

# Research Proposal Approval Format for Institutional Review Board (IRC)

**Research Title:**

Prevalence and contributing factors of female alcohol consumption in Khokana VDC.

Manmohan Memorial Institute of Health Sciences (MMIHS)

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### *For Official Use Only*

*(Please see the check list before Registration of the application form)*

Registration No.:075-6-2-04048-2009

Registration Date:2009

Approved Date:

Name of PI:

Research Site: Khokana VDC

Tentative Date of Initiating the Project:

Duration of the Research Project: 6 weeks

Name of Internal Reviewer: vice principle Pushpa Raj Khanal

Name of External Reviewer:

Signature & Seal of MMIHS:

**Part – I**

Passport size  
photograph

**Administrative Information**

1. Research Title:

Prevalence and contributing factors of female alcohol consumption in Khokana VDC.

2. Name and Title of Principal Investigator responsible for the proposed research:

Maharjan

Last (Surname)

Middle (if any)

Sujata

First name

Nationality: Nepali

Citizenship Number with district name from where it was obtained (only for Nepali)  
283012/274 lalitpur

Passport Number (only for non Nepali citizen):

Signature:

Date:

Postal Address:

Telephone No.:

Mobile No.:

Fax No.:

e-mail:

Sujata\_mh@live.com

Alternate e-mail:

3. Declaration of the head of the Institution (if applicable)

If the proposed research is approved, we will allow him/her to conduct the research in this institution.

Signature:  Date:

Maharjan		Sujata
Last (Surname)	Middle (if any)	First name

Designation:

Name of the Institution

Contact/Postal Address:

Telephone No.:

Fax No.:

Institutional e-mail:

Website:

## Part – II

### Research Proposal Description

#### 4. Research Title:

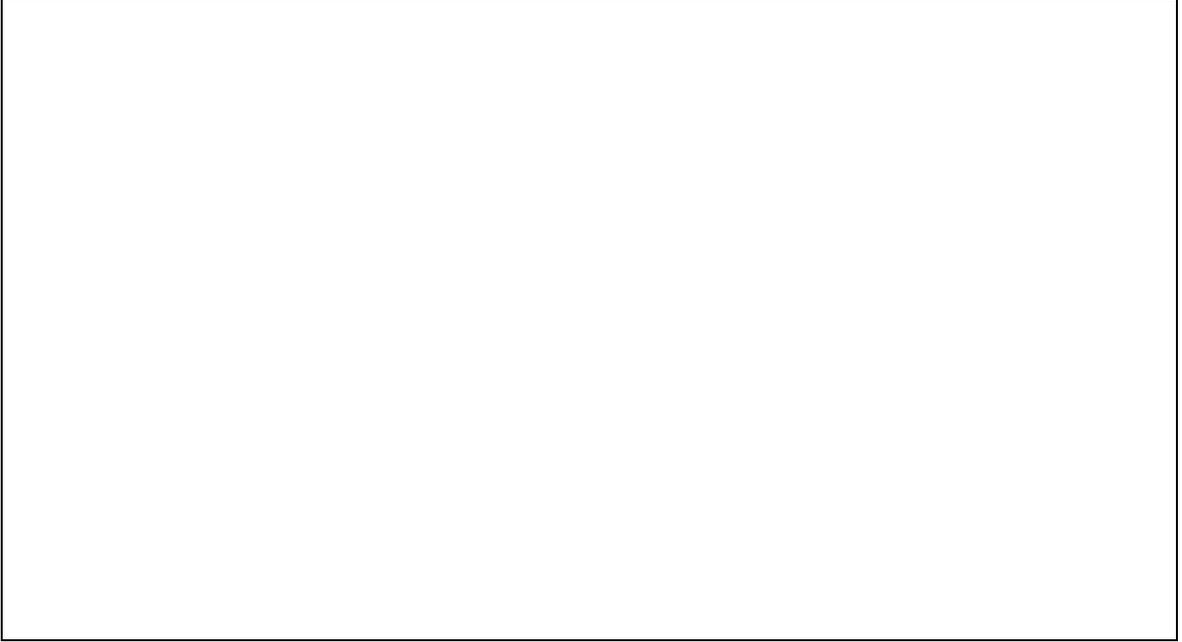
Prevalence and contributing factors of female alcohol consumption in Khokana VDC.

