



GSER-IEC
Good Society For Ethical Research
Independent Ethical Committee
Accredited By NABH
Registered with CDSCO

INTRODUCTION



Good Society For Ethical Research (GSER) was incorporated on 21st September 2012 under the **Society Registration Act XXI of 1860 (Registration No. S/001076NE/2012)**, to provide independent counselling, advice and decision (in the form of “Approval/ Recommendation/ Determination/ Rejection”) and to provide information on health or other clinical research protocols with people.

The primary purpose of GSER is to:

- Ensure the protection of the rights, safety and welfare of human subjects involved in a research project.
- Make sure to provide public assurance of that protection.

INTRODUCTION – GSER-IEC



Good Society for Ethical Research – Independent ethics Committee (GSER - IEC) is an independent Ethical Committee constituted by keeping all necessary ethical guidelines for Ethics committee like:

- Operational Guidelines for Ethics Committees That Review Biomedical Research (**World Health Organization Geneva 2000**)
- Guideline for Good Clinical Practice E6 (**ICH – E-6**)
- Good Clinical Practice Guidelines - India (**Indian-GCP**)
- National Ethical Guidelines for Biomedical And Health Research Involving Human Participants by ICMR (2011).
- New Drugs and Clinical Trial Rules -2019, India

INTRODUCTION – GSER-IEC



Good Society for Ethical Research – Independent ethics Committee (GSER - IEC) is registered and accredited by

- Central Drugs Standard Control Organization (**CDSCO**) Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India (**ECR/69/Indt/DL/2013/RR-19**)
- Department of Health and Human Services (**DHHS**) Office for Human Research Protections (**OHRP No. IORG0007542**)
- National Accreditation Board for Hospitals & Healthcare Providers (NABH) (**EC-CT-2019-0115**)

Composition – GSER-IEC

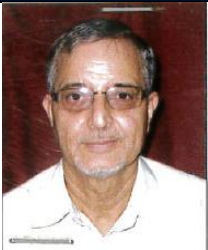





The GSER-IEC is composed of both scientists and non-scientists members for independent in its reflection, advice and decision related to clinical research. SOP of GSER – IEC describes the Terms of Reference (TOR), which provide the framework for the composition, responsibilities and activities of the independent ethics committee. GSER-IEC composed of 14 members and its composition as follows:

- Chairman
- Member Secretary
- Clinician -1
- Basic Medical Scientist including Pharmacologist - 2
- Scientific Members -3
- Legal experts- 2
- Social scientists from non-governmental organization- 2
- Lay person from community -2





Brief profile of – GSER-IEC members



S. No.	Snap of Member	Name and Qualification	Designation	Contact details	Address	Current Affiliation	Total Experience	Date of joining
1.		Dr. Roop K Khar Ph.D., PGDBM, M.Pharm,	Chairman	9582853899 roopkhar@hotmail.com	Flat No- 403, Lalleshwari Apartment, Plot No- GH 12, Block II, Sector 21-D, Faridabad Haryana, Pin code 121001	Professor and Dean Anangpuria Institute of Pharmacy, Alampur Faridabad, Haryana,	42 years	01-10- 2012
2.		Dr. Kanchan Kohli Ph.D., M.Pharm.	Scientific Member	9818335148 kanchankohli@gmail.com	E-156, 1 st Floor, East of Kailash, New Delhi- 110065	Associate Professor, Depart. of pharmaceutics Faculty of pharmacy Jamia Hamdard New Delhi 110062	30 years	01-10- 2012
3.		Dr. Neeraj Kumar Ph.D. M.Pharm.	Member Secretary	9873329254 dr.neekumar@gmail.com	H.No- D/129, St.No- 13, Ashok Nagar, Shahdara, Delhi - 110093	Research Manager Pharamazz India Pvt. Ltd. Surajpur, Greater Noida, U.P	12 years	01-10- 2012
4.		Dr. Vaidehi Garg Ph.D. M.Pharma	Scientific Member	9873123497 Dr.vaidehigarg@gmail.com	53-D, Kamla Nagar, Delhi 110007	Research Associate Dept. of Pharmaceutics Faculty of Pharmacy Hamia Hamdard New Delhi 110062	-	22-02- 2018





Brief profile of – GSER-IEC members



S. No.	Snap of Member	Name and Qualification	Designation	Contact details	Address	Current Affiliation	Total Experience	Date of joining
5		Dr. Anil Sabharwal MBBS, M.D. (Medicine)	Clinician	9810124270 anilsabharwal1@hotmail.com	Sabharwal Clinic, 269/4, Govind Puri, Kalka Ji, New Delhi 110019	Sr. consultant Physician at Banarsidas Chandiwala Institute, Chandiwala Estate, Maa Anandmai Marg, Kalkaji, New Delhi, Delhi 110019	31 years	01-04- 2013
6		Dr. Nilesh Chandra MBBS, M.D. (Biochemistry)	Basic Medical Scientist – Bio- Chemistry	9868010548 nileshchandra1@gmail.com	K5-A, Kailash colony , near Kailash colony metro station, Greater Kailash, New Delhi- 110048	University college of Medical Sciences, Dilshad Garden, New Delhi 110095	8 years	4-09-2015
7		Dr. Devesh Gupta MBBS, M.D. – Pharmacology	Basic Medical Scientist – Pharmacologist	989000743 drdeveshgupta@gmail.com	41/A/14 Pcket Himigiri Apartment Kalkaji Extension, New Delhi 110019	Associate Professor: Pharmacology, AL-Falah School of Medical Science & Research Center and Hospital, Sona Road, Dhuj Village, Faridabad, Haryana 121004	12 years	22-02- 2018
8		Adv. Parveen Rana L.L.B.	Legal Expert	9968122186 ranapravine@gmail.com	H.No. 555, Block-Z, Timarpur, Delhi- 110054	Advocate at Tish Hazari court, Delhi	14 years	01-10- 2012

