3.3.2

Workshops/Seminars conducted on Intellectual Property Rights (IPR) Research methodology, Good Clinical, Laboratory, Pharmacy and Collection practices, Writing for Research Grants and Industry-Academia Collaborations During the Last Five Years

Workshop on Good Clinical Laboratory Practice (GCLP) 2015

Krishna Institute of Medical Sciences, Deemed to be University, Karad has successfully conducted the two days workshop on good clinical laboratory practices in collaboration with National Institute of Virology (NIV, Pune) on 13th & 14th May, 2015. This workshop was conducted in the S1 hall, of the Krishna Institute of Medical Sciences and hands on training was performed in Molecular and Genetic Laboratory. This programme was inaugurated in the auspicious hands of Honorable Vice Chancellor Dr. A. V. Nadkarni, Registrar Dr. M. V. Ghorpade and their august presence of Director of Research, Dr. D.T. Mourya, Director, National Institute of Virology, Pune and Deans of different faculties and head of departments of KIMSDU, Karad.

Twenty delegates from all the different medical testing laboratories of Biochemistry, Microbiology, Pathology and Molecular Biology and Genetics of Krishna Institute of Medical Sciences have participated in a workshop. Dr. D. T. Mourya, National Institute of Virology addressed the gathering and delivered introductory lecture on Emerging and newly emerging diseases and issues on biosafety and biosecurity in laboratory set up, thereafter Dr. Pragya D. Yadav delivered a lecture on biosafety and biosecurity concepts in clinical laboratory set up. Dr. Pradip DeCosta from KEM hospital Pune delivered a lecture on hospital infection control practices for prevention of nosocomial infections in general hospital and ICU setting followed by a video film for use of PPE and PAPR & Glo-germ exercise & importance of hand washing in laboratory as a good laboratory practice for the biosafety of the staff involved in laboratory testing followed by a demonstration lecture on proper uses of Personal Protection Equipments by Dr. P. D Yadav and Dr. D. K. Singh. On day two of the workshop, Dr. P.D. Yadav and Dr. D.K. Singh demonstrated emergency response in laboratory, infectious material and emergency issues like spills etc. in Biosafety Cabinet and laboratory. Dr. Anita Aich and Dr. Deepak Patil demonstrated procedures of Samples registration, labeling and aliquoting and data management. Thereafter, the demonstration and hands- on practices for RNA extraction of CCHF and KFD virus suspected samples was carried out and Setting up Real-time RT-PCR and analysis of RT-PCR for CCHF and KFD virus was demonstrated to the participants. The standard laboratory procedures as per the requirement of ISO: 15189: 2012 were explained by the resource persons. First of all the quality policy and quality objectives of the clinical testing laboratories were discussed to introduce good laboratory practices in the clinical laboratories. The purpose of quality policy document was explained to generate reliable test results for all the clinical tests conducted in all the medical laboratories. The staff was explained regarding the purpose of adequate and prompt and polite services to the patients attending the clinical laboratories for the services.

Management requirements included:Quality System Management: The resource person highlighted the quality management to implement the Quality System in conformance as per the

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ISO 15189:2012 requirements and continually improve its effectiveness in the clinical laboratory testing.

Control of quality documents: The need of maintenance of the quality documents including defined Quality Policy and Quality Objectives, Quality System Procedures, Standard Operative Procedures, Sample Collection documents, Safety documents, Patient records, Internal record documents, external quality control documents and other external origin documents was explained by the resource person. Review of the documentation to the management of the Institute: The need of the management review to be frequently conducting in regular manner to run the laboratory set up with the permissions of the management. Selection, purchase of equipment, chemicals, reagents and consumables required of the testing: The standard procedures to be formulated and maintained for the selection of reagents, kits chemicals, consumables and equipments for the proper test to be conducted. Selection of procedures: The purpose of selection of the procedures for the clinical testing as the major task for the initiating of the test and continuously improve the laboratory practices was highlighted by the resource persons. Quality indicators of the Testing laboratories (Pre-analytical, analytical and post analytical): The necessity of defining quality indicators to monitor and evaluate performance throughout critical aspects of pre- examination, examination and post-examination processes was explained to the participants to monitor the objectives, methodology, interpretation, limits, action plan and duration of measurement. Also, the periodic review of quality indicators for the continual improvement of the laboratory procedures to fulfill the users of the laboratories.

At the end the program was ended up with valedictory ceremony after taking feedback of the training.

