



icmr
INDIAN COUNCIL OF
MEDICAL RESEARCH

भारतीय आयुर्विज्ञान अनुसंधान परिषद INDIAN COUNCIL OF MEDICAL RESEARCH

स्वास्थ्य अनुसंधान विभाग (स्वास्थ्य एवं परिवार कल्याण मंत्रालय)

वी रामलिंगस्वामी भवन, अन्सारी नगर, नई दिल्ली - 110029

DEPARTMENT OF HEALTH RESEARCH (MINISTRY OF HEALTH & FAMILY WELFARE)
V. RAMALINGASWAMI BHAWAN, ANSARI NAGAR, NEW DELHI-110029

No.E16/70/2022-Admn.

Dated:13/1/2023

To

The Directors/Directors-in-charge of
All Institutes/Centers of ICMR

Sir/Madam,

Please find enclosed the following letters which have been received from different Ministries/Departments for information and necessary action:

S.No	Reference No. & Date	Name of Ministry	Subject
1.	D.O. No.4/1/2021-Leg I Dated: 06.12.2022	Ministry of Parliamentary Affairs 40, Parliament House, New Delhi	Sending official communications pertaining to business of Parliament between 10.00 am to 6.00 pm-reg.
2.	No. U-11022/01/2020- HR/8120573 Dated: 09/12/2022	Ministry of Health & Family Welfare, DHR, New Delhi	Registration of Ethics committees for Biomedical and Health Research with DHR – regarding

Yours faithfully


13/1/23

(Jagdish Rajesh)

Assistant Director General (Admin.)

Encl: As above

Copy to: 1. PS to DG/Sr. DDG(A)/Sr. FA

2. All Divisional Heads

3. DDG(A)/ ADG(A)/ ADG(F)

4. Dr. L.K. Sharma, Scientist "E"-soft copy of the same has been mailed at your email ID
(Sharma.lk@icmr.gov.in) for website upload



icmr
INDIAN COUNCIL OF
MEDICAL RESEARCH

भारतीय आयुर्विज्ञान अनुसंधान परिषद
INDIAN COUNCIL OF MEDICAL RESEARCH

स्वास्थ्य अनुसंधान विभाग (स्वास्थ्य एवं परिवार कल्याण मंत्रालय)

वी रामलिंगस्वामी भवन, अन्सारी नगर, नई दिल्ली - 110029

DEPARTMENT OF HEALTH RESEARCH (MINISTRY OF HEALTH & FAMILY WELFARE)

V. RAMALINGASWAMI BHAWAN, ANSARI NAGAR, NEW DELHI-110029

क्रमांक.E16/70/2022-प्रशासन

दिनांक:13/1/2023

सेवा में,

निदेशक/प्रभारी निदेशक

परिषद के सभी संस्थान/केन्द्र

महोदय/महोदया,

विभिन्न मंत्रालयों/विभागों से प्राप्त निम्नलिखित पत्र, सूचना एवं आवश्यक कार्यवाही के लिए संलग्न हैं।

S. No	Reference No. & Date	Name of Ministry	Subject
1.	D.O.No.4/1/2021-Leg I Dated: 06.12.2022	संसदीय कार्य मंत्रालय 40, संसद भवन, नई दिल्ली	सुबह 10.00 बजे से शाम 6.00 बजे के बीच संसद के कामकाज से संबंधित आधिकारिक संचार भेजना के संबंध में।
2.	No. U-11022/01/2020-HR/8120573 Dated: 09/12/2022	स्वास्थ्य और परिवार कल्याण मंत्रालय, डीएचआर, नई दिल्ली	डीएचआर के साथ बायोमेडिकल और स्वास्थ्य अनुसंधान के लिए नैतिकता समितियों का पंजीकरण के संबंध में।

भवदीय,

21 जनवरी

जगदीश राजेश 18/1/23

सहायक महानिदेशक (प्रशासन)

अनुलग्नक:यथोक्त

प्रतिलिपि: 1. महानिदेशक/वरि.उपमहानिदेशक (प्रशा.)/वरि.वित्त सलाहकार के निजी सचिव

2. परिषद के सभी प्रभाग प्रमुख

3. उपमहानिदेशक (प्रशा.)/सहा. महानिदेशक (प्रशा.)/सहा. महानिदेशक (वित्त.)

