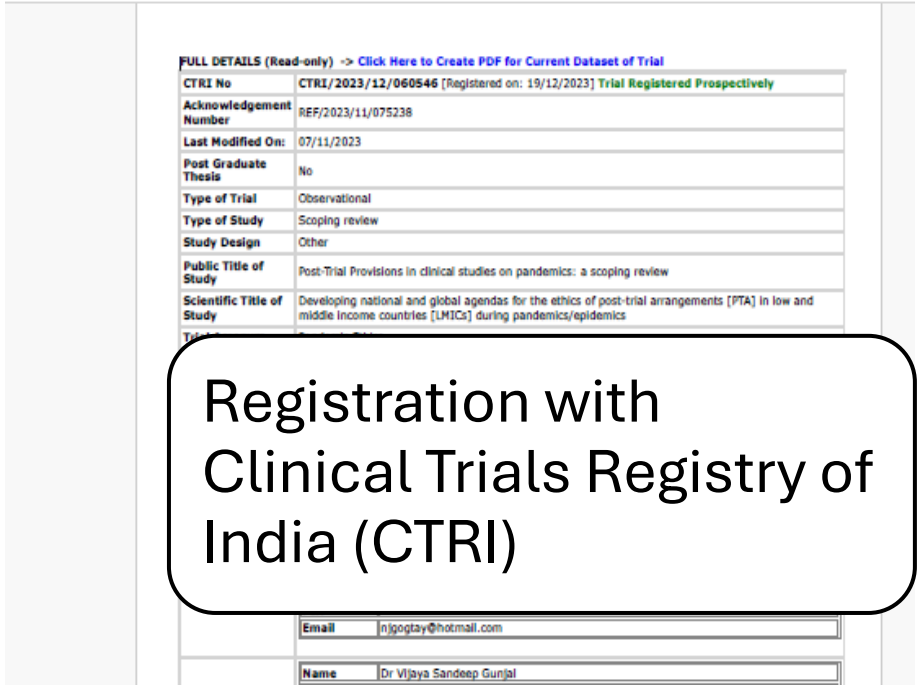


FULL DETAILS (Read-only) -> Click Here to Create PDF for Current Dataset of Trial

CTRI No	CTRI/2023/12/060546 [Registered on: 19/12/2023] Trial Registered Prospectively
Acknowledgement Number	REF/2023/11/075238
Last Modified On:	07/11/2023
Post Graduate Thesis	No
Type of Trial	Observational
Type of Study	Scoping review
Study Design	Other
Public Title of Study	Post-Trial Provisions in clinical studies on pandemics: a scoping review
Scientific Title of Study	Developing national and global agendas for the ethics of post-trial arrangements [PTA] in low and middle income countries [LMICs] during pandemics/epidemics

Email	njgogtay@hotmail.com
Name	Dr Vijaya Sandeep Gunjal

Registration with Clinical Trials Registry of India (CTRI)

INSTITUTIONAL ETHICS COMMITTEE (IEC)-III
Relating to Biomedical and Health Research (BHR).
Seth GS Medical College and KEM Hospital, Mumbai, Maharashtra, India.
Established - 12th October 2019

Registered by: Government of India, Ministry of Health & Family Welfare, Department of Health Research, Registration No. EC/NEW/INST/2021/MH/0003, Valid From 22nd October 2021 to 21st October 2026.

IEC(III)/OUT/820/2023

DCP/R/1114/23
27-10-23

27th October 2023

To,
Dr. Nithya Gogtay,
Dept. of Clinical Pharmacology.

Ref: Your project no. **EC/OA-156/2023** entitled, **Protocol version no. 1 dated 04th October 2023, "Developing national and global agendas for the ethics of post-trial arrangements [PTA] in low and middle income countries [LMICs] during pandemics/epidemics"**, received by IEC-III on 06th October 2023.

Sub: Letter no. DCP/II/1121/23 dated 16th October 2023 regarding submission of reply to IEC-III Exemption review queries to IEC.