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Dr. Kailas D. Datkhile
Senior Research Officer
Molecular Genetics Laboratory
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Karad - 415110

Workshop on Good Clinical Laboratory Practice

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Workshop on Research Methodology 09th Sept. 2015 to 16th Sept 2015

The Workshop on Research Methodology conducted from 09/09/2015 to 16/09/2015. The number of staff and students (PG & PhD) participated in the workshop were:

KIMS: 95 (4 Staff)

KPTh: 6

SDS: 16 (4 Staff)

KINS: 12

PhD: 12

Total: 141

The topics covered in the workshop were: Need of research, Research topic, question and hypothesis, Review of literature, Sampling, Study designs, Basic and advanced statistics including parametric and non-parametric tests, Communication skills, Screening of diseases Qualitative research, Ethics, Development of drug & device, Preparation of research proposal and Application of SPSS.

In all 17 resource persons (12 from outside and 5 in-house) delivered talks during the workshop. For each session pre and post session assessment of the participants was done. It revealed significant improvement in their knowledge regarding the aspects covered in the workshop.

On the last day; in the session 'Presentation of Protocols'; 11 students presented their protocols. This session was chaired by Dr Sanjay Mehendale, Director NIE, Chennai. After each presentation he gave his suggestions and remarks. This gave guidelines to the respective student as well as other participants to develop and modify their protocols. During valedictory also Dr Sanjay Mehendale gave hints to students for conduction of the good research.

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Dr. Supriya. S. Patil

Workshop on Research Methodology
From 09th Sept. 2015 to 16th Sept 2015

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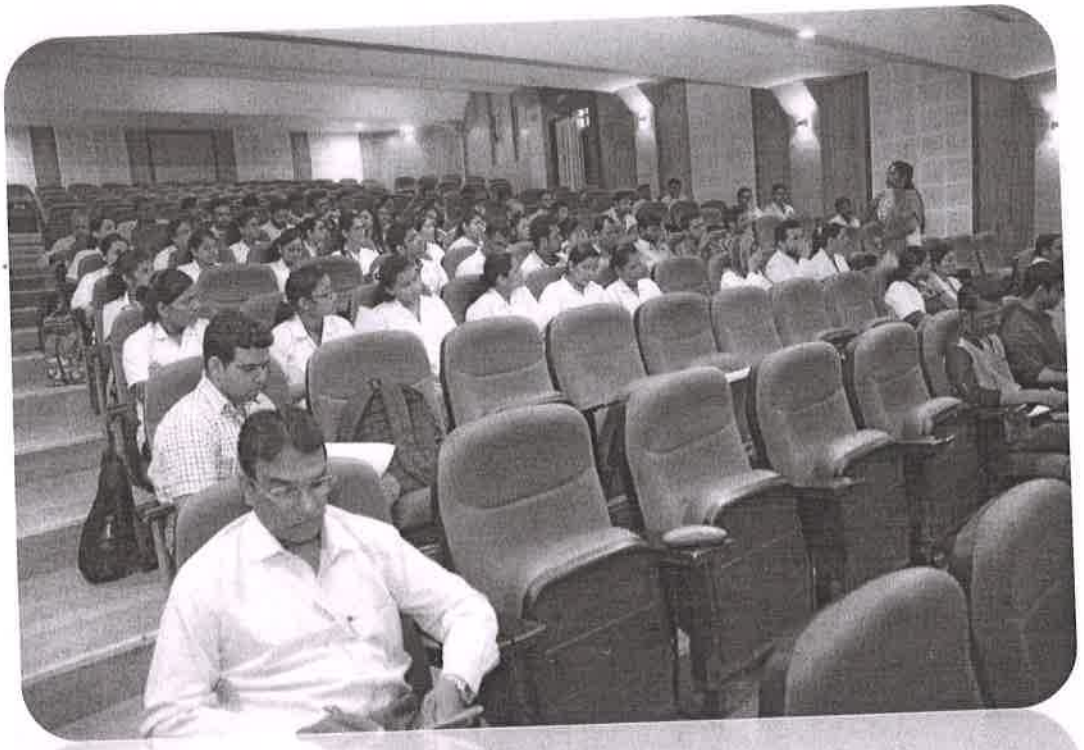