4. डॉ.एल.के शर्मा, वैज्ञानिक ई: वैबसाइट पर अपलोड करने के लिए ईमेल आईडी

(sharma.ik@icmr.gov.in) पर मेल कर दिया गया है।



ADMN-II ADMN <admn2355@gmail.com>

Fwd: Sending official communications pertaining to business of Parliament between 10.00 am to 6.00 pm-reg.

1 message

Jagdish Rajesh <rajeshj.hq@icmr.gov.in>
To: admn2355 <admn2355@gmail.com>

Thu, Dec 15, 2022 at 12:44 AM

Dear Hemant,

Please put up.

With Regards,

Jagdish Rajesh,
Assistant Director General (Admn.)
Indian Council of Medical Research(ICMR),
New Delhi

From: "dhrhq icmr" <dhrhq.icmr@gmail.com>
To: "Jagdish Rajesh" <rajeshj.hq@icmr.gov.in>
Cc: "Aruna Sen" <aruna.sen@gov.in>, "Harish Chandra" <harish.cmondal@gov.in>, "Jatin Singh" <jatin.singh90@gov.in>, "dhrhq icmr" <dhrhq.icmr@gmail.com>
Sent: Thursday, December 15, 2022 1:19:24 PM
Subject: Sending official communications pertaining to business of Parliament between 10.00 am to 6.00 pm-reg.

Sir,

Please find the attached scanned copy of email dated 07.12.2022 on the subject mentioned above received from MoPA for information and compliance.

Regards,
DHR-ICMR Section



संयुक्त राष्ट्रसंघ
ONE EARTH - ONE FAMILY - ONE FUTURE

2928024.pdf
3638K

D. Ab. Singh Adm
13/12/2022

Mr. Sumit
13/12

Reg. sending official communications pertaining to business of Parliament between 10.00 am to 6.00 pm.

D.G. ICMR OF
263820
Date 12/12/22

From : Gudey Srinivas <secympa@gov.in>

Wed, Dec 07, 2022 03:25 PM

Subject : Reg. sending official communications pertaining to business of Parliament between 10.00 am to 6.00 pm.

#1 attachment

To : Manoj Ahuja <secy-agri@nic.in>, Dr(Mr) Himanshu Pathak <dg.icar@nic.in>, RAJESH KOTECHA <secy-ayush@nic.in>, Arun Baroka <sec.cpc@nic.in>, Shri Rajesh Kumar Singh IAS <secyahd@nic.in>, Secretary DoF <fertsec@nic.in>, Ms S. Aparna <secy-pharma@nic.in>, Secy moca <secy.moca@nic.in>, Secretary Coal <secy.moc@nic.in>, Commerce Secretary Office <csoffice@nic.in>, Secy DPIIT <secy-ipp@nic.in>, Secretary Posts <secretary-posts@indiapost.gov.in>, K Rajaraman <secy-dot@nic.in>, ROHIT KUMAR SINGH <secy-ca@nic.in>, Shri Sanjeev Chopra <secy-food@nic.in>, Secretary MCA <secy.mca@nic.in>, Gyanesh Kumar <secy-coop@gov.in>, Govind Mohan <secy-culture@nic.in>, Shri Giridhar Aramane <defsecy@nic.in>, Secretary DP <sdps@nic.in>, Secretary DRDO <secydrdo@gov.in>, Shri Vijoy Kumar Singh IAS <secyesw@nic.in>, Mr Lok Ranjan <secydoner@nic.in>, Dr M Ravichandran <secretary@moes.gov.in>, K. Sanjay Murthy <secy.dhe@nic.in>, Sanjay Kumar <secy.sel@nic.in>, Secretary MeitY <secretary@meity.gov.in>, Ms Leena Nandan <secy-moef@nic.in>, Vinay Kwatra <psfs@mea.gov.in>, Shri Ajay Seth <secy-dea@nic.in>, T.V. Somanathan <secyexp@nic.in>, Sanjay Malhotra <rsecy@nic.in>, Secretary DIPAM <secydivest@nic.in>, Secretary DFS <secy-fs@nic.in>, Jatindranath Swain <secy-fisheries@gov.in>, Secretary MoFPI <secy.mofpi@nic.in>, Mr Rajesh Bhushan <secyhfw@nic.in>, DG ICMR <dg@icmr.org.in>, Shri Kamran Rizvi <shioff@nic.in>, Shri Ali R. Rizvi <secy-dpe@nic.in>, Ajay Kumar Bhalla <hshso@nic.in>, SECRETARY,OL <secy-ol@nic.in>, Dr. Dharmendra Singh Gangwar <secybm@nic.in>, Anuradha Prasad <secy-iscs@nic.in>, Manoj Joshi <secyurban@nic.in>, Apurva Chandra <secy.inb@nic.in>, Ms. Vini Mahajan <secydws@nic.in>, Shri Pankaj Kumar <secy-mowr@nic.in>, O/o Secy Labour Employment <secy-labour@nic.in>, Shri S.K.G Rahate <secy-jus@gov.in>, Dr. Niten Chandra, Law Secretary <secylaw-dla@nic.in>, Secretary LD <secyoffice-ld@gov.in>, Bidyut Behari Swain <secretary-msme@nic.in>, Vivek Bharadwaj <secy-mines@nic.in>, Secretary, Minority Affairs <secy-mma@nic.in>, Bhupinder S Bhalla IAS <secy-mnre@nic.in>.

