

COLLABORATION AGREEMENT

This Collaboration Agreement (hereinafter referred to as "CA") is made and executed on 20/1/2021 (Date) Wednesday (Day) at 11:00 A.M

Between

Department of Pharmacology, Index Medical College Hospital & Research Centre, Indore (Institution Name)- represented by **Dr. /Prof. Prem Nyati**, herein after known as the FIRST PARTY and **Department of Pharmacology, (College name)Amaltas Institute of Medical Sciences, Dewas** represented by **Dr. /Prof. Sharad chandre Wankhede** herein after known as the SECOND PARTY witnesses as follows:

Both the Departments enter this formal collaboration in the form of Collaboration Agreement to promote resource sharing and develop academic and educational collaboration through various activities like:

- Faculty- Student exchange,
- Exchange of personnel as resource persons
- Guest lectures by eminent personalities in the field of Medical Science/health related issues organised by Institutions
- Seminars/ Workshops/ Conferences

The implementation of any type of cooperation depends on the availability of resources at the respective institutions.

This agreement commences on the day of signing by both the parties involved and shall remain in force for the concerned cause, program/Events. The agreement can be extended after discussion with Principal and HODs of the respective departments of both the Institutions.

FIRST PARTY

Dean / Head of the Department

Index Medical College Hospital & Research Centre (M.P.)
Indore

Dean
Index Medical College,
Hospital & R.C., INDORE

Dean
Index Medical College,
Hospital & R.C., INDORE

SECOND PARTY

Registrar
Malwanchal University
Dean/ Head of the Department

Amaltas Institute of Medical Sciences
Dewas

Dean
Amaltas Institute of Medical Sciences
Dewas (M.P.)



AMALTAS Institute of Medical Sciences

(Unit of Amaltas Educational Welfare Society)

Ref No: AIMS/DN/2021/37

Date- 20/01/2021

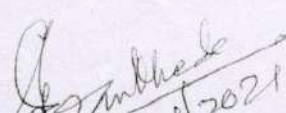
To,
The Committee Members
GCP & NDCT Workshop
Amaltas Institute of Medical Sciences, Dewas

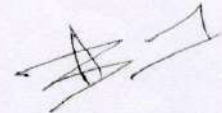
We are organizing a basic workshop on GCP (Good Clinical Practice) and NDCT (New Drugs and Clinical Trials) as per the standards of NABH(National Accreditation Board for Hospitals and Health Care), and ICMR guidelines.

This workshop is being organized at Amaltas Institute of Medical Science, Dewas in collaboration with Index Medical College, Indore and Malwanchal University, Indore on 09th February 2021. This is to train our faculty on the Clinical Trials and GCP, which is the essential component of every clinical research and mandatory for all ethical and scientific committee members as per the request of Honorable Chairman Sir.

It is with great pride and honor that we request you to be a part of the Organizing committee for this workshop

Dr. Abhay John	Associate Professor, Pharmacology	Coordinator
Dr. M. P. Singh	Associate Professor, Physiology	Member
Dr. Ankit Verma	Associate Professor, Orthopedics	Member
Dr. Ashfaq Modiwala	Assistant Professor, PSM	Member
Dr. Arpana Kumari	Tutor, Pharmacology	Member



Dr. S.G. Wankhede
Dean
AIMS, Dewas


Dr. Abhay John
Coordinator
GCP & NDCT Workshop

Dean
Amaltas Institute of Medical Sciences
Dewas (M.P.)

Copy to

- Honorable Chairman/Vice chairman
- HOD, Pharmacology, Index Medical College, Indore
- Vice Chancellor, Malwanchal University
- Registrar, Malwanchal University


Registrar
Malwanchal University
Indore (M.P.)