Workshop on Research Methodology

From 09th Sept. 2015 to 16th Sept 2015

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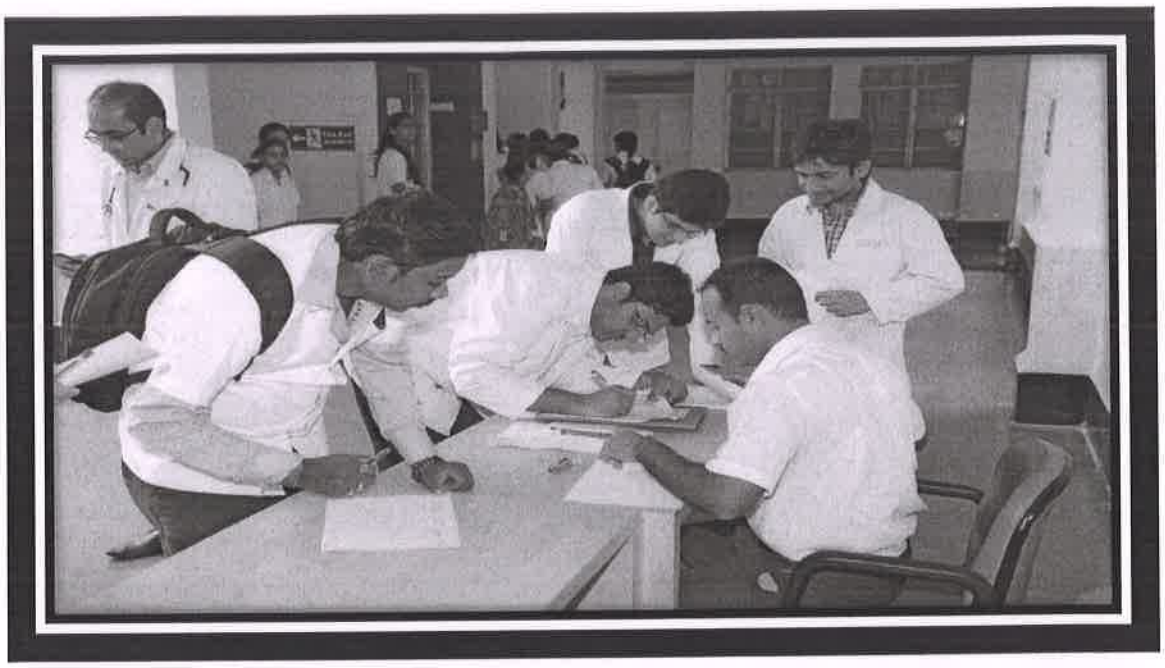

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'Workshop in Research Methodology'

8th to13th August 2016

Krishna Institute of Medical Sciences Deemed University, Karad scheduled workshop in Research Methodology for Post Graduate Students from Faculty of Medicine, Nursing, Dental and Physiotherapy and also for Ph. D. Students as well as for interested faculty members.

Workshop was conducted as per the scheduled programme (Attached Time Table for the workshop) from 8th to 13th August 2016.

The 9th Certificate Course in Research Methodology was conducted for 6 full days. Every day irrespective of lunch break, lecture/discussion sessions were conducted for 6 hours. The total hours of lectures delivered/discussions in 6 days were 34½ hours.

Total 76 delegates from Medical, 12 from Dental, 12 from Physiotherapy, 14 from Nursing, & 4 Ph. D. Students and 3 faculty members attended the workshop (Total 121).

Workshop began with inaugural programme. Dr. A. K. Pratinidhi madam our former Director of Research was Chief Guest. Dr. Sanjay Mehendale, Director National Institute & Epidemiology (NIE), Dr. P. Ganeshkumar, Scientist C (NIE), Dr. Angeline Grace, Scientist C (NIRT), Chennai and Dr. P. M. Durgawale Prof. & Head, Dept. of Community Medicine were also present. In Dr. Pratinidhi madams speech she stressed upon importance of research. In welcome address Dr. Mrs. Supriya S. Patil explained about the importance of this workshop as well as plan for the same. Subsequently topics covered were right from introduction to research, study designs, sampling, sample size, statistical tests, analysis plan and also overview of qualitative research method.

Writing concept paper topic was covered on 2nd day and on same day concept paper template printouts were distributed to all delegates since then emphasis was given on concept paper writing. On 12th August 2016 in afternoon session individually students worked on their own dissertation topics and which was followed by presentations by randomly selected students on 13th August 2016 in morning session surprise MCQ Test – 30 Questions (30 marks) was conducted on 12th August 2016. Total 92 students appeared for examination. Out of them 67 (72.83%) students scored above 50%. Top 10 were awarded with trophy at the time of valedictory programme (List is attached)

All the sessions were informative while maximum sessions were interactive. Apart from

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NIE and NIRT faculty topics covered by faculty from other institutes and KIMSDU were also of good quality. Pre and Post test evaluation will be completed within 2 wks.