JS(AN)
JS(AN)

RB
10/12/22

Secy. ICMR

12/12

1) Dr. Kantho. Bai E

2) US/HCM

14/12/22

Mr. Kapil ASD

mail

Mr Sunil Kumar <secy-mopr@nic.in>, Office of Secretary,
Personnel <secy_mop@nic.in>, Shri V. Srinivas <secy-
arpg@nic.in>, Secy PNG <sec.png@nic.in>, Shri Alok Kumar
<secy-power@nic.in>, Chairman Railway Board Railway Board
<crb@rb.railnet.gov.in>, SECRETARY MORTH <secy-
road@nic.in>, Mr Ajay Tirkey <secy-dolr@nic.in>, Shailesh
Kumar Singh <secyrd@nic.in>, Dr Rajesh S Gokhale
<secy.dbt@nic.in>, SECRETARY DST <dstsec@nic.in>,
Director General CSIR <dgcsir@csir.res.in>, Office of
Secretary Ports Shipping and Waterways <secyship@nic.in>,
Atul Kumar Tiwari <secy-msde@nic.in>, Anjali Bhawra
<secywel@nic.in>, Sh Rajesh Aggarwal <secretaryda-
msje@nic.in>, Dr(Mr) G P Samanta <secymospi@nic.in>,
Sanjay Singh <secy-steel@nic.in>, Rachna Shah <secy-
textiles@nic.in>, Secretary Tourism <sectour@nic.in>,
Lakshmi Naryain <secy-tribal@nic.in>, Mr Indevan Pandey
<secy.wcd@nic.in>, Sujata Chaturvedi <secy-
sports@nic.in>, Secretary Youth Affairs <secy-ya@nic.in>,
chmn@dae.gov.in, chairman@isro.gov.in

Cc : S.S.Patra <ss.patra@nic.in>, SUMAN SUCHITA BARA
<ss.bara@nic.in>

Respected PPS/PS to Secretary,

Please find enclosed d.o. letter of Secretary, M/o Parliamentary Affairs for information and appropriate action.

Regards,

(J.N. Naik)
PS to Secretary, MoPA
T-+911123017663



गुडेय श्रीनिवास
GUDEY SRINIVAS
SECRETARY



भारत सरकार
संसदीय कार्य मंत्रालय
40, संसद भवन
नई दिल्ली - 110001
GOVERNMENT OF INDIA
MINISTRY OF PARLIAMENTARY AFFAIRS
40, PARLIAMENT HOUSE,
NEW DELHI-110001

D.O. No. 4/1/2021-Leg I

2928024
09/12/2022

dated: 06.12.2022

Dear Secretary,

Please find enclosed herewith a copy of D.O letter No. RS.6/12/2022-B dated 23.11.2022 received from Secretary-General, Rajya Sabha regarding sending official communications pertaining to business of the House during office hours only, i.e. between 10.00 a.m. to 6.00 p.m.