Campus : Village Bangar, Dewas-Ujjain Highway, Dist. Dewas 455 001(M.P.)
City Off. : 204, Shree Krishna Classic, 139, Phadnis Colony, A.B. Road, Near Hotel Amaltas, Indore-452 008
Index Medical College Phone : 0731-4215858, 4215959 Fax : 0731-4215959
Hospital & R.C. INDORE
website : www.amaltasgroup.co.in, E-mail : medical@amaltasgroup.co.in



AMALTAS Institute of Medical Sciences

(Unit of Amaltas Educational Welfare Society)

Ref No:-AIMS/DN/2021/38

Date- 20/01/2021

To,
The Faculty Members
Amaltas Institute of Medical Sciences,
Dewas

With a great sense of pride and honors, we take this opportunity to invite you as a participant in a one day basic workshop on GCP (Good Clinical Practice) and NDCT (New Drugs and Clinical Trials) as per the standards of NABH(National Accreditation Board for Hospitals and Health Care), and ICMR guidelines.

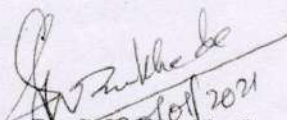
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This is to train our faculty on the Clinical Trials and GCP, which is the essential component of every clinical research and mandatory for all ethical and scientific committee members .

This workshop will cover the following topics:

- Prospects of Clinical Trial & Biomedical Health Research in India. Roles and responsibilities of Stack holders(Sponsors, Investigators and regulators).
- Overviews of Good Clinical Practice- Definition and Evolution, Principles of GCP; CDSCO, WHO,ICH
- Informed Consent, Confidentiality, Privacy, vulnerable population
- Ethical consideration; EC/IRB members and their roles and responsibilities
- Safety consideration in CR; Documentation, Data handling and record keeping
- Monitoring, Audit and Inspection in Clinical Trials
- NDCT Rules 2019.

This is a free workshop being organized by AIMS, Dewas. For registration, kindly contact Dr. Abhay John (Associate Professor, Pharmacology) Mob: 9004044826

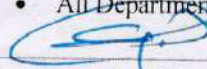

Dr. S.G. Wankhede
Dean
AIMS, Dewas
Amaltas Institute of Medical Sciences
Dewas (M.P.)


Dr. Abhay John
Coordinator
GCP & NDCT Workshop

Copy to

- Honorable Chairman/Vice chairman
- HOD, Pharmacology, Index Medical College, Indore.
- Vice Chancellor, Malwanchal University
- Registrar, Malwanchal University
- All Departments Heads


Registrar
Malwanchal University
Indore (M P)