#### 5. Proposal Summary (maximum 500 words):

A community-based cross-sectional survey with cluster sampling method (probability proportionate to size) will be carried out to estimate the prevalence of alcohol consumption among female in Khokana VDC to identify the factors associated with this habit. A representative sample of 144 women aged 15 years and above will be interviewed. According to the WHO, Prevalence rate of female alcohol consumption is increasing day by day 9.6 % females are former drinkers.0.48% female have the alcohol use disorders. Based on reviewed literature, it was found that there were high prevalence rate of female alcohol consumption among female in both developed and developing countries. Also many studies have shown the strong association of female alcohol consumption with different contributing factors such as age, education, occupation, marital status, peer pressure, family member stress.

A semi-structured questionnaire will be developed on the basis of objective and interview guideline will be used.

The burden of the alcohol among the suburban community will be revealed by this study. Thus the information will be utilized to devise appropriate intervention program to reduce the burden of alcoholism. Ultimately the findings will be beneficial to devise policy and plan to reduce the burden of alcoholism



## 6. Introduction:

### Background of Study (maximum 500 words):

Alcohol is a drug and may be classified as a sedative, tranquilizer, hypnotic or anesthetic depending upon the quantity consumed<sup>7</sup>. Alcohol is produced via the anaerobic fermentation of sugars by yeast and involves glucose molecules ( $C_6H_{12}O_6$ ), carbon dioxide ( $CO_2$ ) and energy. Alcohol consumption and alcohol-related problems are considered public health priorities worldwide. Alcohol consumption has shown a decline in the developed countries in recent times, it has been raising rapidly in developing countries including Nepal. There are significant gender differences regarding the development of problems caused by alcohol. Compared with men, women's risk of alcohol use has a disproportionate effect on their lives and health, including consequences on reproductive function and pregnancy. The effect of alcohol consumption on the body depends on how often it is consumed, how much and the alcohol content of the drinks. Frequent alcohol use may encourage alcohol dependence or, alcoholism<sup>9</sup>. Alcohol related problems, including addiction, family violence and so on, become an additional burden on families and communities already struggling with poverty. Perversely, experience shows that, once developing societies have begun to reduce poverty problems and create economic growth, alcohol consumption tends to rise, with a corresponding rise in related harm.

The World Health Assembly in 1983 has declared alcohol-related problems to be a major public health concern all over the world. Harmful use of alcohol results in 2.5 million deaths each year. Alcohol consumption has a social aspect to it, but it is often abused. The origin of the alcohol production and consumption of alcohol beverage is as old as the origin of the books. Alcoholic beverages have a long tradition in Nepal.

In worshipping Gods and Goddesses as well as other ritual practices, alcohol is still offered by quacks and faith healers in some communities.<sup>3</sup>

Some people in Nepal generally believe that alcohol is a medicine for cold, pain, tension and tiredness; some believes that the celebration, parties, and festivals are success if alcohol is served. Generally they take alcohol thinking as a given right by their religious.<sup>4</sup>

Now a day's female is a serious issue. Not only on social impact, have this habit directly effect on health of pregnant mother, which also affect fetus. According to the World Health Organization (WHO) and World Bank sponsored Global Burden of Disease study, alcohol is the fifth-ranked risk factor for premature death and disability in the world, and the greatest risk factor in some developing countries.<sup>10</sup>

Few studies have been done in this regard. The alcohol consumption habit is increasing day by day in female also. The habit of the alcohol in the female may be one of the serious problems. Thus the study was focused to identity the problems of alcohol consumption among the women in khokana and this study will be a valuable tool for design and implement the awareness programs for the female alcohol users.

Statement of the Problem and Rationale / Justification (maximum 500 words)

320000 young people between the age of 15 and 29 die from alcohol-related causes, resulting in 9% of all deaths in that age group in worldwide. 15.1 million alcohol-abusing or alcohol-dependent individuals in the United States, approximately 4.6 million (nearly one-third) are women. This study revealed younger women (aged 18-34) report higher rates of drinking-related problems than do older women, the incidence of alcohol dependence is greater among middle-aged women (aged 35-49).