Dear Dr. Gogtay,

This is in reference to the above-stated letter. The IEC-III
its full board online meeting held on 20th October 2023,
dated 23/09/2023 submitted on 18th October 2023 wa
satisfactory.

The IEC-III accords exemption from review and grants yo
study. However, the IEC-III has not received the following document:

1. HSMC permission letter.

Institutional Ethics Committee approval

Health Ministry Screening Committee approval, Govt of India

Version date 23-11-24, 11 pm

Our research question

How has post trial access evolved in India?

Part of Work Package 1 (WP1) of the pandemic ethics project

Evolution of post trial access in a lower and middle income country - an analysis of Indian ethical and regulatory guidelines

Nithya Gogtay and Team, King Edward Memorial Hospital, Mumbai

FERCAP 2024, Kathmandu

Manuscript submitted to the Indian Jr of Medical Ethics

Methods- ethics

Protocol accorded a waiver by the Institutional Ethics Committee

Original proposal with its multiple components accorded IEC approval and approval of the Health Ministry Screening Committee (HMSC), Indian Council of Medical Research, Govt of India

Methods- websites searched

Indian Council of Medical Research (ICMR)

Department of Biotechnology (DBT)

Department of Science & technology (DST)

Central Drugs Standard Control Organization (CDSCO)

Hand searched and electronically searched

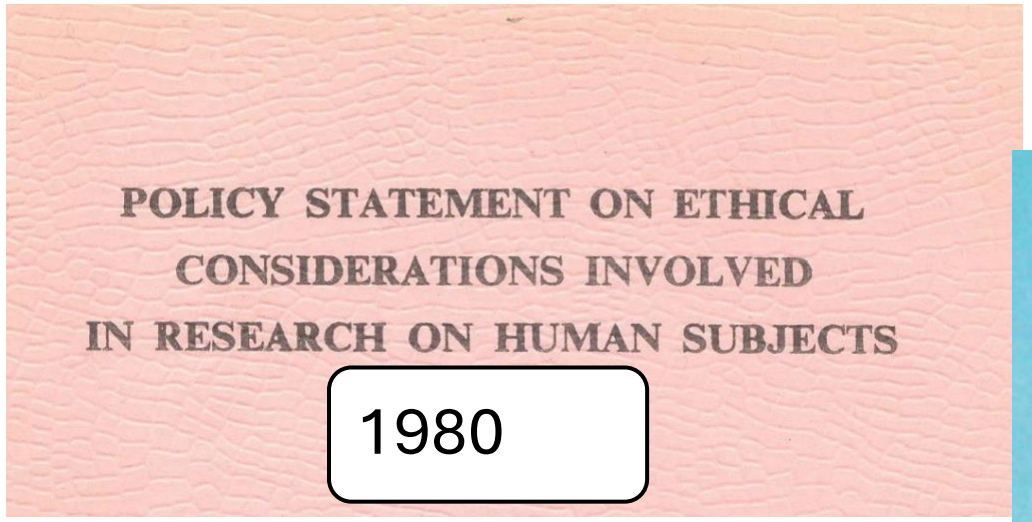
Methods- search terms used

- post trial access, post research access
- post-trial obligations
- post- research benefit/s
- long term extended studies, expanded access
- long term follow up studies
- benefit sharing, post-trial benefit
- post- trial modalities, post- research plan
- compassionate use, off label use
- extended use post- trial intervention/drug supply program

