



Health Research Ethics and Evaluation of Medical/Health Institutes designated as Research Centers in Nepal

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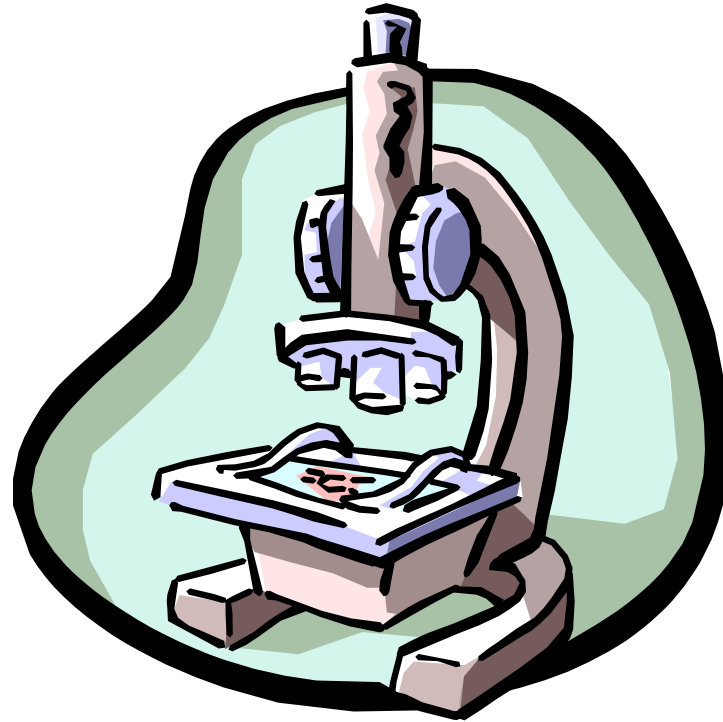
Ph.D. (Tropical Medicine)

Nepal Health Research Council

Presentation focused on

- General Introduction
- Ethical Review Process in NHRC
- Evaluation of Medical/Health Institutes designated as “Research Center” in Nepal
- Current Challenges

If a health research system is the “brain” of a health system



... then health research ethics represents its “conscience”!

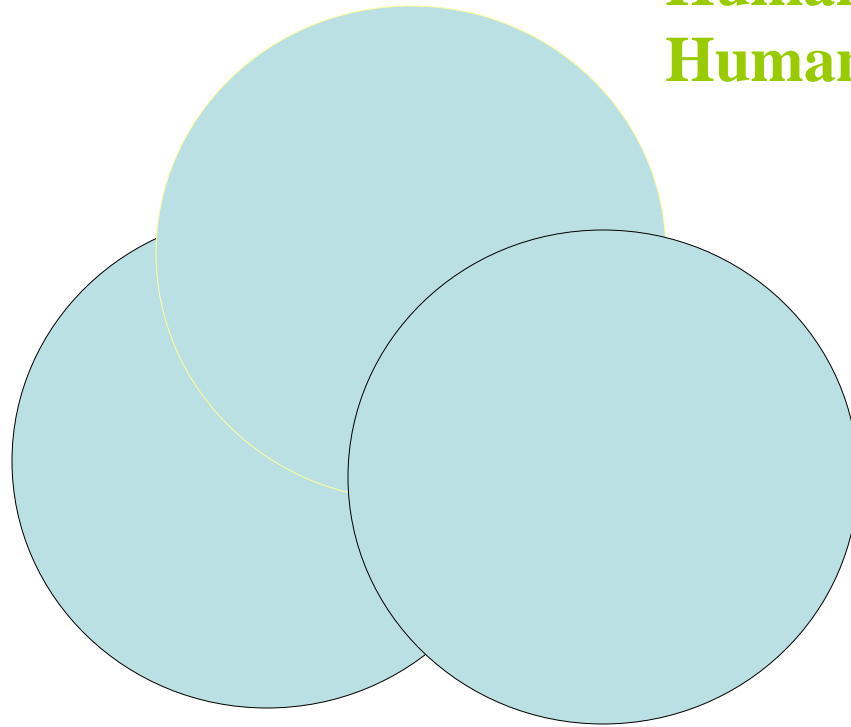
The players in health research



Who bears the burden of research failure to support essential national health research?

