

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

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

2nd Floor, IRCS Building,
1, Red Cross Road, New Delhi-110001.

Dated, the 12th 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

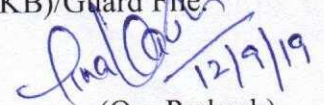
Tele : 011-23736085

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:

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(Om Parkash)

Under Secretary to the Government of India