IK Gujral Punjab Technical University
Main Campus

Department of Food Science and Technology

Minutes of Meeting

The second meeting of the campus Board of Studies Clinical Research was held 27/11/2020 at 11:00 AM through Skype.

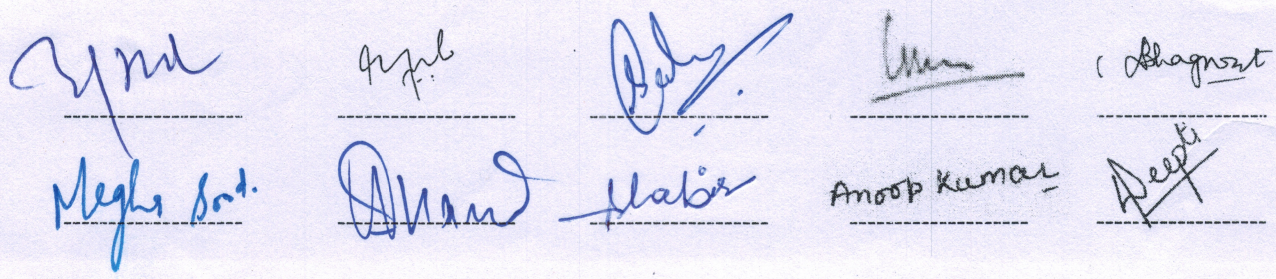
The following members were present:

1. Dr Rajneesh Kant Sachdev, HOD, Food Engineering, IKGPTU *(Chairperson)*
2. Dr R.K. Goel, Professor, Department of Pharmaceutical Sciences and Drug Research, Punjabi University, Patiala
3. Dr Shalini Salwan, Professor, Department of Pharmacology, Punjab Institute of Medical Sciences, Jalandhar
4. Dr G. D. Gupta, Professor, ISF College of Pharmacy, Moga
5. Dr Deepak Prabhakar Bhagwat, Associate Professor, School of Pharmacy, Maharaja Agrasen University
6. Dr Megha Sood, Associate Professor, Department of Pharmacology, Punjab Institute of Medical Sciences, Jalandhar
7. Dr Gazal Sharma, Assistant Professor, Department Food Science & Technology, IKGPTU, Main Campus
8. Dr Shabir Sidhu, Assistant Professor, Department Food Science & Technology, IKGPTU, Main Campus *(Coordinator)*
9. Dr Anoop Kumar, Assistant Professor, Department of Pharmacology & Toxicology, NIPER, Raebareli.
10. Dr Deepti Rathee, Manager- Aggregate Reports, Worldwide Medical and Safety, Pfizer Healthcare India Pvt. Ltd., Chennai, Tamil Nadu

The following members could not attend the meeting due to busy schedule:

1. Dr Gaurav Bhargawa, Department of Chemical Sciences, IKGPTU, Main Campus
2. Dr Barinderjit Singh, Assistant Professor, Food Engineering, IKGPTU(Member)
3. Dr Abhishek Kaler, Drug Safety Scientist, Parexel International India Pvt Ltd., Chandigarh
4. Dy. Director / Assistant Director CR&A, Deptt. of CR&A, IKGPTU
5. Mr Ravi Thakur, Student Representative, Department Food Science & Technology, IKGPTU, Main Campus

Chairperson BOS took up the formal agenda items point wise.



Agenda for Ratification

2.1.1 Paper setter panel for end semester examination (May 2020)

The paper setter panel prepared by department faculty was ratified by the Board of Studies.

2.1.2 MST question paper pattern

The question paper pattern adopted for the conduct of MST & end semester exam for the May 2020 examination (MCQ/ and Open Book Test) was ratified by the Board of Studies. It was also approved to follow this modified pattern for future MST. The pattern of end semester exam will be as notified by university in COVID-19 times. Further, it was decided that the previously approved question paper pattern will be adopted once the student's start attending class in the campus regularly.

Matter pertaining to the award of credits for co-curricular activities

The Board of Studies approved the rectifications in the guideline for the award of credits for co-curricular activities. As per the modified scheme 01 credits shall be awarded for "Participation in Seminar/ Conference/Symposium (related to the specialization of the student)" & two credits shall be awarded for "Participation in Training/ Workshop (related to the specialization of the student) for duration of one week (05 days) or more". It was approved that the modified scheme will be applicable from Batch 2018 onward. The modified scheme is as follows:

Name of the Activity	Credit Points
Successful completion of MOOCs Courses (4 weeks)	04
Successful completion of MOOCs Courses (2 weeks)	02
Hospital Training (minimum 4weeks)	02
Participation in Seminar/ Conference/ Symposium (related to the specialization of the student)	01
Participation in Workshop/ Training of duration one week (05 days) or more (related to the specialization of the student)	02
Presentation in Seminar/ Conference/ Symposium / (related to the specialization of the student)	02
Presentation in Seminar/ Conference/ Symposium / (related to the specialization of the student) and with award	03
Research / Review Publication in indexed in Scopus / Web of Science*	03
Research / Review Publication in peer reviewed journals*	02
Minimum ten days residential camp organized by NSS/ Youth Affairs	02
Inter University participation in cultural or sports activity	02
Inter University award in cultural or sports activity	03
Inter College participation in cultural or sports activity	01
Inter College award in cultural or sports activity	02