It is accordingly requested to adhere to the timelines while sending official communications connected with the business of the Rajya Sabha.

With regards,

Yours sincerely,

JS(4N) / JS(4N)

(Gudey Srinivas)

To

All Secretaries
Government of India
(all Ministry/Departments)

Health Research

महोदय
P.C. MODY

14/11/22
24/11/22

महामन्त्री, राज्य सभा
SECRETARY GENERAL, RAJYA SABHA
29, Parliament House, New Delhi-110001
Tel: 23017355, 23034695, Fax: 23792940
E-mail: secygen.rs@sansad.nic.in

D.O.No.RS.6/12/2022-B

Dated the 23rd November, 2022

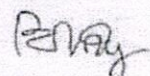
Dear Shri. Srinivas,

As you are aware, the next (258th) Session of Rajya Sabha is scheduled to commence from Wednesday, the 7th December, 2022. You may appreciate that due to various procedural and technical requirements of the Rules of Procedure and Conduct of Business in the Council of States (Rajya Sabha), it is not possible for the Secretariat to process communications relating to business of the Houses received after the office hours and as such they would be processed only on the subsequent day. It is, therefore, necessary that the Ministries/Departments send official communications pertaining to business of the House during office hours only, i.e., between 10.00 a.m. to 6.00 p.m.

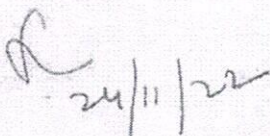
2. Your kind attention in this regard is invited to D.O. letter dated 13th July, 2022 of this Secretariat (copy enclosed) wherein it was *inter alia* requested to advise all Ministries/Departments to ensure timely submission of official communications pertaining to business of the House to the Secretariat. However, it had been observed during the last few Sessions that various notices/communications required under the rules of procedure were sent by Ministries/Departments at the eleventh hour causing avoidable inconvenience to the Hon'ble Chairman and the Secretariat. I, therefore, request you to once again impress upon the Ministries/Departments of the Government of India to strictly adhere to the specified time for sending official communications connected with the business of the Rajya Sabha.

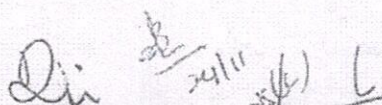
3. Besides, the information regarding the listing of Government legislative and other business for next day in Rajya Sabha may also be furnished to this Secretariat by the Ministry of Parliamentary Affairs at the earliest, but in any case not later than 6.00 p.m., so that the List/Revised List of Business, for information to Members of Rajya Sabha could be issued timely.

Yours sincerely,


(P.C. Mody)

Shri Gudey Srinivas,
Secretary,
Ministry of Parliamentary Affairs,
40, Parliament House,
New Delhi.


24/11/22


24/11/22

प्र.सो. मोदी
MODY



महामन्त्री, राज्या सभा
SECRETARY GENERAL, RAJYA SABHA
29, संसद भवन, नई दिल्ली-110001
Parliament House, New Delhi-110001
Tel: 23017355, 23034695 Fax: 23792940
E-mail: secygen@pdsensed.nic.in

D.O.No.RS.6/12/2022-B

Dated the 13th July, 2022

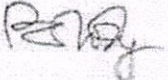
Shri Gyanesh,

As you are aware, the next (257th) Session of Rajya Sabha is scheduled to commence from Monday, the 18th July, 2022. You may appreciate that due to various procedural and technical requirements of the Rules of Procedure and Conduct of Business in the Council of States (Rajya Sabha), it is not possible for the Secretariat to process communications relating to business of the Houses received after the office hours and as such they would be processed only on the subsequent day. It is, therefore, necessary that the Ministries/Departments send official communications pertaining to business of the House during office hours only, i.e., between 10:00 a.m. to 6:00 p.m.

2. Your kind attention in this regard is invited to D.O. letter dated 28th January, 2022 of this Secretariat (copy enclosed) wherein you were *inter alia* requested to advise all Ministries/Departments to ensure timely submission of official communications pertaining to business of the House to the Secretariat. However, it had been observed during the last Session that various notices/communications required under the rules of procedure were sent by Ministries/Departments at the eleventh hour causing avoidable inconvenience to the Hon'ble Chairman and the Secretariat. I, therefore, request you to once again impress upon the Ministries/Departments of the Government of India to strictly adhere to the specified time for sending official communications connected with the business of the Rajya Sabha.