According to the WHO, Prevalence rate of female alcohol consumption is increasing day by day 9.6 % females are former drinkers.0.48% female have the alcohol use disorders. Cross sectional study conducted at Sri-Lanka among 97.8% women revealed that prevalence rate of female alcohol consumption was 34.7%. This study shows significant positive association observed between alcohol consumption and illiteracy ( $p < 0.0001$ ), marriage ( $p < 0.001$ ), parental drinking ( $p < 0.01$ ).

A recent national survey of drinking in China revealed that 15.0% of the women were current drinkers. Among respondents who endorsed alcohol consumption, 51.0% of the women reported excessive drinking, 7.8% respectively, reported frequent drinking, 26.6%, respectively.

Research conducted in Dharan which suggests that the prevalence of alcohol consumption among the women in Dharan was nearly 17%. It increased with increasing age groups. The women aged 50 years and above were more likely to take alcohol than the women in the reproductive age (OR=2.4,  $P < 0.0001$ ). The business and laborer class women were more likely to

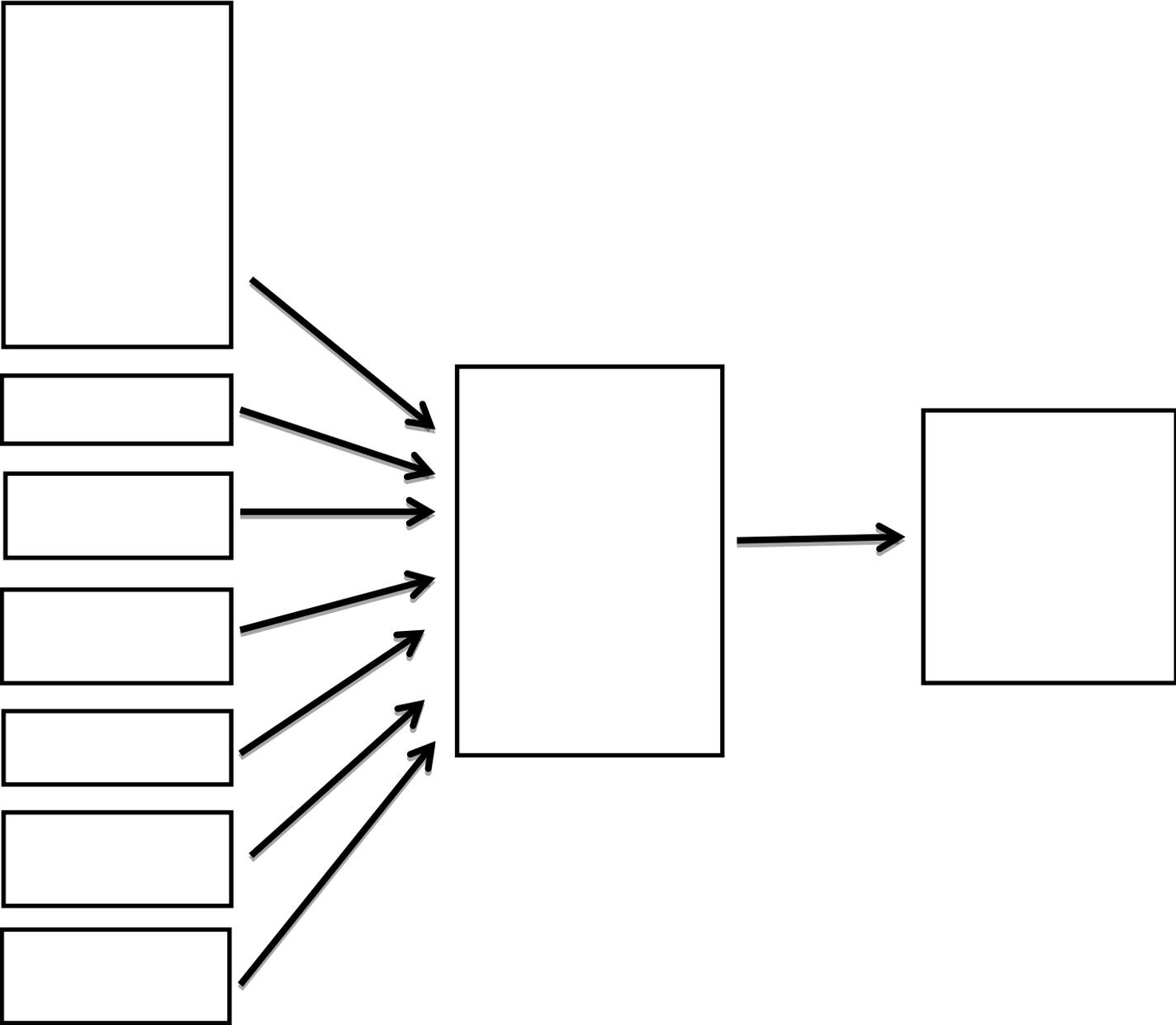
have alcohol habit than the housewives.<sup>6</sup>

