

Report

Training Workshop on Ethics in Health Research

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BACKGROUND

Janaki Medical College (JMC) organized a two-day training workshop with the cooperation of experts from the Nepal Health Research Council (NHRC), Ramshah Path, Kathmandu, Nepal, with notice from the department of research and publication on December 20, 2022. The NHRC is a national apical body responsible for supporting quality health research in the country with the highest level of ethical standards. It started as a Nepal Health Research Committee under the Ministry of Health, chaired by the Secretary of Health in 1982 AD (BS 2039) and the Council of Ministers under Article 129 of the constitution of the Government of Nepal, 1990 enacted the NHRC [1]. Janaki Medical College was

established in Ramdaiya, Bhawadi of Dhanusha District in Madhesh Province in December 1999 affiliated to Tribhuvan University and delivers health education and health care services running MBBS, MD and allied paramedical courses through its competent professionals in medical academia [2]. The theme of the training workshop was 'Ethics in Health Research'. The training came up between the 26th and 27th of December, 2022 (11-12 Poush 2079) in Academic Block at the Janaki Medical College Teaching Hospital, Ramdaiya Bhawadi, Kshireswarnath Municipality, Madhesh Province Nepal.

The purpose of this training was to orient Institutional Review Committee (IRC) proposed members and to enable all participants to understand, share and apply the moral principles stated in the code of research ethics. The training methodology was interactive and trainers engaged participants in discussions and kept the forum open for feedback, queries and suggestions. These discussions and interactive sessions were supported through training material such as pre and post-test, power point presentations and handouts.

All of the 12 facilitators were from Nepal Health Research Council (See Annex 1a and

1b). Out of total 18 participants, 17 were from Janaki Medical College (JMC) and one from Madhesh Institute of Health Sciences (MIHS) (See Annex 2). Photographs of training workshop are listed (See Annex 3)

Workshop Objectives

1. To orient proposed members of IRC on Ethics in Health Research and Ethical Review Process
2. To enhance the knowledge and skill in reviewing health research proposals

Day 1 – 26th December, 2022, Monday

Introduction to training workshop and objectives

On 26th December 2022, the first day of training started at about 10 am with the conduct of formalities – joining zoom, welcome address, the introduction of participants, introduction to the aim and objectives of the workshop, and a pre-test. Pre-training assessment test was obtained from the participants. Throughout the 12 sessions from experts, there were a lot of conversations, queries, explanations, and experience sharing. The major discussions held on the history of NHRC and evolution of ethics, principles of research ethics, informed consent, guidelines of IRC formation, community participation in research, standard of care in research, and monitoring of approved research.

SESSION I: An Overview of Nepal Health Research Council and its Roles and Responsibilities

Dr. Pradip Gyanwali, Executive Chief (Member Secretary), NHRC officially began the training program by presenting the first

session, which provided an overview of the Nepal Health Research Council's functions. He discussed the background of medical research in Nepal and stated that the Nepal Medical Research Committee (NMRC), the country's first regulatory organization for medical research, was established on April 15, 1982, by the Ministry of Health. The Nepal Health Research Council (NHRC) was formally established by an act of parliament on April 12, 1991, over ten years after it had been active in overseeing health research in the nation. The primary responsibility of NHRC is to coordinate and promote health research for the benefit of Nepalese citizens. The Ministry of Health and Population (MoHP) is designated as a line ministry for reporting by the NHRC. The growth of health research in Nepal, the NHRC's guiding principles, its ongoing research projects, the COVID-19 clinical research in Nepal, and its long-term objectives were all topics of discussions that he led. Major discussions included:

- NHRC Act 1991
- NHRC Executive Committee
- Nepal health Policy, 2019
- Promoting high-quality health research for improving the health of people in Nepal
- Evidence generation and Promotion
- Recent major health Research Evidences such as Chronic disease survey (2016-2018), STEPS Survey(2019), Mental Health Survey (2019), rATA Project (2022)
- NHRC collaborations and publications

SESSION II: An Overview of Guidelines for Institutional Review Committees (IRCs) for Health Research in Nepal 2016

The second trainer during the 1st day of training, Dr. Meghnath Dhimal, Chief, Research Section, NHRC delivered the session on key features of IRC Guidelines 2016, formation, composition, and role of an IRC, IRC office and its quorum and IRC's relationship with NHRC. He highlighted IRC as an independent body comprised of medical, scientific, and non-medical members, whose responsibility is to ensure the protection of the rights, safety, and well-being of human participants in a particular research project, and to consider general health research ethics, thereby providing public reassurance.