Camp  Dean
Village Bangar, Dewas-Ujjain Highway, Dist. Dewas 455 001(M.P.)
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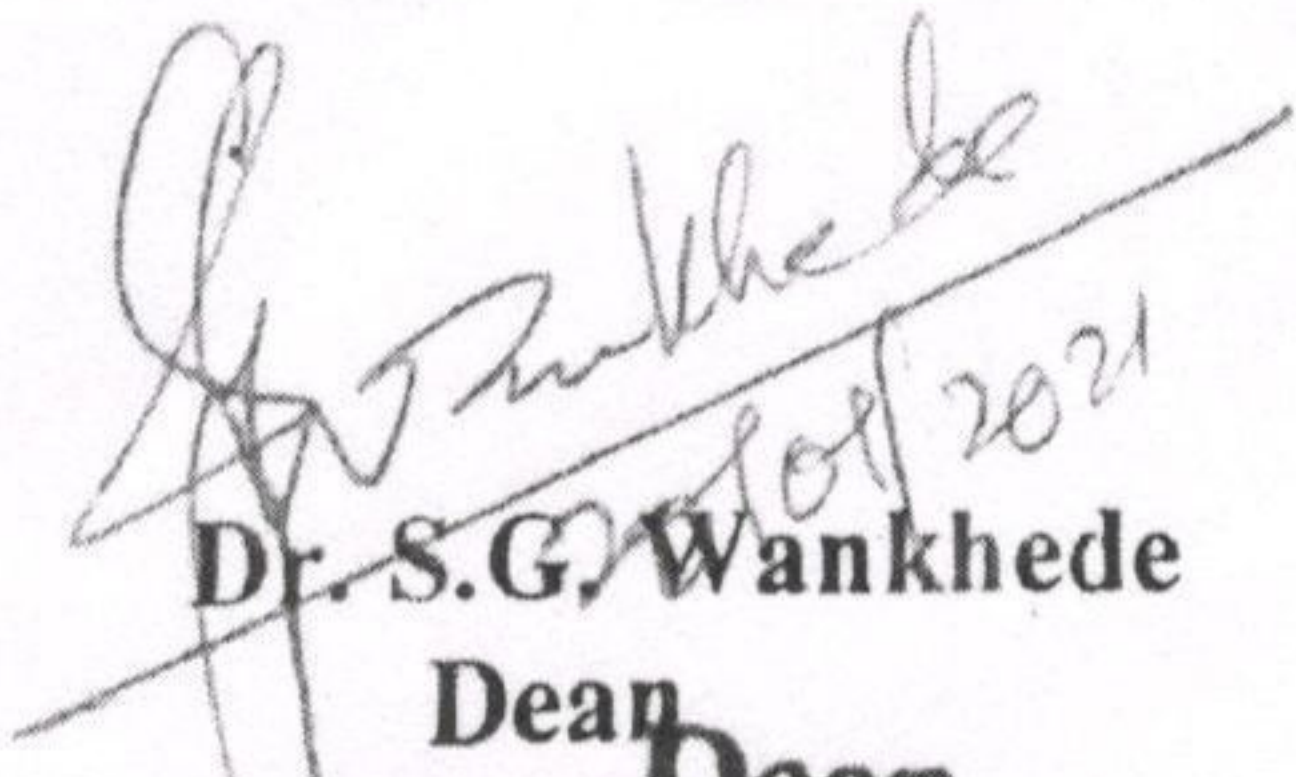
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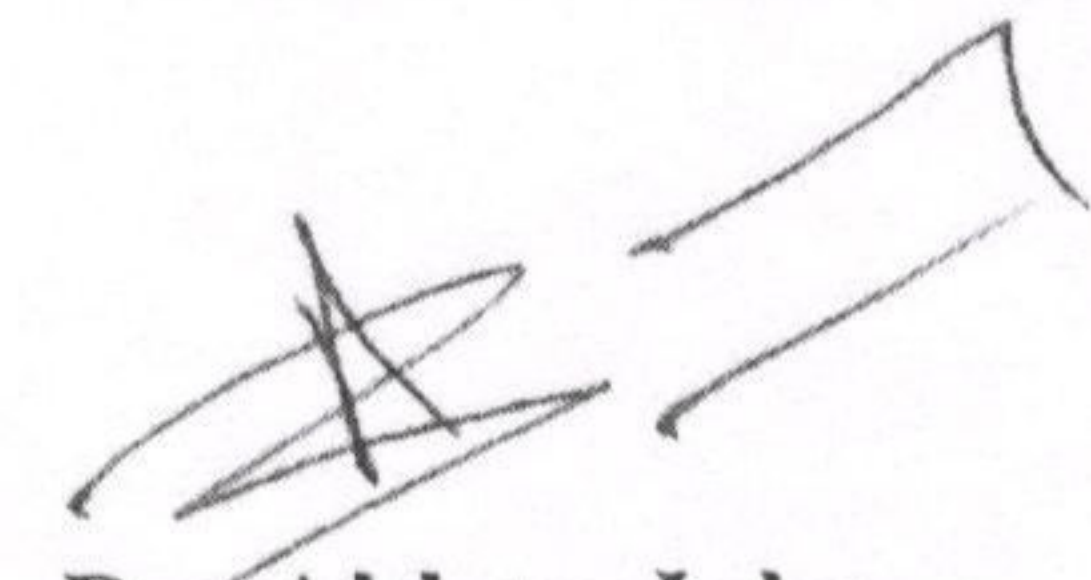
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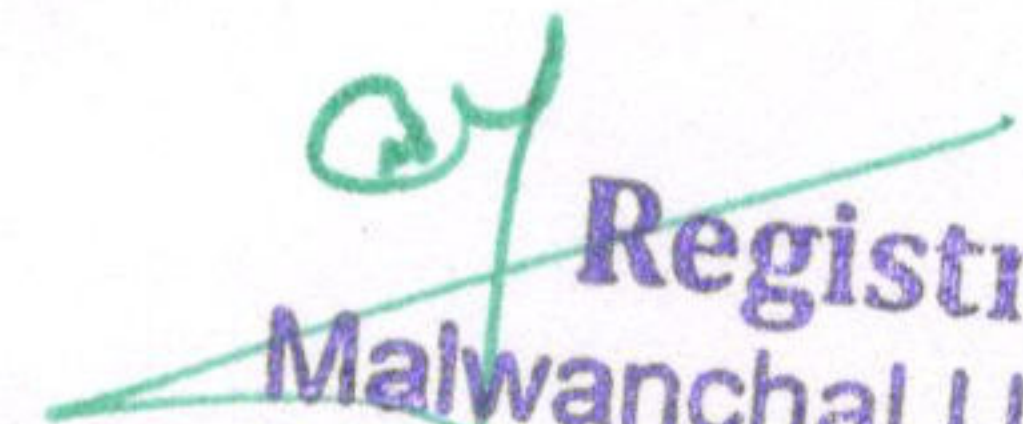
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Dr. S.G. Wankhede
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AIMS, Dewas
Amaltas Institute of Medical Sciences
Dewas (M.P.)