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Updation of scheme & curriculum of Msc. Clinical Research (Batch 2020 onward)

2.3.1 3 Updation of scheme

In the previously approved scheme SWAYAM/MOOCs courses are included under the mandatory category of "Generic Elective". During implementation of this practical difficulties were encountered at the university level like assigning of unique course codes as per university system of coding of the courses. Further, if any student is not able to clear the exam of the course in first attempt the student will not be awarded the certificate which would show in the DMC of student as back log. In light of these points, it was decided to temporarily remove these courses from the mandatory category of "Generic Elective" till these difficulties are resolved. It is pertinent to mention that SWAYAM/MOOCs courses will remain part of co-curricular activities in the scheme.

The syllabus of courses, Medical Writing, Quality Management in Clinical Trials, Clinical Study Design, Clinical Trial Operations and Clinical Research Regulation & Ethics was revised and accordingly the codes were also revised. The new approved scheme is as follows:

Second Semester

Course Code	Course Type	Course Name	Load			Marks			Credits
			L	T	P	Internal	External	Total	
UC-MSCR201-19	Core Theory	Pharmacotherapeutics -I	3	1	-	30	70	100	4
UC-MSCR202-20	Core Theory	Clinical Research Regulations & Ethics	3	1	-	30	70	100	4
UC-MSCR203-19	Core Practical	Clinical Research Lab II	-	-	4	30	20	50	2
UC-MSCR204-19	Ability Enhancement	Professional Communication Lab	-	-	4	30	20	50	2
UC-MSCR205-20	Skill Enhancement	Medical Writing	2	-	-	15	35	50	2
UC-MSCR206-19	Skill Enhancement	Journal Club	-	-	4	50	-	50	2
UC-MSCR XXX	Discipline Specific Elective Theory	Elective –III	2	-	-	15	35	50	2
UC-MSCRYYY	Generic Elective Theory	Elective –IV	2	-	-	15	35	50	2
		Total	**12**	**2**	**12**	**215**	**285**	**500**	**20**

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Discipline Specific Elective Theory (Elective-III)

Subject Code	Subject Name
UC-MSCR 211-19	Fundamentals of Epidemiology
UC-MSCR 212-19	International Regulatory Affairs

Generic Elective Theory (Elective-IV)

Subject Code	Subject Name
UC-MSCR 213-19	Biostatistics in Clinical Research
UC-MSCR 214-19	Poisoning and Management

Third Semester

Course Code	Course Type	Course Name	Load			Marks			Credits
			L	T	P	Internal	External	Total	
UC-MSCR301-19	Core Theory	Pharmacotherapeutics -II	3	1	-	30	70	100	4
UC-MSCR302-20	Core Theory	Clinical Study Design	3	1	-	30	70	100	4
UC-MSCR303-19	Core Theory	Research Methodology	2	-	-	15	35	50	2
UC-MSCR304-19	Core Theory	Pharmacovigilance	2	-	-	15	35	50	2
UC-MSCR 305-19	Core Practical	Clinical Research Lab III	-	-	4	30	20	50	2
UC-MSCR 306-19	Skill Enhancement	ICT Skills Lab	-	-	4	30	20	50	2
UC-MSCR 307-19	Skill Enhancement	Journal Club	-	-	4	50	-	50	2
UC-MSCR 308-19	Research Work	Synopsis	-	-	4	50	-	50	2
UC-MSCR XXX	Discipline Specific Elective Theory	Elective –V	2	-	-	15	35	50	2
UC-MSCRYYY	Generic Elective Theory	Elective –VI	2	-	-	15	35	50	2
		Total	**14**	**2**	**16**	**280**	**320**	**600**	**24**

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Discipline Specific Elective Theory (Elective-V)

Subject Code	Subject Name
UC-MSCR 311-20	Clinical Trial Operations
UC-MSCR 312-19	Medical Coding

Generic Elective Theory (Elective-VI)

Subject Code	Subject Name
UC-MSCR 313-19	Pharmacoeconomics & Health Technology Assessment
UC-MSCR 314-20	Quality Management in Clinical Trials

2.3.1 3 Updation of curriculum

The syllabus of the following courses was updated (annexure-I):

1. Clinical Research Regulations & Ethics (UC-MSCR 202-20)
2. Medical Writing (UC-MSCR 205-20)
3. Clinical Study Design (UC-MSCR 302-20)
4. Clinical Trial Operations (UC-MSCR 311-20)
5. Quality Management in Clinical Trials (UC-MSCR 314-20)