In his presentation, he covered a framework for the formation of IRCs, the functional procedures they should adhere to when reviewing and approving health-related research proposals, and how to make sure that the provisions of national guidelines released by the NHRC are followed each time a health-related research proposal is reviewed, approved, and monitored. The IRC ought to conduct prompt, competent, and unbiased reviews of research proposals. The tasks of the IRC should be executed free of bias and any political, institutional, or professional influence. The IRC has the authority to ask for research protocol modifications, and to enforce and monitor the conduct of research projects. Additionally, he spotlighted that the IRC should be pluralistic and multidisciplinary. The chief executive officer or head of the institution should not be the member of any IRC. The IRC should have the freedom to work independently and decide on the merits of research proposals without interference.

Also, he emphasized all IRC members should have the necessary expertise, appropriate educational degree, and research

experience in health-related research processes. IRC members should be appointed by the institutional authority. The selection process should be transparent. Conflicts of interest should not exist when making appointments. The head of the institution should only appoint the chairperson. The chairperson will appoint the other members, including the member secretary. A gender balance should be established in the membership of IRC. The significant discussion points were:

- History of health research in Nepal
- Health research regulation in Nepal
- An overview of Guidelines for IRC in Nepal
- IRC office and appointment of IRC Members
- IRC's Role in supervision and monitoring of health-related Research
- IRC's relationship with NHRC
- Research proposals requiring ERB, NHRC approval
- Special instructions to IRC's

SESSION III: An Overview of National Ethical Guidelines for Health Research in Nepal 2022

The National Ethical Guidelines for Health Research in Nepal 2022 session was attended by Ms. Namita Ghimire, Ethical Review Monitoring and Evaluation Section, NHRC. She described about the four ethical principles of autonomy, beneficence, non-maleficence, and justice that are essential to research involving human subjects. These four internationally recognized ethical principles are also the foundation of ethically valid health research. Furthermore, it is equally important to respect the environment of research participants to protect their well-

being and the dignity of the community. She highlighted:

- Ethical issues in health research
- Responsible conduct of health research
- Ethical review process, responsible conduct of health research and qualification of researchers
- Different types of review and also emphasized the do's and don'ts for IRC
- Informed consent process in health research
- Specific requirements for specialized research
- Establishment of Institutional Review Committees

SESSION IV: Elements of Review for Ethical Aspects of Research

After lunch on Day I, Prof. Dr. Ramesh Kant Adhikari, Chairperson, ERB, NHRC led the session on the review of ethical aspects of research. He noted that the IRC's main responsibility is to evaluate research proposals and the materials that support them, paying particular attention to the informed consent procedure, the supporting materials, and the acceptability and practicality of the protocol. Key discussions included:

- Ethical elements involved in research with human participation
- Technical components of health research
- Ethical Principles of health Research
- Elements of technical review
- Tasks of review committee

SESSION V: Issues in Protocol Review

Prof. Dr. Mohan Sharma, Director, Research Department, Institute of Medicine presented an interesting session on protocol review issues. He described protocol review as an assessment of the protocol to ensure that the study can be completed successfully given the available resources and capabilities. He discussed how decisions about the review question, inclusion criteria, search strategy, study selection, data extraction, quality assessment, data synthesis, and dissemination plans should be addressed. Major discussions included:

- Importance of Ethical review
- Components and Categories of Review
- Steps in Protocol evaluation process

SESSION VI: Accessing Literature using Research4life Programme

Mr. Chandra Bhushan Yadav, Library and Information Officer, NHRC conducted the webinar session on accessing literatures using Research4life Programme. He emphasized that one of the most significant and noteworthy aspects of search engines to access and acquire information easily. Various search engines can play an important role in obtaining medical information for researchers, medical professionals and lay people. He also explained Research4Life has provided researchers at more than 11,000 institutions in over 125 lower- and middle-income countries with free or low-cost online access to over 198,000 leading journals and books in the fields of health, agriculture, environment, applied sciences and legal information since 2002. Major areas of focus were:

- How to build a search strategy
- Use the access options on the Research4Life platform

- Use Summon to search across Research4Life programmes
- Use Google Scholar to search for resources available via Research4Life
- The values of Research4life
- Search engines available on the Web

- Informed consent Evaluation Form
- Elements of Information Sheet
- Elements of certificate of Consent
- Different Samples of Informed Consent

Day Second (27 December 2022, Tuesday)

Recap of Day 1

Day 2 started off with the previous day's recap, participants were asked to share the learning of first day. Participants shared their learning and also provided feedback on training contents, and training delivery of Day 1. They appreciated that contents were in line with the training objectives and easy to understand and they liked the training methodology. Ms. Namita Ghimire from NHRC reviewed the sessions of the Day 1 again and the Day 2 session initiated.