Dr. Abhay John
Coordinator
GCP & NDCT Workshop

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- HOD, Pharmacology, Index Medical College, Indore
- Vice Chancellor, Malwanchal University
- Registrar, Malwanchal University
- All Departments Heads


Registrar
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AMALTAS INSTITUTE OF MEDICAL SCIENCE

Village - Bangar, Dist.- Dewas, Ujjain - Dewas High Way

Date: 20/01/2021

S. No.	NAME	DEPARTMENT	SIGNATURE
1.	Hemant Tayde	Anatomy	
2.	Renu, Indu Parmar	Physiology	
3.	Nazneen Qureshi	Biochemistry	 20.01.2021
4.		Pharmacology	
5.	Sheetal Thakur	Pathology	
6.	Aishwariya Poojari	Microbiology	
7.	Dr. S. S. Gupta	Forensic Medicine	
8.	Shankar Prayapati	PSM	
9.	DR RAKESH RAMELAI	Medicine	
10.		Surgery	
11.	Ritu Soni	Pediatrics	
12.	Dr. Preeti Jain	OBG	
13.	Shubham Barli	Orthopedics	
14.	Arti Prajapat	ENT	
15.	Seema Kharghar	Ophthalmology	
16.	Suman Kumawat	TB Chest	
17.	Seema Kharghar	Skin & VD	
18.	Sakawat	Radiology	
19.		Anesthesiology	
20.	Suman Kumawat	Psychiatry	
21.		Dentistry	

Registrar
Malwanchal University
Indore (M.P.)



AMALTAS Institute of Medical Sciences

(Unit of Amaltas Educational Welfare Society)

Ref.No.:-AIMS/DN/2021/45

Date: 13/02/2021

REPORT ON GCP WORKSHOP

Amaltas Institute of Medical Sciences, Dewas had organized GCP workshop in collaboration with Index Medical College Hospital and Research Centre, (IMCHRC) under Malwanchal University, Indore. A two-day Offline Training Workshop on "Good Clinical Practices (GCP) and New Drugs and Clinical Trials Rules 2019" conducted on February 09th 2021. Dr Abhay John, Prof. and Head of department in Pharmacology, Amaltas Institute of Medical Sciences, Dewas coordinated and arranged this workshop providing insight into various concepts, methods, indicators, and tools essential for any clinical trial.

The broad aim of this training workshop was to enhance the understanding of participants about GCP and NDCT Rules 2019 which is very essential component of every clinical research as well as indispensable for being the member of Ethics Committee.

The inaugural ceremony commenced with the lighting of the lamp by a group of dignified persons like Chairman of Index Group of Institutions, Dr. Preeti Taneja professor emeritus (retired from M.G.M. Medical College, Indore), Dr. S.G.Wankhede – Dean, AIMS. Dr. S. G. Wankhede had emphasized on the importance and proper management of any clinical trial. He formally inaugurated event and started the Workshop that proceeded on February 9th, 2021. He heartily welcomed all the guests, participants, faculty members and clinical researchers in this one day workshop. He also stressed on the importance of this workshop as well. Total number of participants was 45 who registered for this workshop.