.2 Research conducted in Sunsari district, where the prevalence rate of female alcohol consumption was 16.8% at 2004 and this shows that the alcohol consumption among the women has been nearly doubled in the period of 9 years because Sunsari Health Survey 1994 had reported 8.3% women consumed alcohol in Sunsari. 4

### **Rational of the problem:**

This study was so chosen to know the prevalence of this habit and the factors affects to consume alcohol. It has also set the relationship between alcohol drinking habits to the other factors. Finally, the problems and the reason of alcohol intake in female are highlighted. The burden of the alcohol among the suburban community will be revealed by this study. Thus the information will be utilized to devise appropriate intervention program to reduce the burden of alcoholism. Ultimately the findings will be beneficial to devise policy and plan to This study will be explored the prevalence of this habit and the factors affects to consume alcohol. It has also set the relationship between alcohol drinking habits to the other factors. Finally, the problems and the reason of alcohol intake in female are highlighted. The burden of the alcohol among the suburban community will be revealed by this study. Thus the information will be utilized to devise appropriate intervention program to reduce the burden of alcoholism. Ultimately the findings will be beneficial to devise policy and plan to reduce the burden of alcoholism. The study can be the baseline study for the future population based study. reduce the burden of alcoholism.

**Conceptual framework:**



Research Objectives / purpose / aim of the study:

General

To identify the prevalence and assess the strength, causes and problem of alcohol consumption in khokana VDC.

Specific

To identify the prevalence rate of female alcohol consumption  
To assess the factors related to the habit of alcohol consumption.  
To identify the problems of alcohol consumption among women.

7. Research Design and Methodology

Research Method

Qualitative  Quantitative  Combined

**Study Variables:**

Independent variables
Demographical variables
Smoking habit
Peer pressure
Family member
Availability
Mass media
Dependent variable
Prevalence and contributing factors of female alcohol consumption
Problems due to alcohol consumption

**Type of Study (Specify):**

Descriptive Cross Sectional Study Design
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**Study Site and Its Justification:**

This study will be conducted in khokana VDC in lalitpur district because it is a typical newari community where there most of the female are consuming alcohol due to different reason. There are also lots of effects due to alcoholism. And this is my home town so that it is feasible to conduct research.
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**Study Population (Specify):**

Female of khokana VDC above 15 years of age.
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**Study Unit:**

Ward no. 2 and 5
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**Sampling Methods / Techniques (Specify):**

Population is homogeneously distributed in the wards, the cluster sampling with Probability Proportionate to Sample Size (PPS) technique was used to represent the target population.

**Sample size (with justification):**

Two cluster of size 144 females (>15years) will be selected from ward 2 and 5. Because population is homogeneously distributed in the wards, the cluster sampling with Probability Proportionate to Sample Size (PPS) technique will be used.

**Data Collection Technique / Methods (Specify):**

Interview guideline will be used to collect the data because most of the housewives of khokana VDC are illiterate so that interview technique is suitable for the data collection.

**Data Collection Tools: (please attached in annex)**

**Pre-testing the Data Collection Tools (if applicable):**

Pre-testing will be done in similar site Bungamati VDC.

### Validity and Reliability of the Study Tools:

Following points will be considered to maintain the validity and reliability:

- Review of the literature.
- Consulted with subject teacher, research expert and supervisor.
- Pre-test had done involving of 10% of total people.
- On the basis of feedback some modification of the questions had done.