Brief profile of – GSER-IEC members



S. No.	Snap of Member	Name and Qualification	Designation	Contact details	Address	Current Affiliation	Total Experience	Date of joining
9		Adv. Pankaj Musyuni L.L.B, M.Pharm.	Legal expert	8750597345 Musyunipharmacy@gmail.com	108/4A, II Floor Madangir, New Delhi 110062	Advocate and patent agent Lex Orbis, 709/710, Tolstoy Hause, 15-17, Tolstoy Marg, Near Star union Dai-Chi, Delhi 110001	2 years	22-08- 2018
10		Mr. Harbans Wadhwa BA, PGDBM	Social Scientist / NGO Representative	9873478225 hswadhwa@gmail.com	QU 210-A, Visakha Enclave, Pitampura, Delhi 110088	Headt Product testing at Consumer voice (An NGO) at Pitampura, Delhi	28 years	01-10- 2012
11		Mr. Rajat Oberoi B.Pharm.	Social Scientist / NGO Representative	9810956100 rajat_5539@yahoo.co.in	3201,Ram Bazar, Mori Gate, Delhi- 110006	Secretary cum Coordinator at Prothsahan Team NGO), Dilshad Garden, Delhi	5 years	01-10- 2012
12		Mr. Rohit Mittal B.A.	Lay Person	9582420884 rohitm.d17@gmail.com	17-D, Kamla Nagar, First Floor, Delhi 110007	17-D, Kamla Nagar, First Floor, Delhi 110007	15 years	01-10- 2012

Brief profile of – GSER-IEC members



S. No.	Snap of Member	Name and Qualification	Designation	Contact details	Address	Current Affiliation	Total Experience	Date of joining
13		Ms. Meenakshi M.A., B.A.	Lay Person	8800226397 Mvc85vv@gmail.com	C- 85, C Block , Vivek Vihar, Delhi 110095	Primary Teacher New Oxford Public School, Vivek Vihar, Delhi 110095	5 years	07-07-2016
14		Mr. Fayazul Islam M.B.A., B.Pharm.	Scientific Member	9911228114 fayazul@gmail.com	M 32 B, 1 st floor, Gali No- 5, Abul Fazal enclave Part-1, New Delhi -25	Pharmacist and Regulatory consultant, Delhi	5 years	01-10-2012

Document Required for GSER-IEC review



At GSER, we follow our SOP for Document submission for any protocol review. In brief, we will use our checklist for contents of a submitted package . Submitted may contains following documents:

- Protocol handling Fee
- Clinical study Protocol
- Informed Consent Document in English and Hindi / local language with translation certificate
- Back translated Informed Consent Document with translation certificate
- Randomization schedule (if applicable)
- Product Monograph/ Information sheet
- Proposed methods for subject accrual including advertisement (s) etc. proposed to be used for the purpose.
- Principal Investigator's current CV with MRC
- Insurance Policy / Compensation for participation and for serious adverse events occurring during the study participation.
- Investigator's Agreement with the Sponsor.
- Investigator's Undertaking
- DCGI notification (if applicable)

Submission Deadlines for GSER-IEC review

Submission time lines:

For fresh protocols: - minimum 10 days and maximum 20 days

For expatiate review: - minimum 7 days maximum 10 days

Our Clients



1. Clianza Research Limited, Noida, Uttar Pradesh 201301
2. Auriga Research Limited, 3/15, Kirti Nagar Industrial Area, New Delhi-110015
3. Global Health Research Group, 31, south Patel Nagar, New Delhi 110008.
4. Institute of Nuclear Medicine & Allied Sciences (INMAS), Brig. S. K. Mazumdar Marg, Delhi 110054.
5. Fortis Clinical Research Limited, Sunflag Hospital and Research Centre, Faridabad -121002 Haryana,
6. Max Neeman International, Max House, 1, Dr. Jha Marg, Okhla Phase III, New Delhi-110020.
7. JSS Medical Research India Pvt. Ltd. Faridabad, Haryana 121003
8. CliniExperts Services Private Limited, Unit No. 510, C-58, Shahpuri Tower, Janakpuri, New Delhi- 110058
9. Oral Healthcare Research Centre, GSKCH, R&D Centre, Plot 67, Sector 32 Gurgaon, India
10. Wockhardt Limited. Level -1, West Wing, Wockhardt Towers, G block, Bandra Kurla Complex, Mumbai – 400051