

Country Report for ABN Member States: Current Issues, Challenges and Recommendations

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Outline of the presentation

- ▶ Summary of the research regulations in Nepal
- ▶ Existing initiative in Nepal
- ▶ Summary of the ethical challenges
- ▶ Plan and recommendations
- ▶ Other achievements/ on going / upcoming bioethics initiation in Nepal

Establishment of Nepal Health Research Council in the year 1991

- ▶ Autonomous government body by an act of parliament
 - ▶ **Regulation of health research in the country**
 - ▶ Health research capacity building of the researcher
 - ▶ Evidence generation
 - ▶ Promoting the use of evidences



NHRC ACT 1991

3. Establishment of Council: (1) The Nepal Health Research Council is hereby established to do, or cause to be done, high-level study and research works on health.

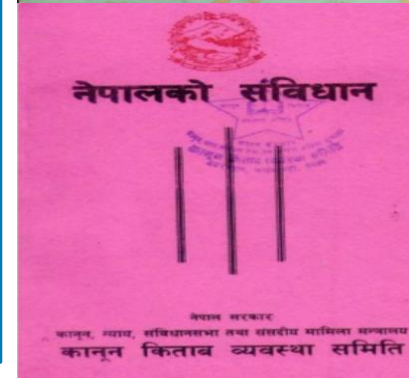
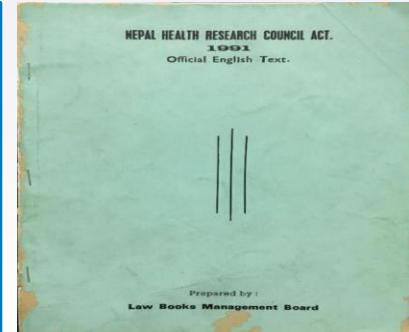
11. **Permission to be Obtained to do Research Relating to Health:**

(I) After the commencement of this Act, Individual or organization interested to do research in the field of health shall have to Obtain permission from the Council.

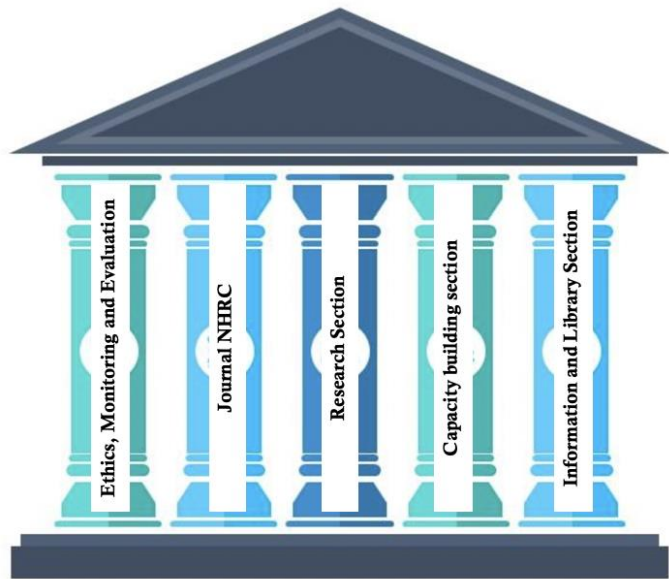
(II) The Council may also specify terms and conditions as prescribed while giving permission pursuant to sub- section (I).

12. **Special Rights of the council:** (1) The Council may issue necessary directives to the person or organization involved in the research work relating to health permitted for research pursuant to Section 11.

(2) In case any person or organization carries out research works without obtaining permission pursuant to Section 11 or does not abide by the terms and conditions as prescribed or directives of the Council, while carrying out the research work by obtaining permission, **the council may warn such person or organization or prohibit to carry out the research work for a specified period.**



NHRC Pillars



Ethics, Monitoring & Evaluation

- Independent ERB board
- 56 IRCs in academic and research institutions
- FERCAPP Accredited in 2019
- Digital application system
- Ethical approval and monitoring



Journal of NHRC

- Biomedical Peer-reviewed journal
- Open Access
- Indexed and four issues per year
- Co-operation with 4 international editors association