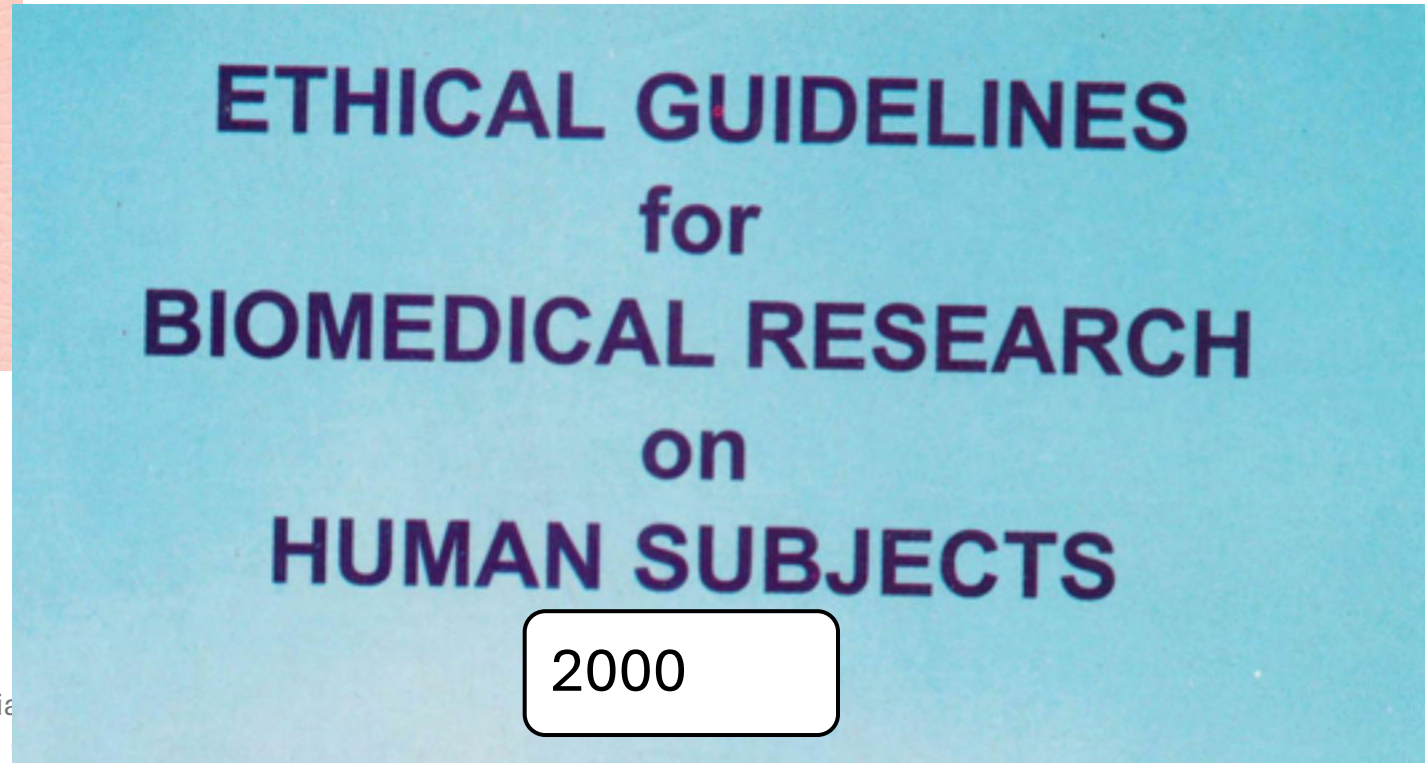
After several rounds of discussion with the pandemic ethics team with its network of members