### Potential Biases (if applicable):

### Limitation of the Study:

- The study is limited to khokana VDC only. Therefore this study cannot be generalized.
- This academic research will be conducted within limitation of time, location and resources.
- The study is limited to small sample size.

### 8. Plan for Supervision and Monitoring:

### 9. Plan for Data Management and Analysis:

After the collection of information the data, it will be checked for completeness. The data will be coded and entered in SPSS 16.0 version. The collected will be processed and analyzed by using simple descriptive statistics in terms of percentage and frequency. Necessary findings will be presented on the relevant tables.

**10.Expected Outcome of the Research:**

This study will show the high prevalence rate of female alcohol consumption and different factors affected to this habit. This study will show the problems experienced by female during consumption.

**11.Plan for Dissemination of Research Results:**

The researcher intends to disseminate the findings of the study through submission of written report to the following institute and persons.

- One copy of research will be submitted to my advisor.
- One copy of research report will be given to MMIHS library.
- One copy of research report will be prepared for self.
- One copy of research report will be prepared for Khokana VDC Office.

**12.Plan for Utilization of the Research Findings (optional):**

**How is the research project going to strengthen the research capability of the host institution: Nepali Researcher (if submitted from abroad):**

13. Work Plan (*should include duration of study, tentative date of starting the project and work schedule / Gantt chart*):

**WORK PALN**

SN	Activities	1 <sup>th</sup> week	2 <sup>nd</sup> week	3 <sup>rd</sup> week	4 <sup>th</sup> week	5 <sup>th</sup> week	6 <sup>th</sup> week
1	Literature review	✓	✓	✓	✓	✓	
2	Topic selection	✓					
3	Topic presentation	✓					
4	Proposal writing/ presentation		✓				
5	Pre-testing			✓			
6	Data collection				✓	✓	
7	Data analysis					✓	
8	Report writing					✓	
9	Defense						✓
10	Submission of the report						✓

## Part – III

### Ethical Consideration

14. Regarding the human participants:

Are human participants required in this research? If yes, provide justification.

Yes (*provide justification*)      No

Because I am going to conduct the research related with the human habit n their problems so that a human participant is required for getting detail information.

How many participants are required for the research? Explain.

There should be about 144 participants required because this sample size came by using cluster sampling calculation.

What is the frequency of the participant's involvement in the research? Explain.

The participants are involved for a single time because it is cross-sectional study.

Clearly indicate the participant's responsibilities in the research. What is expected of the research participants during the research?

- ❖ During research the participants are expected to be co-operative.
- ❖ During research the participants are expected not to leave any questions.
- ❖ During research the participants are expected to to answer according to their own knowledge.
- ❖ During research the participants are expected to tick answer clearly.

Are vulnerable members of the population required for this research? If yes, provide justification.

All women included above 15 years of age .

Are there any risks involved for the participants? If yes, identify clearly what are the expected risks for the human participants in the research and provide a justification for these risks.

No any risk to the participants.

Are there any benefits involved for the participants? If yes, identify clearly what are the expected benefits for the participants.

#### 15. Informed Consent Form / Ethical Issues:

Statements required in the Informed Consent Form include:

A statement that the human participants can withdraw from the study at any time without giving reason and without fear. State clearly how the participants can opt out the study.

A statement guaranteeing the confidentiality of the research participants.

If required, a statement on any compensation that might be given to the research participant and or their community.

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 the date.

*(Informed Consent form should be submitted in English and in the language appropriate to the research participants)*

Obtaining the Consent

How informed consent is obtained from the research participants?

Verbal       Written

Please indicate who is responsible for obtaining informed consent from the participants in this research study?

.....the researcher sujata maharjan  
.....

Is there anything being withheld from the research participants at the time the informed consent is being sought?

If yes, explain  
.....

Is the research sensitive to the Nepali culture and the social values?

Yes       No  Explain.

.....

Is health insurance (*if applicable*) being made available to the research participants? If yes, please provide the necessary insurance data.

.....

(Include in consent form)

16. If Clinical trial, continue (if not go to Part IV)

In case of a clinical trial address the following:

The trial treatment  
.....

A detailed explanation of the trial procedures including all invasive procedures.  
.....

