



## PHARMACY COUNCIL OF INDIA

(Constituted under the Pharmacy Act, 1948)

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New Delhi – 110 020

Ref.No.14-150/15-PCI/12273

Circular

27 JUL 2022

To,

1. All Institutions approved by PCI-  
- u/s 12 of the Pharmacy Act, 1948.  
- for conduct of course

2. All Examining Authorities (Universities/Board)

Sub: Registration of Ethics committees for Biomedical and Health research with DHR-reg.

Sir/Madam

Please find enclosed herewith the Letter No.-U-11022/01/2022-HR/8120573 dt. 02.06.2022 of Ministry of Health and Family Welfare regarding **Registration of Ethics committees for Biomedical and Health research with DHR**, which is self explanatory.

It is for compliance by the concerned Institutions.

Yours faithfully

(ARCHANA MUDGAL)

Registrar-cum-Secretary

**File No.U-11022/01/2020-HR**

**No.U-11022/01/2020-HR/8120573**  
Government of India  
Ministry of Health and Family Welfare  
(Department of Health Research)

2<sup>nd</sup> Floor, IRCS Building,  
1, Red Cross Road,  
New Delhi – 110001

**Dated, the 2nd June, 2022**

**To,**

**The Secretaries/Principal Secretaries**  
Health and Family Welfare Department  
State Government/Union Territory Administrations

**Subject: Registration of Ethics committees for Biomedical and Health Research with DHR – regarding.**

**Sir/Madam,**

I am directed to refer to this Department's letter No.U-11024/01/2018-HR(Part-2)/8015255 dated 12<sup>th</sup> September 2019 (copy enclosed) on the subject cited above and to say that Chapter IV of the 'New Drugs and Clinical Trials Rules, 2019' which was notified in the Gazette of India vide G.S.R.227 (E) dated 19.03.2019 mandates that all ethics committees related to biomedical and health research involving human participants shall be required to register with the authority designated by the Central Government in the Ministry of Health and Family Welfare, Department of Health Research (DHR).

2. The National Ethics Committee Registry for Biomedical and Health Research' (NECRBHR), was set up at Department of Health Research in 2019 to facilitate processing of such applications, seeking registration of ethics committees for biomedical and health research involving human participants. With effect from 15.09.2019, it is a mandatory requirement under law for those ethics committees conducting or intending to conduct biomedical and health research, involving human participants, to get registered with the designated authority in the DHR.

3. The above provisions of 'New Drugs and Clinical Trials Rules, 2019 thus make it obligatory for all the entities/institutions/researchers/ stakeholders whether in public or private, who are conducting or intending to conduct biomedical health research, involving human participants are required to get themselves registered with the designated authority in the Department of Health Research in terms of provision of chapter IV of the 'New Drugs and Clinical Trials Rules, 2019.

4. Therefore, the studies/ research proposals involving human participants, their biological material and data that are not reviewed by ethics committees fulfilling the above requirements should not be considered or approved by any agencies for funding purposes.

5. You are, therefore, requested to kindly get enforced the above provisions strictly in the institutions like Medical/dental/pharmacy/nursing/ state funded/ centrally funded organizations for the purpose of academics or otherwise. This will also strive towards improving the quality and responsible conduct of biomedical research in the country.

**Encl.: As stated.**

Yours faithfully,

Digitally Signed by Daulat

Ram Meena

Date: 02-06-2022 18:24:47

Reason: Approved (D.R. Meena)

Deputy Secretary to Government of India

**Copy to:**

1. Secretary, Department of Health and Family Welfare, New Delhi.
2. Secretary, Ministry of AYUSH, New Delhi.
3. Secretary, Department of Biotechnology, New Delhi.
4. Secretary, Department of Science & Technology, New Delhi.
5. Secretary, Department of Higher Education, Ministry of Education, New Delhi.
6. Secretary, University Grants Commission, New Delhi.
7. Secretary, Department of Atomic Energy, New Delhi.
8. Secretary, NMC / DCI / NCI / PCI, New Delhi.

**Copy, also, to:**

1. Sr. PPS to Secretary (DHR)/ PS to DG (ICMR), New Delhi.
2. PPS to JS (AN), DHR.
3. Sr. DDG (Admin), ICMR, New Delhi.

By Speed post /E-mail

No.U-11024/01/2018-HR (Part-2)/8015255

Government of India

Ministry of Health & Family Welfare  
(Department of Health Research)

2<sup>nd</sup> Floor, IRCS Building,  
1, Red Cross Road, New Delhi-110001.

Dated, the 12<sup>th</sup> September, 2019.

To

The Secretaries / Principal Secretaries,  
Health and Family Welfare Department,  
State Governments / Union Territory Administrations.