Results

- A total of 11 guidelines were evaluated

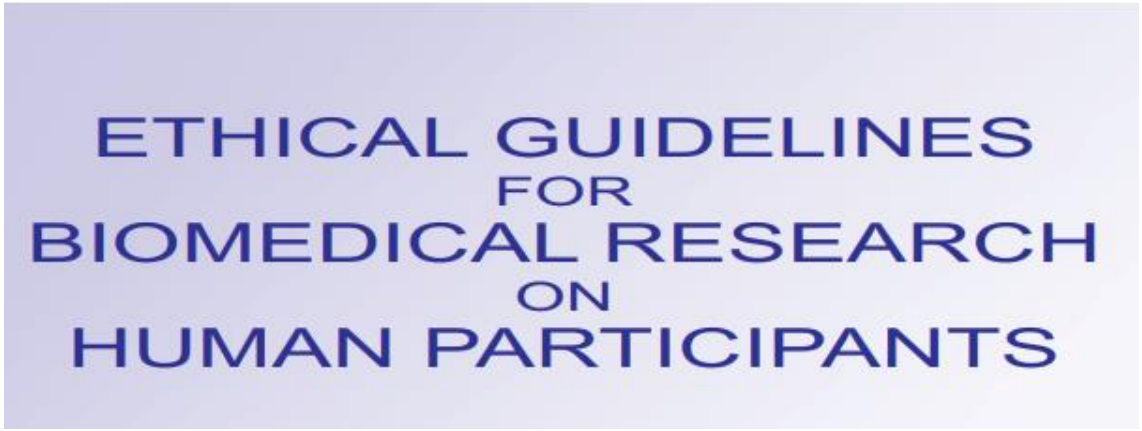


The Indian Council of Medical Research (ICMR) is the Apex body in India for formulation, coordination and promotion of biomedical research.



Results – cont’d

- Indian Council of Medical Research- first mention - 2006



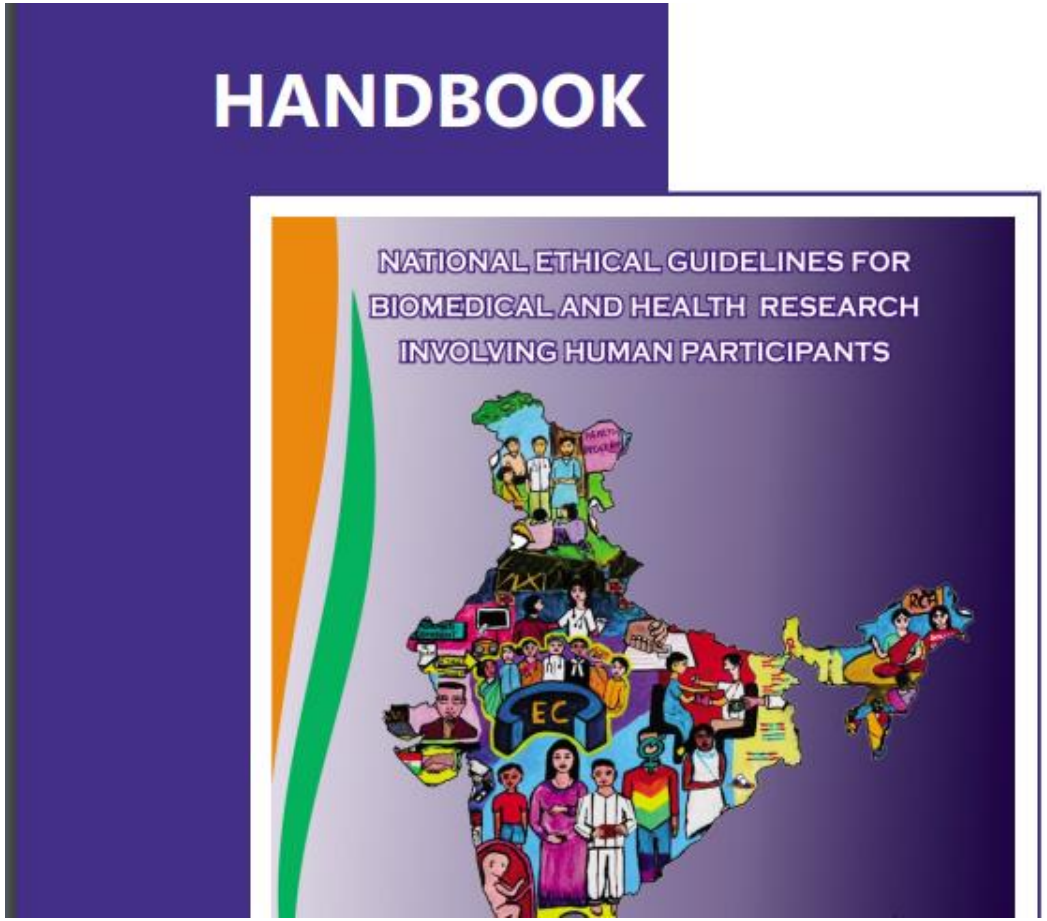
ICMR guidance - 2006

Whenever possible, IEC should consider an *a priori* agreement with stakeholders.

