, provide total sample size for the study.



**Description of sample size and sampling technique \***

Provide the details of the planned number of participants for the study and explain how the sample size was determined, including the sampling unit, technique, key assumptions, and final calculation.

**Sampling Units/Flow Chart.**  Not applicable

In description of sample size and sampling technique, provide detail of sample size calculation and sampling method. Please cite at relevant places. **This section must contain reference with hyperlinks of all citations done in introduction and methods.**

If additional document is required, please upload.

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### Primary Outcome

**Name \***

Enter the full name of the primary outcome being measured.

Avoid abbreviations. Be specific about what is measured and how.

**Metric/method of measurement \***

Describe how the primary outcome will be measured, including specific methods or metrics used.

**Timepoint \***

primaryOutcomeSpecify the timing of measurement of outcome. In case of observational study --it can be "at the time of survey" " two years prior to survey" etc. In case of interventional study, it may be weeks/months after intervention or baseline (e.g. 12 weeks post-treatment).

### Secondary Outcomes (optional)

Not applicable

You can add up to 5 secondary outcomes

### Data Collection \*

Upload Questionnaire document how study data will be gathered, including methods, tools, and sources, including any plans for pretesting, describe the validity or reliability of the tools used.


B I U S T ↻ </> H<sub>1</sub> H<sub>2</sub> H<sub>3</sub> H<sub>4</sub> ≡ ... ≡ ≡ x<sub>2</sub> x<sup>2</sup> ↻ ↻ ≡ ≡ ≡ ≡ ↶ ↷

type here...

### Add Questionnaire \*

Not applicable

Upload Questionnaire(s) document how study data will be gathered, including methods, tools, and sources, including any plans for pretesting, and describe the validity or reliability of the tools used.\* If you have multiple data collection tools, please make a single PDF file and then upload.



Drag and drop or click to upload  
PDF, DOCX. Max size: 5 MB

### Data Analysis \*

Explain the planned approach for analyzing the collected data, including statistical methods or qualitative techniques.

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**Data Management \***

Describe plans for data entry, coding, security, and storage, including processes to ensure data quality (e.g., double entry, range checks). Include references to detailed data management procedures if not in the protocol.

Rich text editor with toolbar (B, I, U, S, T, L, </>, H1-H4, bold, italic, list, x2, x2, link, unlink, indent, outdent, undo, redo) and a text area containing "type here..."

**Data Monitoring**

Does your study require a special data monitoring committee or board?  
 Yes  No ✓

**Limitations or Biases in the study \***

Describe any potential limitations or sources of bias in the study that could affect the validity, reliability, or generalizability of the results.

Rich text editor with toolbar (B, I, U, S, T, L, </>, H1-H4, bold, italic, list, x2, x2, link, unlink, indent, outdent, undo, redo) and a text area containing "type here..."

Please provide details of data collection, analysis, management and monitoring. Upload questionnaire or research tools

Submit Protocol

Save & Exit

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**Ethical Consideration**

Provide information on human subject involvement, potential risks, safeguards, and ethical considerations. This ensures that your study complies with national and international research ethics standards and regulatory requirements of the relevant drug regulatory authority.

**Study Risk due to nature of the 'Participants'**

Does this study involve human subjects?  
Indicates whether the research directly involves human participants, either through interaction, observation, or collection of personal/medical data.  
 Yes  No ✓

**Study risk due to 'Study Procedures'**

Is there use of new medical Treatment or Test? \*  
Indicates whether the study introduces an untested or experimental medical intervention, diagnostic test, or therapeutic approach that may have unknown risks or benefits  
 Yes  No ✓

Will any biological samples be collected during the study?  
Specifies if the study will gather human biological materials (e.g., blood, urine, tissue) for testing, analysis, or storage.  
 Yes  No ✓

**Is there use of non ionizing radiation? \***

Indicates whether the study uses a radiation-emitting device or procedure (e.g., X-rays, CT scans, radiotherapy) that is not part of standard care.

Yes  No

**Is there involvement of pain or psychological distress? \***

Specifies whether study procedures could cause discomfort, pain, anxiety, or emotional harm to participants.

Yes  No

**Collection of sensitive/personal data \***

Refers to gathering identifiable or sensitive information, such as health records, sexual history, or financial status, which may require extra confidentiality safeguards.

Yes  No

**Use of assisted reproductive technology types \***

Identifies if the study involves fertility treatments such as in vitro fertilization (IVF), surrogacy, or gamete manipulation.

Yes  No

**Genetic or genomic research \***

Specifies if the study includes genetic testing, DNA sequencing, or genomic analysis to detect inherited conditions or predispositions.