SESSION VII: Review of Informed Consent Document

In a presentation on informed consent, Ms. Santoshi Adhikari, Research Officer, Ethical Review M & E Section, NHRC emphasized every facet of the review of informed consent. She underlined that informed consent is a method by which the researcher approaches prospective participants before enrollment. The participant must be informed of the research's goals and objectives, their roles and responsibilities, the research processes, and any potential advantages and disadvantages of participating. Prior to starting any research involving human subjects, informed consent must be documented. The privacy and confidentiality of the participant's personal information must also be respected during the entire study. She discussed:

SESSION VIII: Selection of Appropriate Statistical Methods for Data Analysis

Dr. Umesh Raj Aryal, Statistician, NHRC led a session on data analysis and statistical techniques. He implied that the use of statistical techniques is crucial for scientific research. As a matter of fact, statistical approaches predominate in scientific research since they cover planning, designing, data collection, analysis, interpretation, and reporting. However, without statistical analysis, the research project outcomes are just worthless raw data. Determining statistics in research is of utmost necessity to justify research findings. His major discussions highlighted:

- Statistical analysis and design
- Establishing a sample size
- Testing of hypothesis
- Concepts of Variables
- Types of statistical research methods that aid in data analysis
- Common errors done during analysis
- Advanced statistical methods

SESSION IX: Enhancing Quality of Review

Ms. Ghimire, Ethical Review M & E Section, NHRC emphasized the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) recognition program as a monitoring and evaluating program for continuous quality improvement of ethical review systems. The major discussions included:

- SIDCER recognition program methods
- Standards of quality ethical review
- SIDCER recognition criteria
- Completeness of review Process
- Systems thinking approach

SESSION X: Conduction of EC Meeting, Format of EC Minutes, Format of SoPs, Documentation and Archiving

Ms. Ghimire after session IX, spent a considerable amount of time discussing running IRC meetings, and minuting documentations and archiving. She made a point of saying that documentation serves as proof of the work you have completed. Major highlights were:

- Preparation for EC Meeting
- Format of EC Minutes
- Format of SOP
- Management of Study files
- Files of EC members/Staffs
- Maintenance of Active files
- Tracking the files
- Communication Records
- Management of Database
- Module feedback reports
- Annual Module Review forms

SESSION XI: Publishing Article in a Journal

Prof. Dr. Gehanath Baral, Chairperson, NHRC presented about publishing an article in a journal. He emphasized that scientific writing is not just writing about science; it is an art. It is a technical form of writing that is designed to communicate scientific information to other researchers and scientists. Clarity, economy, and the correct use of words and phrases are requirements for scientific writing. He also highlighted the peer review process, moral dilemmas, journal selection,

and indexing. Important hallmarks of publishing a scientific article were discussed including:

- Process of publishing an article
- Choosing an appropriate Journal
- Writing the manuscript
- Structure of Full article
- Steps in publishing an article
- Peer review process of an article
- Ethics Issues in publishing
- Reasons for rejection of research papers

SESSION XII: Experience Sharing of IRC

Dr. Hari Prasad Dhakal, Coordinator, IRC Accreditation Sub-Committee, NHRC provided an overview of the main duties and roles of IRC using his prior experiences with the organization. He emphasized the support for strategic planning and problem-solving on initiatives aligned with the IRC's main goals. His contributions included developing IRC, managing and mentoring other team members, and mediating during times when difficult conversations and crucial decisions needed to be made. He underlined the need for IRC members to have great interpersonal skills, positive attitude, a high level of personal initiative, and the capacity to function successfully in a highly diverse workplace. His experiences shared were:

- Purpose of IRC
- Establishment and renewal of IRC
- Need for support from the institution's management
- Non-interference of management in ethical review process and approval
- Need of infrastructure and all logistics
- Relation of IRC with ERB-NHRC
- Need for SOP for operation of IRC

- Circulation of agendas of meeting to IRC members 48 hours before meeting
- Quorum in IRC meeting
- Minuting of meeting decisions
- Periodic monitoring of the approved research
- Challenges faced by IRC

Training Evaluation and Post test

At the end of the training, all the participants were given a Post-test evaluation form to complete. The pre and post test analysis showed the training did result in significant improvement in knowledge. The overall evaluation also showed participants acquired new skills.