Sometimes more than the benefit to the participant, the community may be given benefit in indirect way

After the clinical trial is over, if found effective, it sould be made mandatory that the sponsor should provide the drug to the patient till it is marketed in the country

Post trial access to the vaccine should be given first to the community from which the participants were drawn.


HANDBOOK
NATIONAL ETHICAL GUIDELINES FOR
BIOMEDICAL AND HEALTH RESEARCH
INVOLVING HUMAN PARTICIPANTS
EC


INDIAN COUNCIL OF MEDICAL RESEARCH
2017


INDIAN COUNCIL OF
MEDICAL RESEARCH
2018

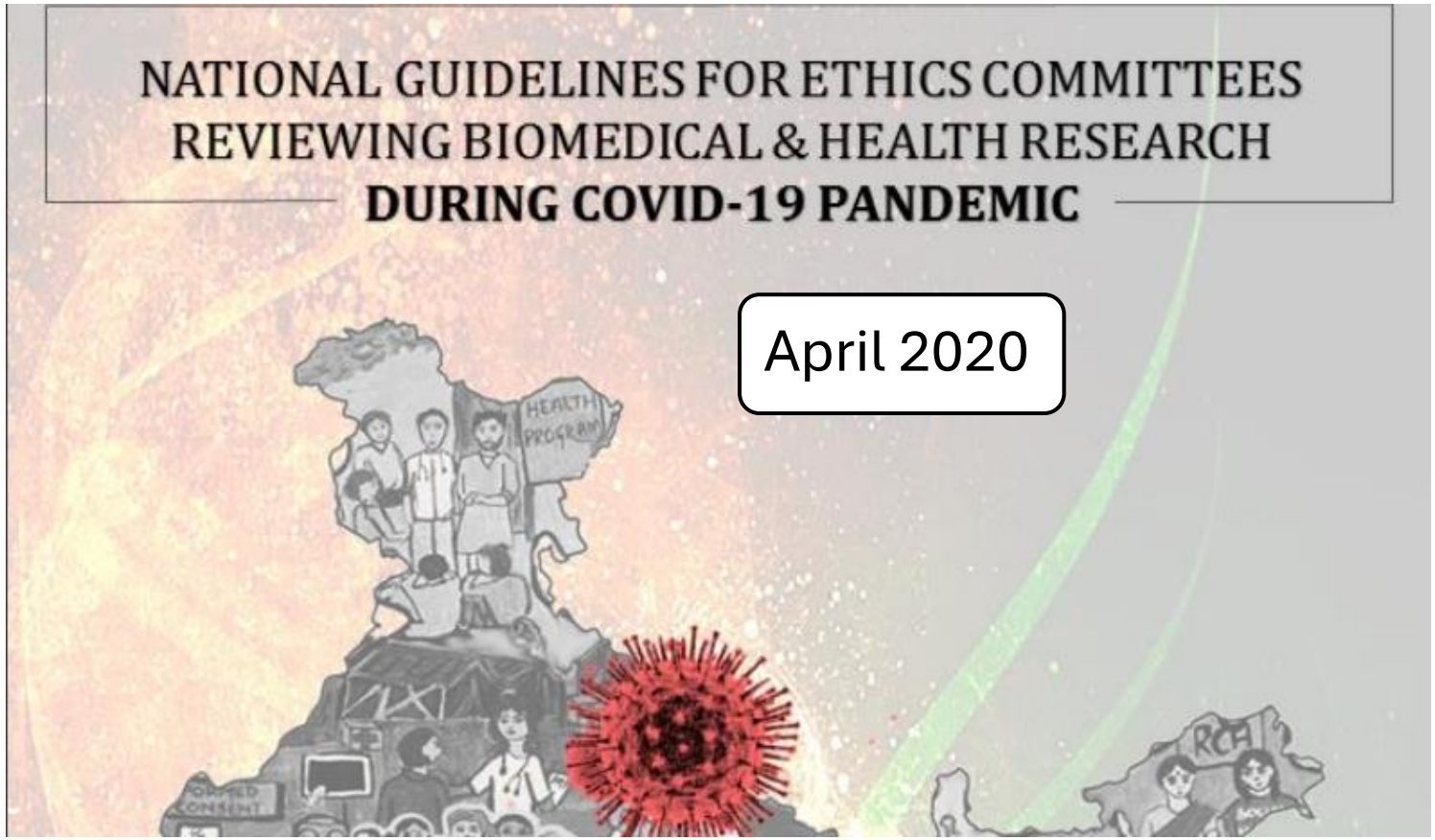
Indian Council of Medical Research (ICMR) - 2017 guidelines – most comprehensive coverage