Yes  No

**Stem cell research \***

Indicates whether the study uses human stem cells, including embryonic, adult, or induced pluripotent stem cells, for research purposes.

Yes  No

**Biosafety risk \***

Assesses whether the study involves hazardous biological agents, pathogens, or materials that could pose risks to researchers, participants, or the environment.

Yes  No

**Risk and Benefits**

**What is the anticipated risk involved in research? \***

Indicate the overall level of potential harm, discomfort, or inconvenience participants may face during the study (e.g., minimal, moderate, high).

Select risk level

**What are the anticipated benefits of the research? \***

Select the expected positive outcomes of the study, such as improved knowledge, new treatments, or public health benefits.

Select anticipated benefits

ⓘ Select as many as applicable

**Confidentiality and Data Protection Measures \***

Explain how data will be collected, who can access it, how it will be stored, and measures to ensure confidentiality before, during, and after the trial.

B I U S T\* H1 H2 H3 H4 ... X2 X2

type here...

**Plan for the Communication of Protocol Amendment \***

Describe the process for notifying investigators, ethics committees, sponsors, and other relevant parties of any protocol amendments post approval.

B I U S T\* H1 H2 H3 H4 ... X2 X2

type here...

Please complete these sections

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## Implementation Plan

Tell us where and when your research will be conducted, who's involved in implementation, and how it's being supported. This helps us assess site readiness and assign the appropriate ethics committee.

### Timeline


The timeline fields can be updated after the approval of the proposal.

#### Date of First Enrollment \*

Jun 02, 2026 


ⓘ When do you expect to enroll your first participant?

#### Anticipated Date of Last Enrollment \*

Jun 02, 2026 

ⓘ When do you expect to complete data collection?


#### Anticipated Study Completion Date \*

Jun 02, 2026 

ⓘ When do you expect to complete the final report?

### Recruitment Status

Select the current stage of participant enrollment in the study.

Pending: Participants are not yet being recruited or enrolled at any site 

ⓘ The recruitment status field can be updated after the approval of the proposal.

### Countries of recruitment

Indicate whether the study is conducted in multiple countries. If yes, select all countries where participants will be recruited from the dropdown list.

#### Is this a multi-country research? \*

Yes No

#### Countries

Nepal 

### Research Sites(Geographical Area)

#### Is study nation-wide?

Indicate whether the research will be conducted across the entire country.

Nationwide  Nationwide with randomly chosen provinces Not Nationwide

#### How is research being implemented?

Through Research Institution(s) As an Independent Researcher

#### Is the research multi-site?

Specify if the study involves more than one research site (Research Institution/hospital).

Yes  No

#### Implementing Institution/Site

If you are not able to find your institution, you can type the name and add it.

Patan Academy of Health Sciences (PAHS) 

#### Institution Name

Patan Academy of Health Sciences (PAHS)

#### Site Contact Phone

+977 9851061846

#### Site Contact Email

irc-pahs@pahs.edu.np

#### Site Contact Name

IRC pahs

#### Number of Beds

Not applicable



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**Submit Protocol** Save & Exit

Provide details about your selected payment method and submit proof of payment. This information ensures proper processing of your submission and helps verify that all required fees have been settled.


---

**Protocol Submission Fee**  
NPR 5,000

**1 Fee Calculation**  
Condition: Nepali Researcher Under 2 Lac - Budget <= 2 Lakhs

**Payment Method**

**Payment Proof**  
 Upload a scanned or digital copy of your payment voucher.



Drag and drop or click to upload  
PNG, JPG, PDF, DOC Max size: 5 MB

Upload Payment Proof

**Deposited/Paid Amount**

**Transaction Date**

**Payment remarks**

Select "Not Yet" of your proposal is not under payment category

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**Submit Protocol** Save & Exit

**Protocol Routing Summary**  
 Based on your responses, your protocol will be routed according to the national ethical guidelines of Nepal. Below is the Ethics Committee to which your submission will be assigned for review and approval.

---

**Assigned IRC for Review & Approval**

Based on interventional study / multi-site study / international collaboration / budget threshold.

**1 Routing Reason**  
Routed due to multisite implementation

**IRCS with access to this proposal information**  
 This protocol will be visible to the IRCs of all participating institutions listed below, as required for multi-site studies.

PAHS-IRC

Submission Note (Optional)

Add notes about your submission

- I confirm that all information provided is accurate and complete to the best of my knowledge, and complies with national ethical guidelines. I agree to submit the final report within one year after the end date of the protocol, provide annual progress reports as required, and submit any proposal amendments for review before implementation.

This declaration is required in order to submit your protocol for ethics review.

Save & Continue

Submit Proposal