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Annexure-I

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 202-20	Clinical Research Regulations & Ethics	3	1	-	30	70	1.5	3	4
Module-I									**09 Hrs**
Evolution of Regulatory Control									
European Medicines Agency (EMA)									
Vaccine Act, Biological Control Act, Pure food drugs act, Food and Drug Administration (FDA), Kefauver Harris amendments act, Waxman Hatch act, Code of federal regulations, PDUFA									
International Council for Harmonisation (ICH)									
Drugs and cosmetic act 1940 and rules 1945									
Module-II									**13 Hrs**
Regulatory Aspects of Different Regions									
Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Paper NDA									
Market authorization holders (MAH), its procedures									
Regulation of medical devices									
Regulation of vaccines									
Safety Report filing									
Regulation of non-prescription drugs									
Regulation of Complementary Medicine									
Module-III									**14 Hrs**
Regulatory Guidelines									
International Conference on Harmonization (ICH) GCP guidelines									
Overviews of good laboratory practice (GLP)									
Schedule Y of Indian Drugs and Cosmetic Act, New Drugs and Clinical Trials Rules (2019)									
Basic regulation of bioavailability/ bioequivalence (BA/BE) studies									
Common Technical Document: Format of dossier									
Module-IV									**09 Hrs**
Ethics in Clinical Research									
Evolution of ethics in clinical research: Nazi human experimentation, Thalidomide disaster, Tuskegee experiment, Nuremberg Code, Declaration of Helsinki, Belmont report									
Establishment of Council for International Organizations of Medical Sciences (CIOMS), National Institutes of Health (NIH) and Indian Council of Medical Research (ICMR) guidelines									
Compensation to subjects/patients for clinical trial related injuries									

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Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 205-20	Medical Writing	2	-	-	15	35	1	2	2

Module-I	**12 Hrs**
Introduction to Medical writing and Healthcare Communication	
The Writing Process: prewriting strategies and steps in writing process	
Online search techniques	
Rules of writing: basic structure of write up; plagiarism and copyrights	
Module-II	**12 Hrs**
Scientific Writing: writing case reports, drug monograph and abstract writing	
Regulatory writing: medical writing in clinical research, study design, observational studies, experimental studies	
ICH-E3guidelines-Structure and content of clinical study reports	
Common Technical Document: Format of dossier, eCTD	

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 302-20	Clinical Study Design	3	1	-	30	70	1.5	3	4

Module-I	**12 Hrs**
Inclusion and exclusion criteria	
Screening and recruitment of subjects	
Methods of randomization, blinding	
Placebo	
Endpoints: primary, secondary, composite, surrogate	
Module-II	**12 Hrs**
Type of Studies	
Observational studies: case report, case series, cross-sectional studies, case control study, cohort study, relative risk and odd ratio	
Experimental studies: randomized trial, open label study, cross over, equivalence trials, superiority trials and non-inferiority trials	

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Module-III	**12 Hrs**
Phases of clinical trials	
Designing phase I, II, III and IV trials: design types (dose ranging, safety studies, proof of concept studies, cluster randomized, factorial design, sequential design), their characteristics, and parameter to measure	
Module-IV	**12 Hrs**
Trial designs of common diseases like CVS (anti-hypertensive drugs), CNS (neurodegenerative diseases), cancer and metabolic disorders BA-BE study designs	
Trials for special population: paediatric, geriatric, pregnant women and lactating women	

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 311-20	Clinical Trial Operations	2	-	-	15	35	1	2	2

Module-I	**12 Hrs**
Selection of clinical trial sites, site-initiation visits, clinical investigators and making budget and outsourcing clinical trial related work and selection of vendor	
The roles and responsibilities of the following in CT: sponsor, institution, clinical trial coordinator, clinical investigator	
Documents required at site, site initiation and conduct activities, protocol, CRF, ICD, investigator brochure, clinical trial agreement, ethics committee and regulatory approval, site-initiation visits	
Recruitment, IP/IMP/pharmacy file receipt and storage, clinical trial site master file, databases, SOPs	
Roles and responsibilities of monitors and auditors/inspectors, monitoring visits, audits and inspections, independent data monitoring activities	
Module-II	**12 Hrs**
Contingency planning to prepare for unexpected situations	
Site close-out activities, suspending and premature termination of a trial	
Handling missing data, query and resolution, database lock	
Site close-out report, clinical study report, submission to ethics committee and regulatory agency, publication of results	

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Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 314-20	Quality Management in Clinical Trials	2	-	-	15	35	1	2	2

Module-I	**12 Hrs**
Quality Control, Quality Assurance and Total Quality Management	
Overview of QA and QC in clinical trials and their comparison	
Total quality management	
Good clinical practice guidelines for quality assurance	
Corrective and Preventive Action (CAPA) program, Root Cause Analysis (RCA)	
Module-II	**12 Hrs**
Audits/Inspections	
Audits, its process and important aspects, types of audits	
Clinical Quality Assurance Audit	
Regulatory inspections	
Source document verification	
Risk based quality management & monitoring	

The meeting ended with vote of thanks to the Chair.

Dr R.K. Goel

Dr Shalini Salwan

Dr G. D. Gupta

Dr Deepak Prabhakar Bhagwat

Dr Megha Sood

Dr Anoop Kumar

Dr Gazal Sharma

Dr Deepti Rathee

Dr Shabir Sidhu

Dr. Rajneesh Kant Sachdev
(Chairperson)