Views/Points

**Human Rights &
Humanity**



**Ethical design &
conduct of research**

**Scientific &
Technical Competence**

Milestones of Ethical Review Process in Nepal

Milestones of Ethical Review Process in Nepal

- **1982** NMRC established
- ERC, Research proposal approval, Research focal points issues raised.
- **1983** ERC policy preparation started.
Policy making work initiated for the proposal submitted by foreign researcher.
- **1986** There should be at least one Nepali researcher among the foreign researcher's team who wanted to conduct health research in Nepal.
- **1987** Research has to be conducted after NMRC permission only.
- **1990** 1% charge should be taken from all kinds of proposals submitted for approval.

Milestones of Ethical Review Process in Nepal

- **1991** NHRC Established
Reviewing process formulation work initiated.
- Identification of research priority area was initiated.
- **1995** Health research priorities formed.
- Guidelines and conditions in considering research proposals were formed.

Milestones of Ethical Review Process in Nepal

- **1997** First NHRC Ethical Guidelines.
- **1998** High Level Consultative Meeting to Identify Priority Issues for Research in Health (**31 July 1998**).
- Conference on Prioritization of ENHR Area (**12-14 August 1998**).
- **2000** Consultative Meeting on Development of National Ethical Guidelines for Health Research in Nepal (**12-15 November 2000**).

Milestones of Ethical Review Process in Nepal

- **2001** National Ethical Guidelines for Health Research in Nepal.
- **2002** Dissemination of National Ethical Guidelines of NHRC (**29 August 2002**).
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- Workshop on National Health Research Agenda, Policy, Priority (**31 August - 2 September 2002**).

Milestones of Ethical Review Process in Nepal

- **2003** 2% will be charged for the proposal having budget more than US\$ 10,000, and US\$100 will be charged for the project having budget less than US\$ 10,000. **(25 August 2003)**

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- **Published:** National Health Research Policy.

Strengthening the Capacity

Training Workshop on **Ethical Issues in International Health Research** organized by NHRC and sponsored by *WHO* held in *BPKIHS*, Dharan, Nepal **(8-11 July 2003)**.

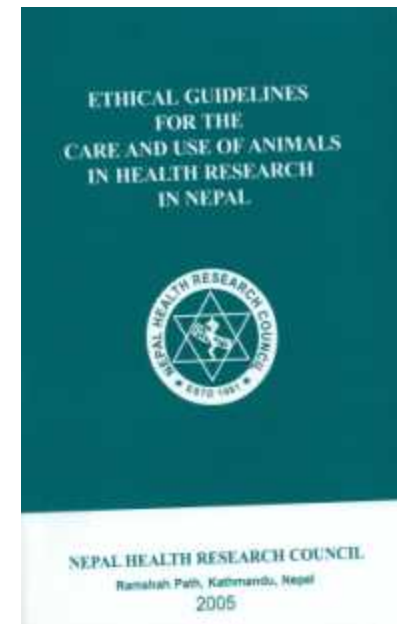
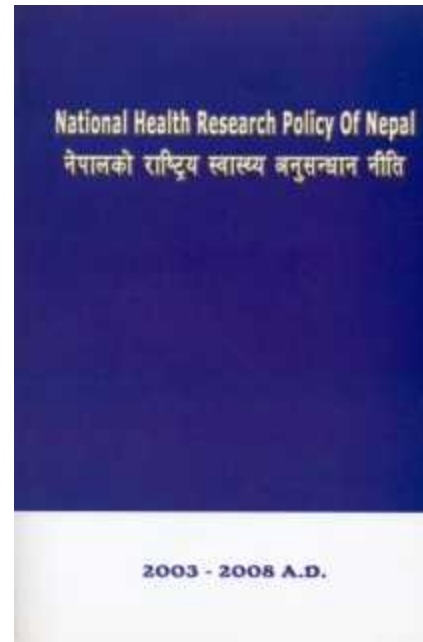
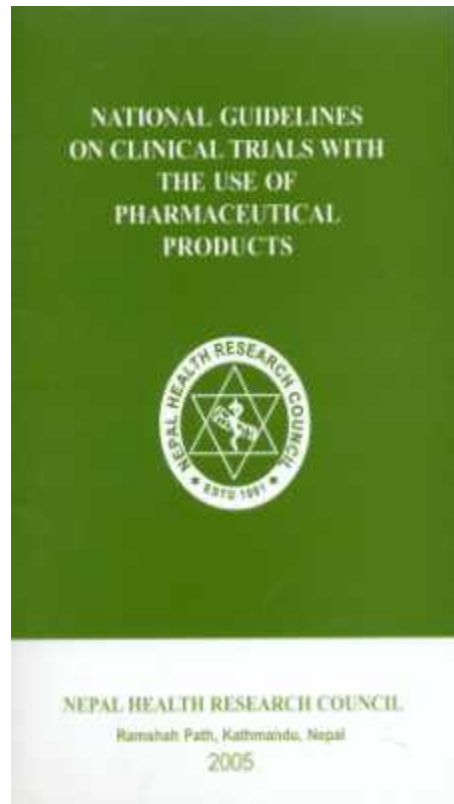
- Training on **Research Ethics** jointly conducted by *NHRC* and *FHI – Nepal* held in *Park Village Hotel & Resort*, Budhanil-Kantha, Kathmandu, Nepal **(29-30 August 2003)**.