The speakers intended to train the medical faculties, clinical researchers, and members of Ethics Committee about the importance of International Guidelines on Good Clinical Practices and how it came into existence. They also enlightened the participants about Indian GCP Guidelines and ICMR guidelines that are followed by our regulatory agencies for clinical trial and Biomedical Research. The training content included interrelated Modules/Lectures on different topics. And to enforce the quality standards of Clinical trials in India, NABH (National Accreditation Board of Hospitals and Health Care), a constituent body of quality council of India provides training on GCP guidelines and also looking for Accreditation process of Ethics Committee and Clinical trial. EC Members or any Clinical Researchers can directly enroll for such workshop on NABH website.

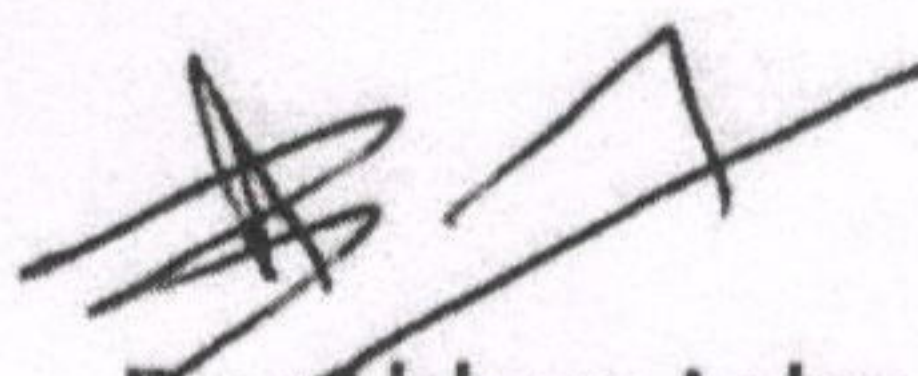
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The first session of the training familiarized the participants with concepts of clinical trial, the major prospects and methods to conduct a Clinical trial, understanding confidentiality and privacy of participant (Patient) and also introduce the participants with importance of informed consent in Clinical trial. The training session started with the first lecture by **Dr. Aarti Sahasrabuddhe, Professor Dept. of Community Medicine, IMCHRC** depicting the Overviews of Good Clinical Practice and included Definition, Evolution and Principles of GCP; her lecture was so designed that enabled the participants to have a comprehensive understanding of CDSCO, WHO and ICH. She further elaborated on ethical consideration, Ethics Committee/ IRB members and their roles and responsibilities in providing ethical clearance in any clinical trial. An one hour lecture was scheduled from 10:00 AM i.e. on 9th Feb 2021. The second lecture was by **Dr. Prem Nyati** explaining the Prospects of Clinical Trials and Biomedical Health Research in India. He also put a light on roles and responsibilities of Stake holders (Sponsors, Investigators and Regulators) in any clinical trial. He further gave a picture of the NDCT rules 2019 (New Drugs and Clinical Trials rules 2019). NDCT rules 2019 are now applicable to all new drugs, investigational new drugs for human use, clinical trial, BA-BE study and Ethics Committee.

The last lecture of the day was by **Dr. Suraj Tripathi** illuminating about Informed Consent, Confidentiality and Privacy about the subjects participating in a clinical trial and about the selection of vulnerable population for any study. He further focused on Safety Considerations in any Clinical Research Study. He also focused on documentation, data handling and maintenance of record in any clinical trial.

To assess the effectiveness of the training program, different evaluation methods were employed during the training program such as pre & post evaluation test and feedback from the participants. The results of pre and post self-assessments revealed participants' knowledge and understanding of subjects that were enhanced after the training. Further, the participants reported the training sessions were relevant to their work and enhanced their knowledge and skills and they were very satisfied with the overall arrangements and organization of the training and enjoyed the training atmosphere and learnt a lot from the resource.

This one day program was summed-up with a valedictory session chaired by esteemed dignitaries and after the successful completion of workshop certificate were distributed to all the participants.



Dr. Abhay John

Organizing Secretary

Associate Professor & HOD, Dept. of Pharmacology

Amaltas Institute of Medical Sciences, Dewas

Department of Pharmacology
Amaltas Institute of
Medical Sciences, Dewas


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