- Section - Post research access and benefit sharing (Section -2.11)
- The benefits accruing from research should be made accessible to individuals, communities and populations whenever relevant
- The EC should consider the need for an *a priori* agreement between the researchers and sponsors regarding all the points mentioned above.
- Post research plan/benefit sharing, if research on biological material and/or data leads to commercialization
- Sponsors and researchers should strive to continue to provide beneficial interventions, which were part of the research initiative even after the completion of research and till the local administrative and social support system are able to provide regular services.

National Ethical Guidelines for Biomedical Research Involving Children

2017

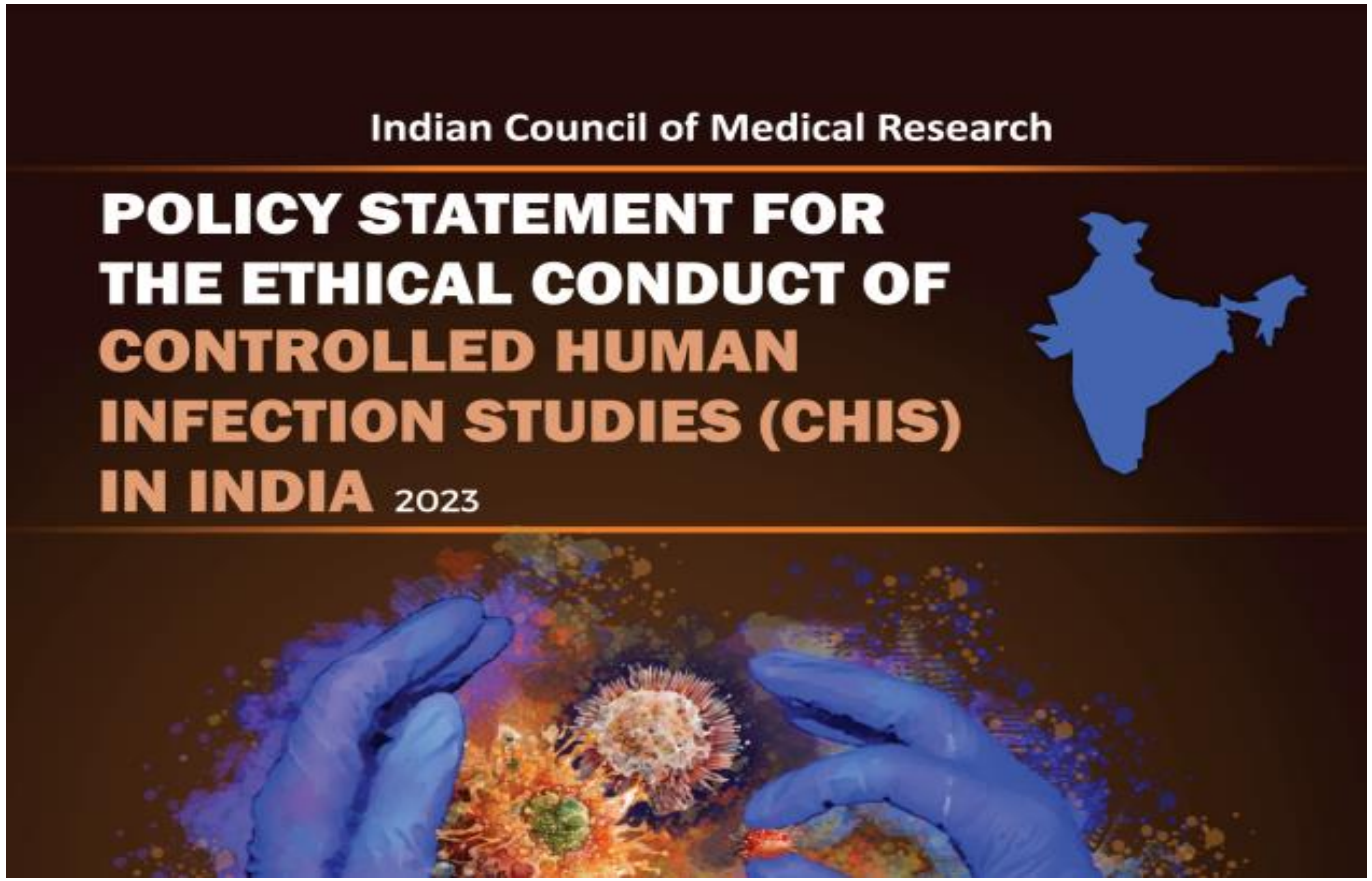
Benefit sharing should be done, if research on biological material and/or data may lead to commercialisation.


