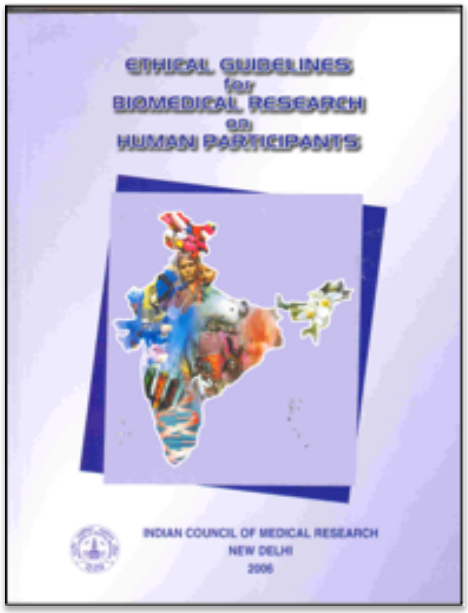
ICMR's COVID-19 Guidelines and Fast tracked Approvals for Drugs and Other Interventions

Nandini K. Kumar
Former Deputy Director General Senior Grade (ICMR)
Vice President Forum for Ethics Review Committees in India

Guidelines

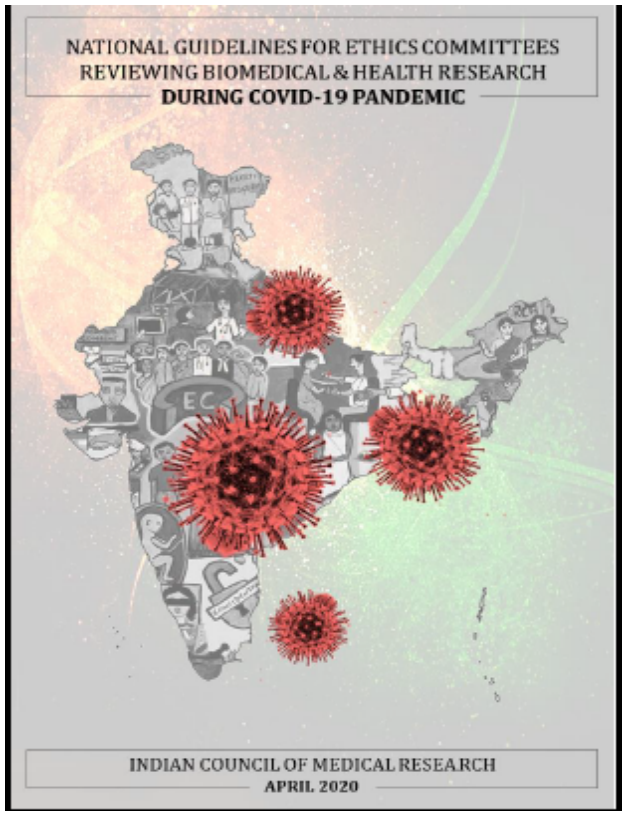


Part of chapter in Ethics Review Procedures

Section 12

National Guidelines For EC in COVID Research

Research during COVID-19 Pandemic



- Statement of General Principles
- General Ethics Issues
- Ethical Review Procedures
- Informed Consent
- Vulnerability