For the valedictory programme Dr Patwardhan, observer from Maharashtra Medical Council was present, who was present throughout the workshop. Maharashtra Medical Council has given 4 credit points for this workshop. Certificates will be given to delegates who have satisfactorily completed the workshop. It was declared that last date for submission of protocols will be 24th August 2016.

Total expenses for the workshop were 1,10,893/-. Detailed statement of expenses is attached herewith.

Dr. Mrs. Neelima A. Malik, Hon'ble Vice Chancellor, KIMSDU visited on 11th August 2016 addressed delegates. She encouraged students about participant in research activities as well as other extracurricular activities.

I am thankful to Dr. M. V. Ghorpade, Registrar, KIMSDU for his guidance and support. I extend my thanks to Dr. P. M. Durgawale, Prof and Head, Dept of Community Medicine for his encouragement, guidance and support. I extend my sincere thanks to all resource persons. I am very much thankful to Dr. Arun R. Risbud sir, Director of Research, KIMSDU as well as all staff members from research office; because of their co operation and help smooth conduction of workshop was possible. I extend my thanks to Miss. Archana Kaulgekar, Assist. Registrar, for her co- operation and help in MMC credit points.

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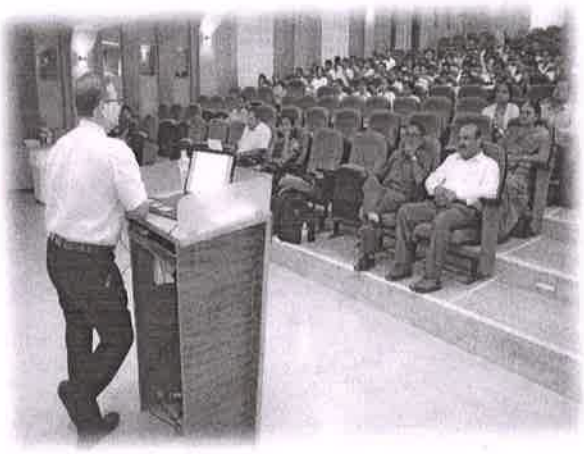
Dr. Supriya. S. Patil

Workshop on Research Methodology

From 8th August. 2016 to 13th Sept 2016



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Workshop on Research Methodology
From 8th August. 2016 to 13th Sept 2016

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Workshop on Research Methodology

From 8th August. 2016 to 13th Sept 2016

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REPORT OF CDE PROGRAM

Conducted by:- Faculty of Medical Sciences, KIMS "Deemed to be University", Karad.

Topic: "Workshop on Research Grant writing" - Turning research into impact

Faculty: - Dr. P. M. Durgawale, Professor & Head, Department of PSM at KIMSDU Karad.

Venue: SI Hall, KIMS, Krishna Institute of Medical Sciences "Deemed to be University", Karad

Date: 11:00 AM on 13th September 2016

No. of Participants: - 87

Event plan/ report:

KIMS, Krishna Institute of Medical Sciences "Deemed to be University", Karad conducted workshop on "Research Grant writing - Turning research into impact" for health care professionals of KIMSDU Karad. The faculty for the workshop Dr. P. M. Durgawale, is Head & professor Department of PSM at KIMSDU Karad.

A total of 87 delegates were present that included health care professionals of KIMS, School of Dental Sciences, and physiotherapy KIMS "Deemed to be University", Karad. The main points discussed were on how to utilize research outcomes and the importance of communication activities and strategies to turn research output into impact. The speaker had also touched on the use of knowledge to solve public health problems stating from the different types of research. He explained the need for effective communication activity necessity to enhance research utilization at each level followed by improvement of the way of conveying evidence-based research to policy-makers and to bridge the gap between policy and evidence. The event was concluded with the valedictory function. The momento and certificate was presented by **Dr. S. T. Mohite** to the Guest speaker, **Dr. P. M. Durgawale** and thanked him for the wonderful lecture. Pre and post tests were distributed before and after the lecture.

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A positive outcome was achieved with a pre test average score of 41% and post test average score of 93%. An ***Advanced Learning Gain (ALG) of 52%*** was achieved. An excellent feedback was achieved from all the beneficiary listeners that attended the program.