NATIONAL GUIDELINES FOR ETHICS COMMITTEES
REVIEWING BIOMEDICAL & HEALTH RESEARCH
DURING COVID-19 PANDEMIC
April 2020
HEALTH PROGRAM
RCH

ICMR ethics guidance during the COVID-19 pandemic

Central regulatory authority to undertake expeditious review process for clinical trials for new drugs/ compassionate use and ensure safety/efficacy monitoring processes.

Facilitate post-trial access of the successful investigational drug/ vaccine free of cost to the trial participants till the same are available in the market.

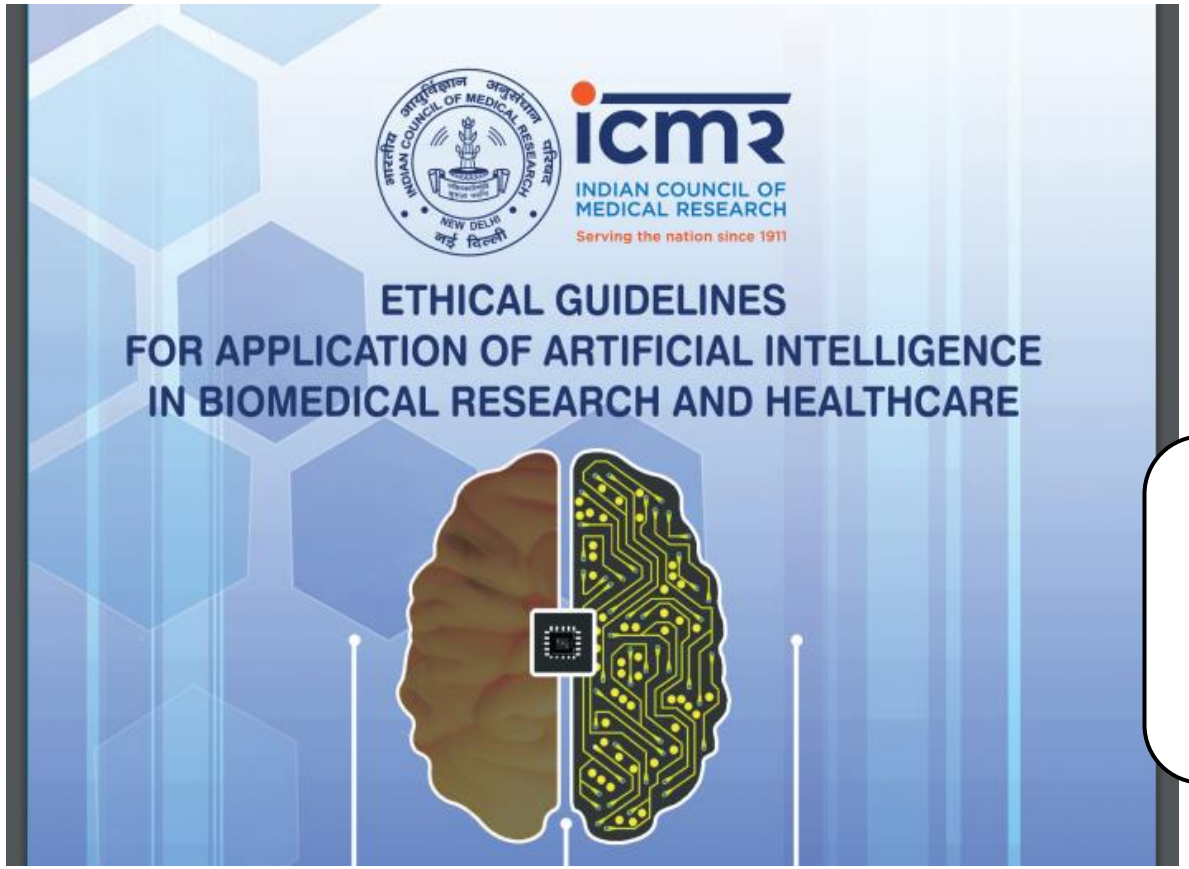


There may or may not be clear and direct benefits to research enrolling for CHIS

Benefits accruing from a study may have relevance to participating individuals or communities. It is ethically and morally imperative to make those benefits available to the participants

Has post-trial access to treatment for the placebo group been considered?

AI guidance - 2023



NO mention of benefit sharing or post trial access

India's regulatory guidance- New Drugs and Clinical Trials Rules (2019)

THE NEW DRUGS AND CLINICAL TRIALS RULES, 2019

[1][GSR 227(E), dt. 19-3-2019]

(As amended vide GSR 778(E) dated 14-10-2022, w.e.f. 14-10-2022)

Whereas the draft of the New Drugs and Clinical Trials Rules, 2018 was published, in exercise of the powers conferred by sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i) vide notification number G.S.R. 104(E), dated the 1st February, 2018, by the Central Government, after consultation with the Drugs Technical Advisory Board, inviting objections and suggestions from all persons likely to be affected thereby, before the expiry of a period of forty-five days from the date on which copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the Official Gazette containing the said notification were made available to the public on the 7th February, 2018;

