



**SRI BALAJI  
VIDYAPEETH (SBV)**  
DEEMED TO BE UNIVERSITY  
ACCREDITED BY NAAC WITH A GRADE



**MAHATMA GANDHI  
MEDICAL COLLEGE &  
RESEARCH INSTITUTE**  
NH-45A, Pillaiyarkuppam  
Puducherry-607403.

*We cordially invite you for the*

**NATIONAL GCP WORKSHOP ON BIOETHICS FOR  
MEMBERS OF INSTITUTIONAL HUMAN  
ETHICS COMMITTEE**

*Organized by*

**INSTITUTIONAL HUMAN ETHICS COMMITTEE**  
Mahatma Gandhi Medical College & Research Institute  
Sri Balaji Vidyapeeth (Deemed to be University)  
Puducherry

*on*

7th August 2019 (Wednesday)  
**MAULANA ABDUL KALAM AZAD HALL**  
**BAPUJI - CENTRAL LIBRARY**  
Mahatma Gandhi Medical College & Research Institute  
SBV CAMPUS  
Puducherry - 607 402.

Valedictory Address and Distribution of Certificates :  
Prof. **Subhash Chandra Parija**, Hon'ble Vice Chancellor, SBV

**Prof. C. Adithan**  
Organising Chairman

**Dr. Siva Ranganathan Green**  
Organising Secretary

**Good Clinical Practice (GCP)** is delineated as an international ethical and quality standard for the design, conduct, performance, monitoring, auditing, recording, analysing, and reporting of clinical trials, that provides assurance that the:

- Rights, safety and well-being of human research participants are well protected.
- Data and reported results are credible and accurate.

### **Learning Objective of the Workshop :**

- To understand current ethical and regulatory prerequisites for directing clinical research in Medical Institutes in India.
- To be aware of the latest national ethical guidelines for biomedical and health research involving participants by ICMR.
- To enable the delegates to understand that by seeking compliance to GCP they can give the public an assurance that the rights, safety and well-being of human participants are well protected and the data from the study results are credible and accurate.
- To understand the principles of GCP, roles and responsibilities of various stakeholders involved in a clinical research.

### **Who should attend?**

- Members of the ethics committee.
- Faculty who want to become members of the ethics committee.
- Faculty Members, Clinicians, Biomedical Scientists who are interested in Clinical Research.
- Hospital / Health care administrators.
- Clinical research and allied Professionals working at clinical trial sites, pharmaceutical companies.

**NATIONAL GOOD CLINICAL PRACTICE (GCP) WORKSHOP  
ON  
BIOETHICS FOR MEMBER OF INSTITUTIONAL HUMAN ETHICS COMMITTEE  
PROGRAM SCHEDULE**

**Date: 07.08.2019**

**Venue: MAULANA ABDUL KALAM AZAD HALL, BAPUJI - CENTRAL LIBRARY**

<b>Time</b>	<b>Topics</b>	<b>Speaker</b>
8.15 - 8.45 am	<b>Registration</b>	
8.45 - 9.00 am	Orientation to workshop	Dr. Siva Green
9.00 - 9.30 am	General ethical principles in biomedical research	Dr. Lokesh
9.30 - 10.10 am	ICMR guidelines 2017 related to the IEC	Dr. Nandini Kumar
10.10 - 10.30 am	Regulatory guidelines related to the IEC	Dr. C. Adithan
<b>10.30 - 10.45 am</b>	<b>Tea break</b>	
10.45 - 11.15 am	Composition of ethics committee members & their responsibilities	Dr. Medha R
11.15 - 11.45 am	Reviewing the proposal submitted to the ethics committee- Intervention studies	Dr. Ananthakrishnan
11.45 - 12.15 pm	Reviewing the proposal submitted to the ethics committee - Non- Intervention studies	Dr. Nandini Kumar
12.15 - 12.45 pm	Participant Information Sheet and Consent Form	Dr. Chandrasekaran
12.45 - 1.05 pm	Reviewing Academic clinical trial	Dr. G. Sivagnanam
<b>1.05 - 2.00 pm</b>	<b>Lunch break</b>	
2.00 - 2.20 pm	Adverse Drug Reaction reporting & monitoring	Dr. Jayanthi
2.20 - 2.40 pm	Compensations for Participants and Research related injury	Dr. Sandhya
2.40 - 3.00 pm	Research in Vulnerable Population	Dr. Melvin George
3.00 - 4.00 pm	Group Exercises: Discussion of Case scenarios	Dr. Melvin George and Dr. Sandhya
<b>4.00 - 4.15 pm</b>	<b>Tea break</b>	
4.15 - 5.00 pm	Panel discussion and open house: <ul style="list-style-type: none"> <li>✓ Role of subcommittee</li> <li>✓ Registration with CDSCO and DHR</li> <li>✓ Waiver of Consent</li> <li>✓ Consent Vs Assent</li> <li>✓ Video – recording of IC</li> <li>✓ Others questions from Participants</li> </ul>	All Experts  <b>Moderator :</b> Dr. Ananthakrishnan
5.00 - 5.15 pm	Valedictory Address & Distribution of Certificates	Prof. Subhash Chandra Parija, Vice-Chancellor, SBV