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Faculty of Dental Science
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Workshop on Research Grant Writing

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Report of Workshop of Good Clinical Practices on 19th -21th October, 2016

Three Days Workshop on "Good Clinical Practices" was conducted from 19/10/2016 to 21/10/2016 by NARRIM Cell of KIMSDU. The program is a collaborative project of KIMS University , NARI ,Pune & IAVI Delhi. This workshop was initiated as a stepping stone in the institute to create awareness in Clinical Practices and Participatory Practices. This workshop was initiated by inauguration programme in the MET Hall. The inauguration was done at the auspicious hands of Honorable Registrar Dr. M. V. Ghorpade, by their august presence of Director of extension activities Dr. Asha Jadhav , Director of Research Dr. Arun R. Risbud, Additional Director of Research Dr. D. K. Agarwal, Dr. S. T. Mohite and others

Fifty two participants attended the workshop. Dr. Sucheta Banerjee Kurundkar(Director Training, Clinical Development Services Agency (CDSA), Dehli, NCR),Dr. Nandini K. Kumar(Former Deputy Directory General, (ICMR) Endowment Chair, Manipal University, Adjunct Faculty, CDSA),Dr. Nabeel M. K.(Consultant, Public Health & Bioethics) were invited as resource persons from NARI. They delivered several talks on GCP and GPP during workshop. The topics covered in the workshop were: Overview of the clinical research process, Investigator responsibilities , Clinical Investigator financial disclosure , Expanded access to and charging for investigational drugs and devices . So it has created a significant awareness among participants and added more information of GCP in their knowledge during the workshop. On the last day of workshop the above topics were discussed, This has developed awareness for participants and faculties to develop Practices and prosecution.

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KIMSDU, Karad

Dr. Sujata V. Patil
Associate Professor in
Dept. of Community Medicine
Krishna Institute of Medical Sciences DU

Workshop of Good Clinical Practices on 19th -21th October, 2016

Workshop of Good Clinical Practices on 19th -21th October, 2016

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Workshop of Good Clinical Practices on 19th -21th October, 2016

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Workshop of Good Clinical Practices on 19th -21th October, 2016

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Overview of Good Clinical Laboratory Practice (GCLP) Workshop

Krishna Institute of Medical Sciences, Deemed to be University, Karad has successfully conducted the two days workshop on good clinical laboratory practices in collaboration with National Institute of Virology (NIV, Pune) on 27th & 28th October, 2016. This workshop was conducted in the S1 hall, of the Krishna Institute of Medical Sciences and hands on training was performed in Department of Molecular Biology and Genetics. This programme was inaugurated in the auspicious hands of Honorable Vice Chancellor Dr. Neelima Malik, Registrar Dr. M. V. Ghorpade and their august presence of Director of Research, Dr. Shailesh E. Pawar, Scientist E, Dr. Varsha Potdar, Scientist D, Dr. Patil K.P., Scientist D and Dr. Tejaswini M Deshmukh, Scientist C from National Institute of Virology, Pune and Deans of different faculties and head of departments of KIMSDU, Karad. Dr. Dr. Shailesh E. Pawar, Scientist E, National Institute of Virology delivered and overview lecture on overview of good clinical laboratory practices after the orientation address of the workshop by Director of Research, Krishna Institute of Medical Sciences, Deemed to be University, Karad. Thirty delegates from all the different medical testing laboratories of Biochemistry, Microbiology, Pathology and Molecular Biology and Genetics of Krishna Institute of Medical Sciences along with different faculties of various colleges had participated in the workshop.

In summary, the resource persons highlighted the major areas of the good clinical laboratory practice standards such as specimen collection, chain-of-custody, and shipping instructions, instrumentation and analytical methods to be used, reference ranges, referral laboratory information, and transmission of results, external quality assurance, validation of test methods, reporting of results, retention of records to be applied to all laboratories performing testing include safety, diagnostic, and endpoint laboratory assays. Safety assays are those tests that are performed to both monitor potential adverse events and to verify the study participants' continued satisfaction of study inclusion/exclusion criteria, as appropriate, for each protocol.