The potential or direct benefits (if any) for the research participants.

.....

Alternative procedure(s) or treatment(s) that may be available.

.....

The risks, discomforts, and inconveniences associated with the study

.....

Provisions for management of any adverse reactions

.....

The provisions of insurance coverage for any permanent disability or death caused directly by the investigational treatment or procedure.

.....

The provision of including the name and address, including telephone numbers of person to be contacted in case of adverse events or for any information related to the trial.

.....

Is there going to be a transfer of any biological materials from the country? Explain.

.....

Is there a Data Safety Monitoring Board?  
If Yes, Mention

.....

Is this trail internationally registered?

.....

**Part – IV**

**ACCEPTANCE OF GENERAL CONDITIONS AND DECLARATION  
BY THE PRINCIPAL INVESTIGATOR**

I hereby certify that the above mentioned statements are true, I have read and understood the regulation of the MMIHS/IRC on the approval of research proposal and will act in conformity with the said regulation in all respects.

If the research is terminated, for any reason, I will notify MMIHS/IRC of this decision and provide the reasons for such actions. I will provide MMIHS/IRC with a written notice upon the completion of the research as well as a final summary/full report of the research study. If I publish the results in a journal, I shall acknowledge the MMIHC/IRC and shall provide the Council with three copies of any such articles.

.....

**Signature of Applicant**

**Date:** .....

**INFORMED CONSENT:**

- ⌚ Describe the manner in which informed consent will be obtained.
- ⌚ Indicate what kind of consent (e.g. parental, child, adult, etc) will be used.
- ⌚ If the subjects are children/adolescents ages 7-18 years, an Assent Form must be included with the IRC application. The signed Assent Form along with the Parental/Guardian Consent Form must be retained on file for at least three years after completion of the research project.
- ⌚ If prisoners / pregnant women, or fetuses are to be included in the research sample, it is likely that a full IRC review will be required and additional human subjects' protections will be expected.
- ⌚ If the subjects do not read or comprehend English, you must provide a consent form in their language as well as in English for IRC review and approval.
- ⌚ If you are requesting a waiver of written consent (i.e. a signature on an informed consent form) from the subjects, you **MUST** justify this request by providing an explanation of why obtaining written consent would add additional risk to the subjects and your alternative provisions for informing them about the study.
- ⌚ If consent documents from another site will be used, you will have to indicate this and provide a copy of the authorized consent document and IRC approval with your application.
- ⌚ You will have to provide any other relevant information if necessary. Please be aware that the PI is legally required to retain all signed Informed Consent forms for at least three years after the project terminates
- ⌚ The Informed Consent form must be written at a level that the subjects will understand. Please use simple language, and avoid clinical jargon.
- ⌚ Attach a copy of the written informed consent form (assent or parental consent where applicable). Consent documents **MUST** be in format requested. See examples on line.
- ⌚ If the study uses database or archival data the use of informed consent is not applicable.

**CONFIDENTIALITY OF DATA: *Confidentiality of data MUST be address for all studies.***

- ⌚ Indicate the extent to which confidentiality of records identifying subjects will be maintained.
- ⌚ Describe the storage and disposal of information where applicable.

## Check List

### For all applicants

1. Covering letter addressed to the Member secretary indicating the submission of the approval of proposal.
2. Proposal will only be accepted if submitted in MMIHS/IRC format.
3. Both printed and electronic version of the proposal should be submitted.
4. Curriculum Vitae of the Principal Investigator & Co-Principal Investigator of the study team should be submitted.
5. If the Principal Investigator is a non Nepali citizen, at least one Co-investigator should be a Nepali citizen.
6. Submission of the application processing fee to MMIHS/IRC
7. Source of funding for the proposed project.
8. If the research study is to be conducted in any hospitals/organization or institution/community, a letter of approval from the related hospital/organization or institution/district authority should be provided.
9. Consent form should be in Nepali & local language (if necessary).
10. Data collection tools should be in Nepali & local language (if necessary) including interview guideline, observation checklist, questionnaires etc.
11. Style of referencing should be in Harvard style.
12. List of abbreviations / acronyms should be provided.

### For students' applicants

1. Approval letter from concern departments.
2. Recommendation letter from Academic Supervisor.