## Organizing Committee

### Chief Patron:

- Shri M K Rajagopalan, Hon'ble Chancellor, SBV
- Dr. Prashanth Rajagopalan, Vice- Chairman, SBV

### Patron:

- Prof. Subhash Chandra Parija, Hon`ble Vice Chancellor, SBV.

### Advisory Board:

- Prof. N Ananthakrishnan, Dean Faculty, SBV.
- Prof. M. Ravishankar, Dean, MGMCRI, SBV.

### Organizing Chairman:

- Prof. C. Adithan, Dean Research, SBV.

### Organizing Secretary:

- Dr. Siva Ranganathan Green, Associate Professor, Gen Med, SBV.

### Treasurer:

- Dr. SudarCodi, Associate Professor, Pharmacology, SBV.

### Speakers:

- Dr. Nandini Kumar, Former Deputy Director General Sr. Grade (ICMR), Adjunct Visiting Prof., Kasturba Medical College, Manipal.
- Dr. N.Ananthakrishnan, Professor, Department of Surgery, MGMCRI.
- Dr. G. Sivagnanam, Professor, Department of Pharmacology, IGMCRI.
- Dr. Chandrasekaran, Retd. Associate Professor, Dr. Ambedkar Govt. Law College.
- Dr. Medha R, Additional Professor, Department of Biochemistry, JIMPER.
- Dr. Jayanthi.M, Additional Professor, Department of Pharmacology, JIPMER.
- Dr. Sandhya. S, Assistant Professor, Dept of Clinical Pharmacology, IEC, JIPMER.
- Dr. Melvin George, Department of Clinical Pharmacology, SRM Medical College & Hospital.
- Prof. C. Adithan, Dean Research, SBV
- Dr. Lokesh. S, Professor and Head, Department of General Medicine, MGMCRI.

**Number of Participants:** Limited to a maximum of 40 seats.

**Registration Fees:**

**Registration :** Rs 1000/- by cash only for early bird registration and Rs 1500/- thereafter till the last date of registration.

**Early Bird Registration:** Till 27 July 2019.

**Last date of Registration:** Till 2 August 2019.

**NEFT details for online transaction :**

Bank:	Indian Bank
Branch:	Main Branch
City	Pondicherry
IFSC Code	IDIB000P042
Account Name:	Mahatma Gandhi Medical College & Research Institute
Account Number:	513231447

**How to register:**

- Kindly send scanned copies of NEFT receipt & duly filled registration form to email: [ihec@mgmcri.ac.in](mailto:ihec@mgmcri.ac.in); and for demand draft (DD) payment, it should be made in favour of **“Sri Balaji Vidyapeeth”, Payable at Puducherry**, and the payment with duly filled registration form should be sent to Dr. Siva Ranganathan Green, Dept of Gen Medicine, MGMCRI, Pillaiyarkuppam, Puducherry.607402.
- Registration forms are downloadable and attached with the brochure.
- Registration can be done offline also by submitting the filled registration forms to any one of the workshop coordinators mentioned below.
- No spot/ last minute registration.

**How to reach us?**

Dr. Siva Ranganathan Green Organising Secretary Mobile No : 9894444774 Email ID: <a href="mailto:ihec@mgmcri.ac.in">ihec@mgmcri.ac.in</a>	Dr. Sudar Codi Treasurer Mobile No : 9894647381 Email ID: <a href="mailto:sudarcodi@gmail.com">sudarcodi@gmail.com</a>
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## REGISTRATION FORM

Name (As required in Certificate): \_\_\_\_\_

Age: \_\_\_\_\_

Gender: \_\_\_\_\_

Designation: \_\_\_\_\_

Affiliation & Official Address: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Mobile Number: \_\_\_\_\_ Email ID: \_\_\_\_\_

Regn. Fee details:

Cash: \_\_\_\_\_ NEFT (UTR No): \_\_\_\_\_ DD No & Bank Name: \_\_\_\_\_

\_\_\_\_\_

Briefly state reason for interest in this workshop:

Briefly state your expectations from this workshop:

Signature:

Date:

### **Contact Details:**

Dr. Siva Ranganathan Green,  
Organising Secretary/ Member Secretary IHEC,  
Department of General Medicine,  
Sri Balaji Vidyapeeth Deemed to be University,  
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