Statement of General Principles

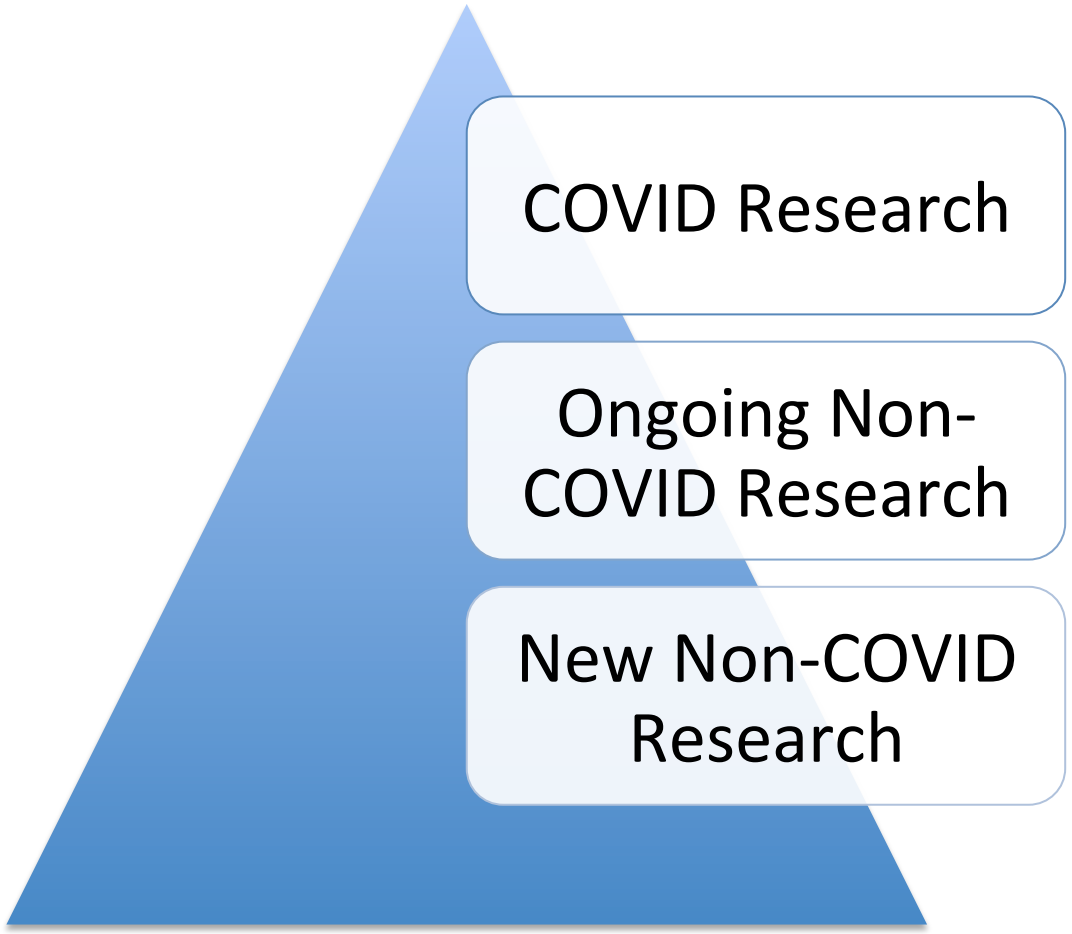
General Ethical Issues

1. Benefit-risk assessment
2. Privacy and confidentiality
3. Distributive Justice
4. Payment for participation
5. Compensation - research related injury
6. Conflict of interest
7. Community engagement

General Ethical Issues

8. Post research access & benefit sharing
9. Storage of biological materials/datasets
10. Collaborative research
11. Public health & socio-behavioural research
12. Role of Agencies/Sponsors & Governance of Research
13. Biosafety in Laboratories & Hospitals

Ethics Review Procedures – Fast Track Approvals



MEURI - Monitored Emergency Use of Unregistered Interventions

No proven effective therapy & Immediate clinical studies not possible
Only GMP product to be used
Preliminary data available & risk-benefit analysis done by external scientific advisory committee
Approved by relevant country authorities and qualified EC
Adequate resources, rescue medicines & supportive treatment available to minimize risk
Patient's informed consent obtained
Timely monitoring & results shared with medical & scientific community

NDCT Rules 2019: Chapter X-75 (7)

1. Local Clinical Trials not required

(i) New drug approved and marketed in countries specified by CLA, and no major adverse events reported;

(ii) there is no probability or evidence of difference in Indian population of the enzymes or gene involved in the metabolism of the new drug or any factor affecting pharmacokinetics and pharmacodynamics, safety and efficacy of the new drug; and

(iii) undertaking in writing to conduct Phase IV clinical trial (exceptions - drug is indicated in life threatening or serious diseases, unmet need in India such as XDR tuberculosis, hepatitis C, H1N1, dengue, malaria, HIV, rare diseases or orphan drug)

Schedule II of NDCT Rules, 2019 - 1(2)

(ii) For drugs intended to be used in life threatening or serious disease conditions or rare diseases and for drugs intended to be used in the diseases of special relevance to Indian scenario or unmet medical need in India, disaster or special defense use .....

- (A) Accelerated Approval Process
- (B) Expeditious review process

Thank You