Benefits from the training workshop

- Understanding the Guidelines for IRC in Nepal
- Relationship of IRC with ERB-NHRC
- Ability to write a proper research protocol, understand the fundamental principles
- Improved capacity to review a research protocol and provide constructive feedback
- Ethical review process and review of journal articles
- Major tasks of review committee
- Important steps in protocol evaluation process
- Monitoring of research work
- How to write an informed consent form
- Understanding the important role of the NHRC in research
- Ethical issues in health research
- How to use Summon to search across Research4Life programmes
- Statistical analysis and design

- Common errors during analysis
- Preparation for EC Meeting and Communication records
- Possible reasons for rejection of research papers
- Non-interference of management in ethical review process and approval

Sharing Experiences from Participants

Before certificate distribution participants were asked for opinions on the two days of training. All participants noted that the program addressed the training workshop objectives. On behalf of all the attendees, Mrs. Lecturer Mala Rijal from the nursing department and Associate professor Dr. Satyam Prakash from Biochemistry Department shared their feedback and perspectives about the two-day training session. Mrs. Rijal emphasized the value of training. Dr. Prakash thanked everyone for actively participating and continued to discuss the benefits of this training course for enhancing their ability to identify and analyze ethical dilemmas. In order to develop the publishing standards and research culture at Janaki Medical College, he also shared about his experiences as managing editor of the Janaki Medical College Journal of Medical Sciences (JMCJMS) since establishment of the Journal. He expressed hope that the higher authorities at Janaki Medical College would fully support the development of the IRC into a functional IRC and its speedy integration with ERB-NHRC. He felt immensely appreciative of all the effort that went into finishing the training session.

Certificate Distribution and Closing of Workshop

Prof. Dr. Jay Narayan Sah, the principal of the JMC, and Prof. Dr. Dharma Datta Subedi, the medical director of the JMC, officiated the

training's certificate distribution and closing ceremony. The event began with a statement of appreciation by Prof Sah, after which he addressed the attendees, asked about their learning experiences, and distributed training certificates. He also emphasized the continuation of in house trainings in the future. During the closing ceremony, Prof. Kshitiz Upadhyay Dhungel, Department of Research and publication recalled the commencement of the research department and journal at Janaki Medical College, the different ideas behind the ERB, IRB, and IRC, and he recounted his experiences as the editor-in-chief of JMCJMS.

Finally, Prof. Dhungel handed the mementoes to Prof. Sah to present to the NHRC members as a remembrance of Janaki Medical College representing Madhesh Province's heritage and identity. The training workshop was officially closed by Dr. Pradip Gyanwali, Executive Chief (Member Secretary), NHRC. He congratulated all the attendees, and thanked all the trainers, Department of research and Publication along with the dignitaries of Janaki Medical College for the successful completion of the two days training workshop.

Suggestions for improvement of the training

- Increment in the duration of the training to 4-5 days and reduction of time spent per day
- Conference hall should be spacious with all physical facilities including Audio/Visual Aids
- Requirement to increase the number of facilitators available on site
- Involvement of participants during workshop should be enhanced

- Number of slides should be kept optimum by the facilitators
- Discussion session should be kept after each session
- Statistical analysis sessions should have the practical session
- Increase the time frame of lunch and relaxation
- Need to maintain the interactive and learner-centered approach
- Pre-test and Post-test scores should have been shown to participants to determine what was learned and areas that need to be strengthened or followed up
- Need to improve on time management
- Registration fee should be either fully waived or partially waived for institutional affiliates

Acknowledgement

I would like to express my deepest appreciation to organizing committee of this training workshop that provided me all the possibilities to complete this report. I am also thankful to the Nepal Health Research Council, the department of research and publication, and the college's authorities of Janaki Medical College for taking the initiative towards this beneficial training and its successful completion at Janaki Medical College Teaching Hospital.

REFERENCES

1. Nepal health Research Council. Website: <https://nhrc.gov.np/>
2. Janaki Medical College. Website: <https://www.janakimedicalcollege.edu.np/>

Appendix 1(a): Training Workshop Schedule (Day I: 26 December 2022, Monday)