Milestones of Ethical Review Process in Nepal

2005

- National Guidelines on Clinical Trial with the Use of Pharmaceutical Products.
- Ethical Guidelines for Care and Use of Animals in Health Research in Nepal.
- Guidelines for Institutional Review Committees for Health Research in Nepal.

Ethical Guidelines and Health Research Policy



NHRC has given permission to function as independent Ethical Review Committee as IRB

- Institute of Medicine (IOM) (*Research Committee – 5 members; Ethical Committee – 6m, Technical Sub Committee –6m*)
- B.P. Koirala Institute of Medical Sciences (BPKIHS) (*Institutional Ethical Review Board – 10m*)
- Royal Nepal Academy of Science & Technology (RONAST) (*Science Research and Development Committee – 7m*) (*Technology Research and Development Committee – 6m*)
- Research Division, Tribhuvan University

Permission in Process

1. Sahid Ganga Lal National Heart Center
(*Existed Ethical Review Committee – 5 members*)

Information Received

2. Medicare National Hospital and Research Center
(*Research Committee – 11 members, Technical Committee – 3m, and Ethical Committee – 3 m*)
3. National Medical College
(*Existed Institutional Review Board – 5 members*)
4. Kathmandu University Teaching Hospital
(*Existed Ethical Review Committee – 9 members*)
5. Tilganga Eye Hospital
(*Existed Ethical Review Committee – 5 members*)

Information not Received

1. College of Medical Science, Bharatpur
2. Kathmandu Medical College Teaching Hospital
3. Manipal College of Medical Sciences
4. National Academy of Medical Sciences
5. Nepal Medical College Teaching Hospital
6. Nepal College of Health Sciences
7. Nepalganj Medical College
8. Novel College of Medical Sciences
9. People's Dental College
10. Purbanchal College of Medical Sciences
11. Ram Janaki Medical College
12. Universal College of Medical Sciences

National Ethical Review Board (ERB) Members

Composition

Co-ordinator – One

Members – Nine

Member-Secretary – One (MS of NHRC)

(Total 11)

Physicians – 4

Child Specialist - 2

Senior Lawyer – 1

Surgeon – 1

Senior Dentist – 1

Oncologist – 1

Psychiatrist – 1

Regular Invitees (2)

Statistician – 1

Ayurvedic Physician - 1

National Ethical Review Board

- Ethical Review Board at National level established as per the NHRC Act 1991.
- To oversee the Health Research involving Human Participants.
- To safeguard the rights, dignity, safety and the well-being of all potential research participants and concerned communities.

Proposal Review Process

- National Ethical Guidelines includes checklist to be used to review the proposal.
- Internal evaluation: Research Officers at NHRC evaluate the proposal before submitting it to ERB meeting. If any comments, sent back to the researcher.
- ERB has a list of potential experts to review the research proposals.
- ERB must meet once in Two Months but generally meets once in a Month.

Proposal Review Process contd.