No mention in the first regulatory document – The Schedule Y of the Drugs and Cosmetics Act-1945

New Drugs and Clinical Trials Rules (2019)

Post-trial access - making a new drug or an IND available to a trial subject after completion of clinical trial through which the said drug has been found beneficial

Rule 27

The sponsor shall provide PTA of the investigational drug- free of cost as per directions of the CLA on the recommendations of the investigator and the ethics committee and written consent of the patient

Department of Biotechnology, Govt of India

If commercialization brings any benefits, say financial, efforts should be made to pass on the same to the donor/community wherever possible

In summary (1)

India as a country first addressed PTA in 2006

The ICMR ethics guidance of 2017 represents as yet the most comprehensive coverage

Lack of coverage in AI guidance (2023) should be addressed

There is a reasonable coverage of PTA in the NDCT 2019 rules

It also important to ensure the barriers to PTA and PTC care are also factored in by the stakeholders designing the access programs

In summary (2)

The narrow thought process in PTA where the focus is on access to the intervention (found beneficial) and usually the individual during a clinical trial should change to the more broad based *post trial care* (PTC) which includes *responsible transition* to ensure continuity of care, future clinical care, or providing alternatives to the participant in the trial

Our guidance documents can now align with the 2024 DoH

and

further evolution of Indian guidance documents will help future participants of clinical trials in the country and this remains an ethical and moral obligation of all stakeholders in the country.