**Subject : Registration of Ethics Committees for Biomedical and Health  
Research – Regarding**

Sir/Madam,

I am directed to say that, in exercise of the powers conferred by the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, in the Ministry of Health and Family Welfare, Department of Health and Family Welfare, has notified the 'New Drugs and Clinical Trials Rules, 2019', on 19.03.2019, in the Gazette of India (Extraordinary) - Part-II, Section 3, Sub-section (i), vide G.S.R.227 (E) dated 19.03.2019. The above Rules, except Chapter-IV thereof, have come into force from the date of their publication in the Official Gazette, i.e., w.e.f. 19.03.2019. The Chapter IV of the aforesaid Rules, relating to Ethics Committees for Biomedical and Health Research, involving human participants, shall come into force on expiry of 180 days from the date of publication of the above Rules, i.e., after 14.09.2019.

2. The Chapter IV of the above Rules provides that any institution or organization, etc., which intends to conduct biomedical and health research, shall be required to have an Ethics Committee to review and oversee the conduct of such research, as detailed in the 'National Ethical Guidelines for Biomedical and Health Research Involving Human Participants', specified by the Indian Council of Medical Research (ICMR). These guidelines may be seen at the website of the Department of Health Research - <https://dhr.gov.in> — under 'Important Links' with the heading 'National Ethical Guidelines for Biomedical and Health Research Involving Human Participants — 'download'.
3. The sub-rule (1) of rule 17 of these Rules provides that such an Ethics Committee - to be constituted in accordance with the said guidelines - shall register itself with the authority to be designated for the purpose by the Department of Health Research (DHR) in the Ministry of Health and Family Welfare. In this regard, an authority has already been designated by the DHR for registration of Ethics Committees for biomedical and health research involving human participants, vide this Department's Office Order No.U-11024/01/2018-HR (Part)/8006615 dated 12.09.2019. Also, a set-up, with the nomenclature 'National Ethics Committee Registry for Biomedical and Health Research' (NECRBHR), has been put in place within the Department of Health Research, vide this Department's ID Note No. U-11024/01/2018-HR (Part)/8006615 dated 12.09.2019, to

facilitate receipt and processing of applications seeking registration, and to assist the authority, thus designated, in the discharge of its duties.

4. The entire process of receipt and processing of the applications, seeking registration of ethics committees for biomedical and health research involving human participants, shall be carried out in the DHR online only. For this purpose, a portal has been developed, to facilitate the task, with the domain name "naitik.gov.in". All entities/institutions/medical colleges/researchers/stakeholders, etc. - whether in public or private and, who are conducting or intending to conduct biomedical and health research involving human participants, are required to submit proposal (s) for registration of Ethics Committees on the above portal. It is now a mandatory requirement, with effect from 15.09.2019, for getting all those ethics committees for biomedical and health research, involving human participants, registered with the designated authority in the DHR.

5. In view of the above, it is requested that attention of all the entities/ institutions/ researchers /stakeholders in your State / Union Territory - whether in public or private, and who are conducting or intending to conduct biomedical and health research, involving human participants — may be drawn to the requirement for registration of Ethics Committees for Biomedical and Health Research in terms of the provisions of Chapter-IV of the 'New Drugs and Clinical Trials Rules, 2019' with the designated authority in the Department of Health Research w.e.f. 15.09.2019.

Yours faithfully,



(Om Parkash)

Under Secretary to the Government of India


Tele : 011-23736085

Copy to :

1. Secretary, Department of Health and Family Welfare, New Delhi.
2. Secretary, Ministry of AYUSH, New Delhi.
3. Secretary, Department of Biotechnology, New Delhi.
4. Secretary, Department of Science & Technology, New Delhi.
5. Secretary, Department of Higher Education, M/o of HRD, New Delhi.
6. DGHS, Nirman Bhawan, New Delhi.
7. Secretary, University Grants Commission, New Delhi.
8. Secretary, MCI / DCI / NCI / PCI, New Delhi.
9. Hospital Section, D/o Health and Family Welfare, New Delhi.
10. DCG(I), CDSCO, FDA Bhawan, ITO, Kotla Road, ND - 110002.
11. Director, BMHRC, Bhopal.
12. Dr. Vijay Kumar, Sc-'G' & Head (BMS Division), ICMR, New Delhi.
13. Dr. Roli Mathur, Scientist 'E' & Head (Bioethics Unit), NCDIR (ICMR), Bengaluru.

Copy, also, to:

PPS to Secy(DHR) & DG (ICMR) / PPS to JS(AN) / Sr. PPS to JS(GN)/  
DS(DRM)/ DS(VK)/ DS(GRR)/ DS(ABS)/NECRBHR/Cons(DKB)/Guard File



12/9/19  
(Om Parkash)

Under Secretary to the Government of India