ERB meeting decides the reviewer for particular proposal. Depending upon the nature of the proposal, it will be reviewed by more than one reviewer.

The proposal including the curriculum vitae of the principal investigator; will be sent to the reviewer in anonymous version as far as possible.

A scoring checklist will be sent to the reviewer in order to maintain the consistency and objectivity of the review process.

Proposal Review Process contd.

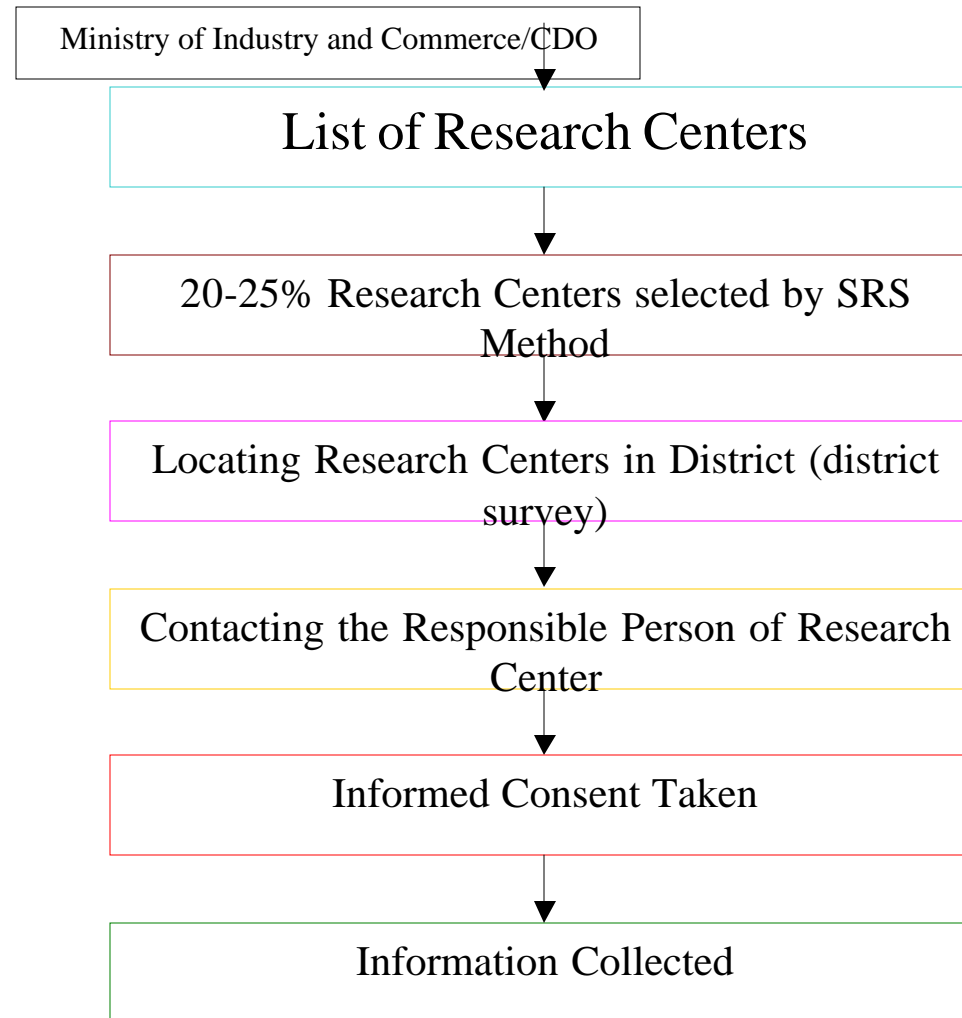
- In the following meeting, summary of evaluation (Internal 25% + External 75%) and the ethical comments are presented to the ERB. If any comments, it will be sent back to the researcher.
- ERB Clearance process takes minimum 1/2 Month to maximum 2 Months.
- After approval from ERB, it is forwarded to the NHRC Executive Board for Endorsement.
- NHRC Executive Board Clearance process takes minimum 1 Month to maximum 3 Months.

