



भारतीय दन्त परिषद
DENTAL COUNCIL OF INDIA
(A STATUTORY BODY CONSTITUTED UNDER THE DENTISTS ACT, 1948)

No.DE-237-Act(Regulations-Ethics)-2020/ 1121

By E-mail/Website

Dated 28 July, 2020

To,

The Principal of all the dental colleges in the country

Sub: Registration of Ethics Committees for Biomedical and Health Research with National Ethics Committee Registry for Biomedical and Health Research, DHR-Regarding.

Sir/Madam,

In continuation of this office letter No.DE-130-Act-2019/7309 dated 13.01.2020, on subject cited above, I am directed to refer GOI's letters No.U-11024/01/2018-HR(Part-2)/8015255 dated 10.12.2020 & 06.03.2020 thereby informing that the Ministry of Health & Family Welfare has notified the 'New Drugs and Clinical Trials Rules, 2019' on 19.03.2019 and according to the chapter IV of the above rules, all entities/institutions/medical college/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 register their Ethics Committees on the portal namely "naitik.gov.in", which is mandatory requirement w.e.f. 15.09.2019.

2. In this connection, it is again requested that all such ethics committees involved in Biomedical and Health Research in your institutions, get themselves registered with Department of Health Research immediately.

Yours faithfully,

(Mukesh Kumar)
Deputy Secretary
Dental Council of India

Copy for Information to:-

The Deputy Secretary, Government of India, Ministry of Health & Family Welfare, Department of Health Research, 2 Floor, IRCS Building, 1, Red Cross Road, New Delhi-110001.

Jd/-
(Mukesh Kumar)
Deputy Secretary
Dental Council of India

CC:-

1. The President, Dental Council of India
2. Server Section for email.

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, 6th March, 2020

To


1. The President, Medical Council of India, Dwarka sector-8, New Delhi-110077
2. The President, Pharmacy Council of India, NBCC Centre, Okhla, phase-1, Delhi-110020
- ✓ 3. The President, Dental Council of India, Kotla Road, Temple Lane, New Delhi-110002
4. The President, Nursing Council of India, NBCC Centre, Okhla phase-1, New Delhi-110020

Subject: Registration of Ethics Committees for Biomedical and Health Research with National Ethics Committee Registry for Biomedical and Health Research, DHR-Regarding.

Sir/Madam,

I am directed to refer to this Department's letter of even number No. U-11024/01/2018-HR (Part-2)/8015255 dated 10th December 2019 (Copy Enclosed) and to say that the response from most of the institutes/Organisations is still awaited as they have not applied for registration under DHR so far. You are therefore requested to kindly issue direction to the institutes under your administrative control in this regard. This may be given wide publicity by hosting the communication and its enclosures on your Department's website.

Yours faithfully,


12/03/2020
(D.R. Meena)

Deputy Secretary to the Government of India
Tele: 011-23736904

Copy to:

- i. DS (VK)/DS (ABS)/DS (GRR)/US (ML)/US (GAR)/US (DK)/US (RJM)
- ii. All the Scientist in DHR

U.11024/01 2018-HR (Part-2) 8015255
Government of India
Ministry of Health & Family Welfare
(Department of Health Research)

2nd Floor, IRC'S 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' (NECRBHHR), 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 Prakash)

Under Secretary to the Government of India

Tel. No. :011-23736085

E-mail ID : om.prakash38@nic.in

To

All Stakeholders / Public-at-large

276

स्वास्थ्य विभाग
Department
प्रति
दिनांक 2-1-20
भारत

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 10th December, 2019.

To

- i. The Dean / Principal,
Medical / Dental / Pharmacy / Nursing colleges.
- ii. Director, ICMR Institutes

Subject: Registration of Ethics Committees for Biomedical and Health Research with National Ethics Committee Registry for Biomedical and Health Research, DHR-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, came 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'.

3. In compliance to the sub-rule (1) of rule 17, 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 (Encl. 1). 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-2)/8015255 dated 12.09.2019 (Encl. 2), to facilitate receipt and processing of applications seeking registration, and to assist the authority, thus designated, in the discharge of its duties. A communication was also sent to the Secretaries/Principal Secretaries, Health and Family Welfare Departments of all the State Governments/Union Territory Administrations to bring the provisions of this rule into the

[Contd. 2]

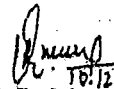
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notice of all the entities/institutions/researchers/stake holders in their respective State/UT vide letter No U-11024/01/2018-HR (part-2)/8015255 dated 12th September 2019 (Encl. 3).

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 via online process 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 register their Ethics Committees on the above portal. It is now a mandatory requirement, with effect from 15.09.2019, 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.

5. In view of the above, it may please be ensured that all such ethics committees involved in Biomedical and Health Research in your Institutions, get themselves registered with Department of Health Research immediately.

Yours faithfully,


10.12.2019
(D.R. Meena)

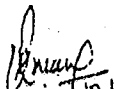
Deputy Secretary to the Government of India
Tele: 011-23736085

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), NCDC (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.


10.12.2019
(D. R. Meena)

Deputy Secretary to the Government of India

WA
By Speed post /E-mail

No.U-11024/01/2018-IR (Paf1-2)/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.

Repetit
New

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'.

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1

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

2. 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.

3. 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)

(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 IIRD, New Delhi.
6. DGHIS, Nirman Bhawan, New Delhi.
7. Secretary, University Grants Commission, New Delhi.
8. Secretary, MCI / DCI / NCI / PCI, New Delhi.
9. Hospital Section, IYO 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.

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DS(DRM) DS(VK) DS(GRR) DS(ABS) NECRBHR Cons(DKB)/Guard File.

(Om Parkash) 12/9/19

(Om Parkash)

Under Secretary to the Government of India