Health Research Section

- Conducts and promotes research
- Primary research on national priority areas
- National and international collaboration
- Establishment of center for Excellence
- Communication of research findings



Capacity Building Section

- Trainings
- Health Research Grants



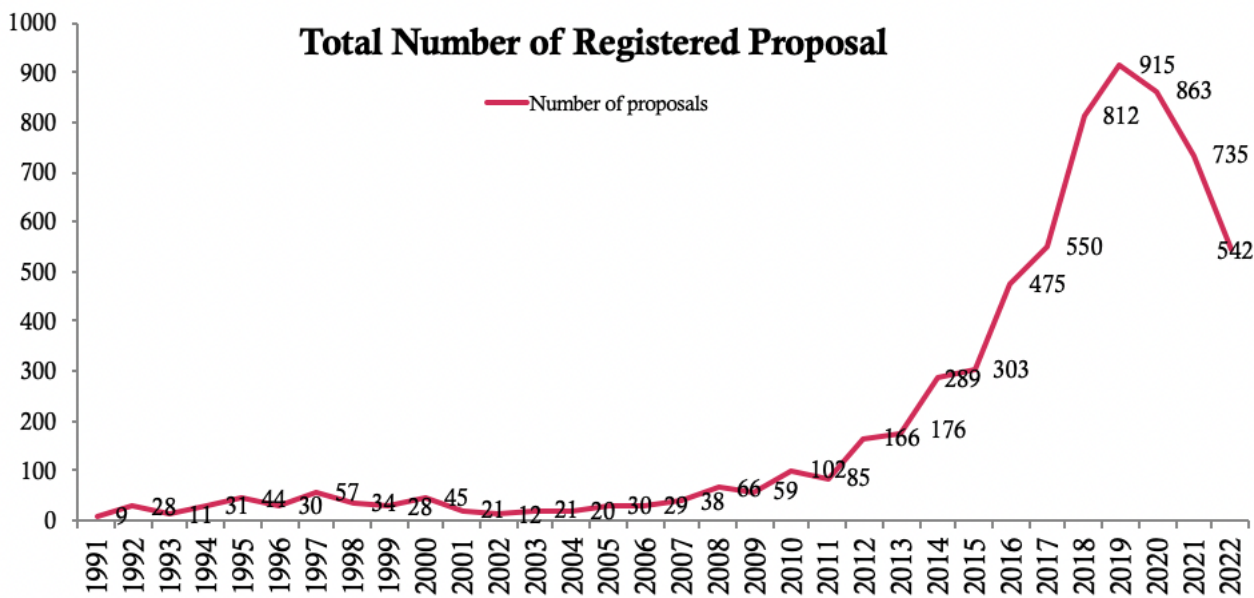
Information and Library Section

- Integrated information
- Technology accessible
- Publicly available modern library