Time	Name of the Trainers	Designation	Topics and Program Schedule
10:00-10:30			Join Zoom / in person workshop / Introductions/Opening of the Program
10:30-11:15	Dr. Pradip Gyanwali	Executive Chief (Member Secretary), NHRC	An Overview of Nepal Health Research Council and its Roles and Responsibilities
11:15-12:15	Dr. Meghnath Dhimal	Chief, Research Section, NHRC	An Overview of Guidelines for Institutional Review Committees (IRCs) for Health Research in Nepal 2016
12:15-01:00	Ms. Namita Ghimire	Ethical Review M & E Section, NHRC	An Overview of National Ethical Guidelines for Health Research in Nepal 2022
01:00-01:30			Lunch
01:30-02:30	Prof. Dr. Ramesh Kant Adhikari	Chairperson, ERB, NHRC	Elements of Review for Ethical Aspects of Research
02:30-03:30	Prof. Dr. Mohan Sharma	Director, Research Department, Institute of Medicine	Issue in Protocol Review
03:30-03:45			Tea Break
03:45-05:00	Mr. Chandra Bhushan Yadav	Library and Information Officer, NHRC	Accessing Literature using Research4life Programme

Appendix 1(b): Training Workshop Schedule (Day II: 27 December 2022, Tuesday)

Time	Name of the Trainers	Designation	Topics and Program Schedule
9:00-9:30			Recap of Day I
9:30-10:15	Ms. Santoshi Adhikari	Research Officer, Ethical Review M & E Section, NHRC	Review of Informed Consent Document
10:15-11:15	Dr. Umesh Raj Aryal	Statistician, NHRC	Selection of Appropriate Statistical Methods for Data Analysis
11:15-12:00	Ms. Namita Ghimire	Ethical Review M & E Section, NHRC	Enhancing Quality of Review
12:00-01:00	Ms. Namita Ghimire	Ethical Review M & E Section, NHRC	Conduction of EC Meeting, Format of EC Minutes, Format of SoPs, Documentation and Archiving
01:00-02:00			Lunch
02:00-02:30	Prof. Dr. Gehanath Bara,	Chairperson, NHRC	Publishing Article in a Journal
02:30-03:15	Dr. Hari Prasad Dhakal	Coordinator, IRC Accreditation Sub- Committee, NHRC)	Experience Sharing of IRC
03:15-03:30			Tea Break
03:30-04:30	Dr. Satyam Prakash	Associate Professor, Biochemistry, JMCTH	Sharing Experiences from Participants of IRC/Feedback
	Mrs. Mala Rijal	Lecturer, Nursing, JMC	
4.30-5.30	Prof. Dr. Jay Narayan Sah	Principal, JMCTH	Certificate Distribution and Closing of Workshop
	Prof. Kshitiz Upadhayay Dhungel	Department of Research and Publication, JMCTH	
	Prof. Dr. Dharma Datta Subedi	Medical Director, JMCTH	
	Dr. Pradeep Gyanwali	Executive Chief, NHRC	

Appendix 2: Attendance List of Participants

S.No	Name	Department	Affiliation	Email
1.	Dr. Satish Kumar Sah	Community Medicine	JMCTH	shonarsatish@gmail.com
2.	Mrs. Khushbu Yadav	Microbiology	JMCTH	meetkhushi20@gmail.com
3.	Mr. Ramesh Nayak	Physiology	JMCTH	nayakramesh130@gmail.com
4.	Mrs. Mala Rijal	Nursing	JMCTH	malarijal4@gmail.com
5.	Dr. Satyam Prakash	Biochemistry	JMCTH	sprakashy2424@gmail.com
6.	Dr. Mina Jha	Anatomy	JMCTH	drminajha@gmail.com
7.	Dr. Ram Chandra Shah	Pharmacology	JMCTH	rampharmashah@gmail.com
8.	Dr. Jitendra Kumar Singh	Community Medicine	JMCTH	jsingdj@gmail.com
9.	Dr. Deepak Raj Paudel	Pediatrics	JMCTH	deepak79727@gmail.com
10.	Dr. Krishna Deo Das	Hospital Administration	MIHS	kddas2014@gmail.com
11.	Dr. Lokeshwar Chaurasia	Pharmacology	JMCTH	dr.lokc34@gmail.com
12.	Dr. Surya Narayan Mahaseth	Microbiology	JMCTH	dosurya@gmail.com
13.	Dr. Jay Prakash Prasad Kumal	Anatomy	JMCTH	jppkumal@gmail.com
14.	Dr. Krishna Adhikari	Surgery	JMCTH	adhikarikrishna@gmail.com
15.	Dr. Khagendra Gautam	Surgery	JMCTH	sanjaya2049@gmail.com
16.	Dr. Sachin Chaudhary	MDGP	JMCTH	sachin716189@gmail.com
17.	Dr. Nishant Mishra	MDGP	JMCTH	nishantmishra98480@gmail.com
18.	Mr. Inarjit Kumar Yadav	Library	JMCTH	inarjit50495@gmail.com

Appendix 3: Photographs