3. Besides, the information regarding the listing of Government legislative and other business for next day may also be furnished to this Secretariat by the Ministry of Parliamentary Affairs at the earliest, but in any case not later than 6.00 p.m., so that the List/Revised List of Business, for information to Members of Rajya Sabha could be issued timely.

Yours sincerely,


(P.C. Mody)

Shri Gyanesh Kumar,
Secretary,
Ministry of Parliamentary Affairs,
40, Parliament House,
New Delhi.

BILL OFFICE

DISTRIBUTION SECTION

16541
13/07/22

No. U-11022/01/2020-HR/8120573

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 9th December, 2022

To,

The Directors, ICMR Institutes
(As per the annexure)

Subject: Registration of Ethics committees for Biomedical and Health Research with DHR - regarding

Sir,

As you are aware that the 'New Drugs and Clinical Trials Rules, 2019' was notified in the Gazette of India vide G.S.R.227 (E) dated 19.03.2019 wherein, Chapter IV of this rules 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. Accordingly, the 'National Ethics Committee Registry for Biomedical and Health Research (NECBHR)', was set up at the Department of Health Research in 2019 to facilitate the 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. In this regard, earlier vide letters of even number dated 12th September, 2019 and 2nd June, 2022 (copies enclosed), the Directors of concerned ICMR Institutes were also requested to ensure that the Ethics Committees of their respective Institutes are registered with NECBHR, DHR.

3. In view of the above, it is again requested to kindly ensure to get registered their respective institutes' Ethics Committee with NECBHR, DHR at the earliest. The Institutes which are already at various stages of registration on the Naitik portal are requested to kindly expedite their process urgently. It may kindly be noted that in

7972
16/12/22

DDG (A)

10.30 am

It is for all Director's

ICMR Institutes to note

compliance

H/1/42420

13/12/22

15/12/22

19/12/22

644005

DDG (A)

B.D. No. 577A/1/11

Mr. Sumit

19/12

I/3559944/2022

cases where institutional EC are not registered with NECRBHR, DHR, no funds may be released under any scheme of DHR/ICMR from the next financial year onwards. A list of the institutes indicating the status of EC registration process, as per the Naitik Portal, is attached herewith at Annexure-I.

Encl: As above.

Yours faithfully

Signed by Daulat Ram

Meena

Date: 09-12-2022 13:48:34

(D.R. Meena)

Director

Tel.No.:011- 23736901

Copy to:

1. Director General, ICMR, Ansari Nagar, New Delhi.
2. ✓ Sr. DDG (Admin), ICMR, Ansari Nagar, New Delhi.

Annexure - I**Login registered only, application not submitted:**

1. Director, ICMR-NIIRNCD, Jodhpur, Rajasthan.
2. Director, ICMR-National Institute of Research in Tribal Health, Jabalpur, Madhya Pradesh
3. Director, ICMR-National AIDS Research Institute, Pune, Maharashtra
4. Director, ICMR-National Institute of Virology, Pune, Maharashtra
5. Director, ICMR-Regional Medical Research Centre, Andaman and Nicobar Islands
6. Director, ICMR -Centre for Ageing & Mental Health, Kolkata
7. Director, ICMR-Regional Medical Research Centre, Bhubaneswar

No login registration:

8. Director, ICMR-Regional Occupational Health Centre, Bangalore, Karnataka (field unit)
9. Director, ICMR-Centre for Research, Management & Control of Hemoglobinopathies, Mumbai, Maharashtra
10. Director, ICMR-National Institute of Cholera and Enteric Diseases, Kolkata, West Bengal
11. Director, ICMR-Centre for Research in Medical Entomology, Madurai, Tamil Nadu
12. Director ICMR-Vector Control Research Centre, Pondicherry
13. Director, ICMR National Animal Resource Facility for Biomedical Research (NARFBR), Hyderabad, Telangana

Provisional expired:

1. ICMR- National Institute of Malaria Research, Delhi
2. ICMR-National Institute for Research in Tuberculosis
3. National JALMA Institute for Leprosy & Other Mycobacterial Diseases, Agra

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

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

Dated, the 2nd June, 2022

To,

The Directors, ICMR Institutes
(As per the Annexure)

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

Sir/Madam,

As you are aware that the 'New Drugs and Clinical Trials Rules, 2019' was notified in the Gazette of India vide G.S.R.227 (E) dated 19.03.2019 wherein, Chapter IV of this rules 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. Accordingly, 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. In this regard, a communication No.U.11024/01/2018-HR(Part-2)/8015255 dated 12th September, 2019 (copy enclosed) was also sent to all the stakeholders.