Exiting Situations

Over 3000 research proposals were approved by IRCs in 2022



What is done

National Ethical Guidelines for Health Research in Nepal 2022



Nepal Health Research Council (NHRC)
Ram Shah Path, Kathmandu, Nepal

January 2022

Nepal Health Research Council

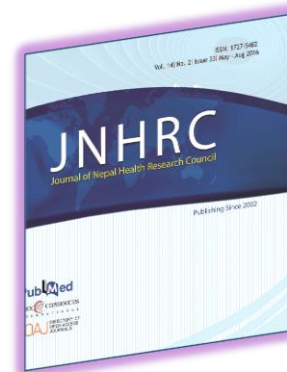
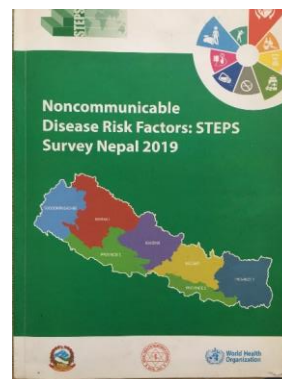
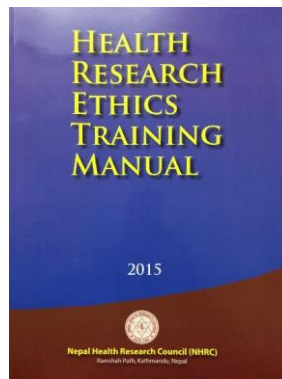
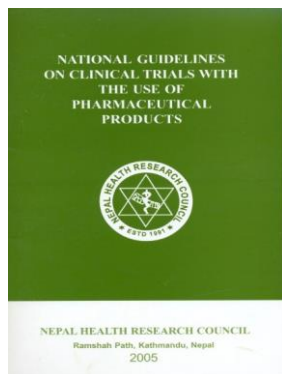
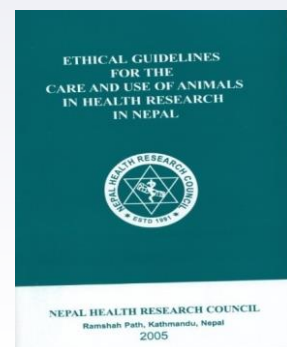
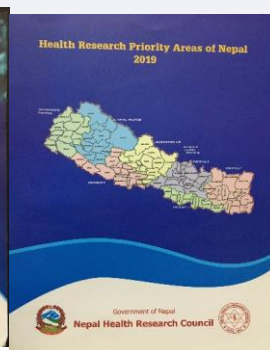
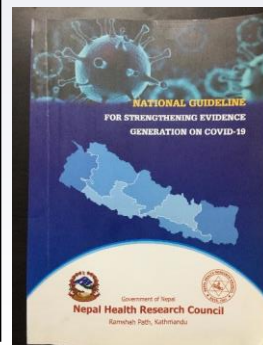


STANDARD OPERATING PROCEDURE (SOP) HANDBOOK
for
ETHICAL REVIEW BOARD

Prepared by
SOP Team
September 2019

Guidelines for
Institutional Review Committees (IRCs)
for
Health Research in Nepal

NEPAL HEALTH RESEARCH COUNCIL (NHRC)



Challenges

- ▶ Lack of Harmonized System / Procedure
- ▶ Inadequate HR and infrastructure
- ▶ Less coordination and collaboration with Academia

- ▶ Lack of budget
 - ▶ Voluntary work
 - ▶ To run the EC
 - ▶ Regular capacity-building training and refresher training



Compliance with Guidelines

- ▶ **Initial review:** fulfilments of the requirements, identifying the level of risk,
- ▶ **Implementation:** compliance with the approved protocol, Guidelines, SOPs
- ▶ **Post-approval:** Report submission, dissemination, authorship, post-research access, and benefit sharing



Possible Recommendations

- ▶ Promoting harmonized system and procedure (Like FERCAP criteria)
 - Develop a **signal online system** for other ECs
 - **Joint review and monitoring** along with **mentoring** on research
 - Strengthen the **infrastructure and HR capacity**, **promoting collaborative** and **multi-disciplinary** research in priorities area
 - Open **Data Sharing and Ownership/IPR, Post-trial access, and benefit sharing**
 - Promote **engaging the community** in the research process
- ▶ Conduct Regular short training programs
 - young researchers and refresher training for EC members and reviewers*
- ▶ Consider putting it in the curriculum in all disciplines
- ▶ In-house short talks, discussions, or seminars



Other ongoing activities

- Bioethics conferences in the occasion of Bioethics day
- Workshop on WHO Benchmark Ethics
- Symposium of RCR
- Policy dialogue on RCR
- Training / workshop Junior researchers, faculty, EC members, Reviewers
- Update guidelines / orientation about guidelines

- Participating different international activities
- FERCAP recognition
- Regular engagement in FERCAP activities from 2019
- 2024 FERCAP conferences in Nepal
- Regular Participation in VoIReEthics activities by European Commission
- Exchange of experts and engaged with ICMR, CDSCO India
- Regular engagement in Bioethics Course of University Oslo Norway



Collaboration Areas

Capacity Building

Trainings/ workshop

Exchange program EC Secretariat
Staffs

Exposer Visit of EC Members/
Secretariat Staffs

Collaborative Research

RCR, Regulations , Research
Ethics , Community
Engagement, Post trial
Benefit ,

Evidence Promotion

Publishing Joint article in scientific
Journal, policy engagement,
community engagement, media
campaigns





▶ Government of Nepal, Nepal Health Research Council

▶ Ramshah Path, Kathmandu

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