Evaluation of Medical/Health Institutes

Evaluation of Medical/Health Institutes

- To find out the number of various organizations/institutes/agencies written the word "Research" in their name,
- To assess their core business,
- To assess their health related research activities,
- To assess the level of progress achieved by them since its establishment, and
- To assess the technical/ethical standards of the research activities (if conducted by them).

Evaluation of Medical/Health Institutes



Evaluation of Medical/Health Institutes

SN	Region	Total No. of RCs	No. of HFs	No. of NGOs	No. of Sampled RCs	No. of consented RCs
1	Eastern	34	15	19	15	14
2	Central	272	78	194	57	51
3	Western	38	14	24	15	14
4	Mid-western	18	1	17	5	2
5	Far western	5	1	4	1	0
	Total	367	109	258	93	81
	Total	100%	30%	70%	25%	22%
	<i>Note: RCs – Research Centers, HFs – Health Facilities designated as RCs,</i>					
	<i>NGOs – Non-Government Organization designated as RCs.</i>					

Evaluation of Medical/Health Institutes

Research Center's Core Business	HF (n=66)		NGO (n=15)		Total (N=81)	
And Their Involvement	n	%	n	%	N	%
Core business						
Research	26	39.4	7	46.7	33	40.7
Others	40	60.6	8	53.3	48	59.3
Involvement in Health Research						
Yes	19	28.8	8	53.3	27	33.3
No	47	71.2	7	46.7	54	66.7
Involvement in other's Research Projects						
Yes	3	4.5	1	6.7	4	4.9
No	63	95.5	14	93.3	77	95.1
Staff involvement in NHRC activities						
Yes	7	10.6	3	20	10	12.3
No	59	89.4	12	80	71	87.7
<p><i>Note: RCs – Research Centers, HFs – Health Facilities designated as RCs,</i></p> <p><i>NGOs – Non-Government Organization designated as RCs.</i></p>						

Evaluation of Medical/Health Institutes

Conducted Health Research						
	HF (n=66)		NGO (n=15)		Total (N=81)	
	n	%	n	%	N	%
Yes	13	19.7	6	40.0	19	23.5
No	53	80.3	9	60.0	62	76.5

Evaluation of Medical/Health Institutes

Health Research							
Aspects		HF (n=66)		NGO (n=15)		Total (N=81)	
		n	%	n	%	N	%
Taken Technical/Ethical Approval							
Yes		2	3.0	3	20.0	5	6.2
No		64	97.0	12	80.0	76	93.8
Maintain Ethical Norms							
Yes		13	19.7	5	33.3	18	22.2
No		53	80.3	10	66.7	63	77.8
Taken Consent from Research Subjects							
Yes		10	6.6	5	33.3	15	18.5
No		56	93.4	10	66.7	66	81.5
Taken Written Informed Consent							
Yes		3	4.5	2	13.3	5	6.2
No		63	95.5	13	86.7	76	93.8

Evaluation of Medical/Health Institutes

- During field observation, it was found that few (15 out of 81) health related organization / center / polyclinic / institute who has written the word "Research" in their title name but not conducted any research agreed to take out the word "Research" from their signboard. Some centers (less than 15%) even did know about the meaning of research.
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- While observing the health facilities designated as research centers, they said that routine examination of blood and urine samples was the research. They also said that the main reason behind putting the word "Research" in their signboard was just to deduct the government tax, compete with other centers, and make the word fancy and catchy for the public to draw their attention towards their center.

Evaluation of Medical/Health Institutes

Out of so called Research Centers in Nepal

Research as Core Business	: 40.7%
Involvement in Health Research	: 33.3%
Involvement in Other's Research	: 4.9%
Conducted Health Research	: 23.5%
Taken Ethical Approval	: 6.2%

Current Challenges

- Making the consistency of Ethical Review Committees (ERC) names
 - *Institutional Review Board*
 - Institutional Review Committee*
 - Ethical Review Committee*
 - Research Committee*
- Standard Operating Procedure (SOP) for Effective Implementation of Ethical Guidelines
- Inadequate Monitoring and Supervision of Various Aspects of Ethical Concerns of Research Projects
- Mechanism of Networking and Coordination among various ERCs in Nepal
- Misuse of the word “Research”
- Inadequate Ethical Practices in Field setting

Changtse

Mt. Everest

Nuptse

8,848m



THANK YOU