

No. U-11024/01/2018-HR (Part)/8006615
Government of India
Ministry of Health & Family Welfare
(Department of Health Research)

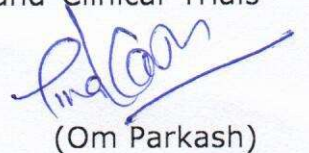
2nd Floor, IRCS Building,
1, Red Cross Road, New Delhi-110001.
Dated, the 12th September, 2019.

OFFICE ORDER

Subject: Designation of Authority in the Department of Health Research for registration of Ethics Committees for Biomedical and Health Research in terms of the sub-rule (1) of rule 17 of the New Drugs and Clinical Trials Rules, 2019.

The sub-rule (1) of rule 17 of the New Drugs and Clinical Trials Rules, 2019 provides that an ethics committee, constituted under rule 16 of the aforesaid Rules, for the purpose of biomedical and health research involving human participants, shall be required to register with the authority, to be designated by the Central Government in the Ministry of Health and Family Welfare, Department of Health Research.

2. Accordingly, with the approval of the Competent Authority, the incumbent of the post of Joint Secretary in the Department of Health Research, under whose charge the subject of biomedical and health research involving human participants is dealt with, is designated as the authority, who shall discharge, on *ex-officio* basis, all the functions assigned to such an authority under the said rules, namely, the 'New Drugs and Clinical Trials Rules, 2019'.



(Om Parkash)

Under Secretary to the Govt. of India
Tel. No.: 23736085

To

- 1) Secretary, D/o Health and F.W., Nirman Bhawan, New Delhi-110011.
- 2) Secretary, M/o AYUSH, AYUSH Bhawan, 'B' Block, GPO Complex, INA, New Delhi - 110023.
- 3) Dir. Gen., ICMR, Ansari Nagar, New Delhi-110029.
- 4) DGHS, Nirman Bhawan, Maulana Azad Road, New Delhi - 110011
- 5) DCG(I), CDSCO Hqrs., FDA Bhawan, Kotla Road, New Delhi - 110002.
- 6) Head (Bioethics Unit), ICMR, NCDIR, Nirmal Bhawan, ICMR Complex (IInd Floor), Poojanahalli Road, Kannamangala Post, Bengaluru - 562110, Karnataka.
- 7) Director, NIMS / CTRI, New Delhi.

Copy to: PS to HFM / PS to MoS(AKC) / PPS to Secretary (DHR) / PPS to JS(AN) / Sr. PPS to JS(GN) / NECRBHR/Cons(DKB)/DHR Website.

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: 12th September, 2019.

NOTICE

Subject : Registration of Ethics Committees for Biomedical and Health Research Involving Human Participants – Regarding.


It is informed 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 requested to submit proposals for registration of Ethics Committees on the above portal. It may be noted that now, it is a mandatory requirement with effect from 15.09.2019, for getting all ethics committees for biomedical and health research, involving human participants, registered with the designated authority in the DHR.


12/9/19
(Om Parkash)

Under Secretary to the Government of India

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To

All Stakeholders / Public-at-large