3. In view of the above, it may please be ensured that all Ethics Committees of ICMR institutes gets registered with DHR, at the earliest.

Encl: As above.

Yours faithfully,

Digitally Signed by Daulat

Ram Meena

Date: 02-06-2022 (18/06/2022)

Deputy Secretary, Government of India

Copy to:

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

Annexure

1. Director, ICMR National Institute Of Pathology, Delhi.
2. Director, ICMR-NIIRNCD, Jodhpur, Rajasthan.
3. Director, ICMR-National Institute Of Research In Tribal Health, Jabalpur, Madhya Pradesh.
4. Director, ICMR-National AIDS Research Institute, Pune, Maharashtra.
5. Director, ICMR-National Institute Of Virology, Pune, Maharashtra.
6. Director, ICMR-Regional Occupational Health Centre, Bangalore, Karnataka.
7. Director, ICMR-National Institute for Research in Environmental Health, Bhopal Madhya Pradesh.
8. Director, ICMR-Centre for Research, Management & Control of Hemoglobinopathies, Mumbai, Maharashtra.
9. Director, ICMR-Regional Medical Research Centre, Andaman and Nicobar Islands.
10. Director, ICMR-Regional Medical Research Centre, Bhubhaneshwar.
11. Director, ICMR -Centre for Ageing & Mental Health, Kolkata, West Bengal.
12. Director, ICMR-National Institute of Cholera and Enteric Diseases, Kolkata, West Bengal.
13. Director, ICMR-Centre for Research in Medical Entomology, Madurai, Tamil Nadu.
14. Director ICMR-Vector Control Research Centre, Pondicherry.
15. Director, ICMR National Animal Resource Facility for Biomedical Research (NARFBR), Hyderabad, Telangana.

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,
DIIR-Regarding.

Sir/Madam,

1. 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 DIIR for registration of Ethics Committees for biomedical and health research involving human participants, vide this Department's Office Order No. U-11024/01/2018-IIR (Part)/8006615 dated 12.09.2019 (Encl. 1). Also, a set-up, with the nomenclature 'National Ethics Committee Registry for Biomedical and Health Research' (NECRBIIR), has been put in place within the Department of Health Research, vide this Department's ID Note No. U-11024/01/2018-IIR (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

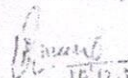
[Contd. 2]

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 13th September 2019 (Incl. 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 DIHR 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 DIHR.

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,


(D.R. Meena)

Deputy Secretary to the Government of India

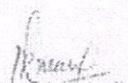
Tele: 011-23736085

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, BMIIRC, 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(DIHR) & DG (ICMR) / PPS to JS(AN) / Sr. PPS to JS(GN)/ DS(DRM)/ DS(VK)/ DS(GRR)/ DS(ABS)/NECRBH/Cons(DKB)/Guard File.


(D. R. Meena)

Deputy Secretary to the Government of India

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'.

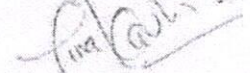
3. The sub-rule (1) of rule 17 of these Rules provides that such an Ethics Committee - to be constituted in accordance with the said guidelines - shall register itself with the authority to be designated for the purpose by the Department of Health Research (DHR) in the Ministry of Health and Family Welfare. 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)

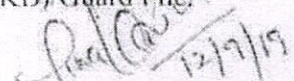
Under Secretary to the Government of India
Tele : 011-23736085

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, Sec-'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.


(Om Parkash)

Under Secretary to the Government of India

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

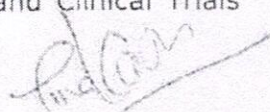
2nd Floor, IRCS Building,
1, Red Cross Road, New Delhi-110001.
Dated, the 12th September, 2019.

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 / CTIRI, 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.