The importance laboratory management was explained by Dr. Shailesh E. Pawar, Scientist E from NIV, Pune which included following points:

- The participants were explained the standards for clinical specimen collection, transport and management. The prescribed formats of the laboratory documents for the procedures describing methods for the following tasks associated with specimens: specimen collection,

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tracking, labeling, preservation, conditions for transportation, storage, and specimen destruction. The laboratory must have documented standard labeling practices in place and demonstrate evidence of adherence. All specimen containers must be properly identified with the unique participant identifiers. Laboratory Testing Request Form (Requisition) A properly completed request form/log or equivalent must accompany each study participant sample to the laboratory; this documentation serves as the integral link between a specimen, the study participant from which it was collected, and the testing requested. The request form must document unique study-participant identifiers, specimen collection date and time, study-participant demographics, specimen type, and the collector's (phlebotomist's) identity. Any discrepant or missing information must be verified promptly, before specimens are processed or stored by laboratory personnel.

- The Acceptance and rejection criteria for the clinical sample for testing should be defined by the laboratory. The laboratory must have in place documented instructions for receipt and inspection of samples (including rejection criteria) and demonstrate evidence of adherence in order to ensure positive study-participant/specimen identification, adequacy, and integrity of the specimen. The specimen inspection process must involve verification of the specimen container label information with the request form or log sheet. Specimen evaluation must also involve checking for the volume and quality of the samples.
- The parameters of the internal audit were explained by the resource persons.

The audit criteria's for sample collection and transportation were:

Collection site, date, and time of specimen collection and shipping; Name, date, and signature of phlebotomist or person who collected the specimen from the trial volunteer; Name, date, time, and signature of driver (if specimen transported); Type of sample; Types of testing requested by clinician or as per study visit requirements, as defined by the protocol and study/analytical plan; Project, site, and collection site names; Identity of the receiver and inspector of the specimens (upon arrival at the testing or storage facility); Date and time of sample receipt; Laboratory sample receiver name and signature; Observed sample condition and documentation of other factors that may affect specimen integrity noted at time of receipt; Sample and/or cooler temperatures at time of receipt. Transporter name and signature, if applicable; Responsibility of laboratory management and laboratory staff thorough documentation of the structure of the

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organization and the respective job descriptions and qualifications, as well as an ongoing documentation of an individual's professional experience, training, and skill-assessment.

The importance of quality policy of the laboratory for ensuring compliance with applicable laws and regulations. Applicable requirements include the following areas: handling radioactive materials, shipping infectious or diagnostic materials, reporting infectious disease testing results, personnel qualifications, retention of specimens and records, hazardous waste disposal, fire codes, medical examiner or coroner jurisdiction, legal testing, acceptance of specimens only from authorized personnel, handling controlled substances, patient consent for testing, confidentiality of test results.

Maintenance of documentation of personal records of the laboratory staff including the following records (in electronic or paper format), Orientation and training, Experience, Education, Applicable licensure/certification, Competency assessments, Continuing education records, Curriculum Vitae (CV, Work-related incident and/or accident records, Dates of employment, Safety training, Attendance at job-related workshops and seminars

Guidelines were explained to follow for the maintenance and calibration of the equipments.

Staff must keep all equipment clean, avoiding any buildup of dust, dirt, and spills that may adversely affect personnel safety or equipment performance. The laboratory must employ and adhere to documented daily, weekly, and/or monthly routine maintenance plans for all equipment utilized, and record completion of these tasks on the appropriate logs in a timely fashion. Any equipment that is out of service for any reason should be clearly identified as such. For equipment that has no standard frequency or requirement for maintenance and function checks, each laboratory should establish a schedule and procedure that reasonably reflects the workload and specifications of its equipment.

One session was dedicated on personnel safety, Safety guidelines were explained to the participants.

Standards for personnel safety included:

- Safety Equipment: Eye wash facility that may be plumbed or self-contained. The availability of disposable eyewash bottles in the work area does not replace the need for an eyewash facility in areas at risk for eye exposure from corrosive chemicals.
- Emergency shower/drench hose
- Fire extinguishers

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- Sharps containers
- An automatic fire detection (e.g. smoke detectors) and alarm system. A fire alarm station in or near the laboratory.
- Separate sinks for hand hygiene need to be included in the design of the laboratory, even if the laboratory space is limit

Maintenance of the documents: The laboratory must document the testing and/or inspection of safety equipment (the laboratory may forego the documentation of the sharps container inspection and replacement). Documents recording the testing and/or inspection of safety equipment must be signed and dated by the personnel performing the task. Records of inspection must be readily available.

Personal Protective Equipment (PPE): The laboratory employer must assess the workplace to determine if hazards are present or are likely to be present which necessitate the use of PPE. PPE must be provided to all laboratory staff and maintained in a sanitary and reliable condition. PPE includes but is not limited to: Gloves (both latex and non-latex), Gowns or laboratory coats (must be fluid resistant), Eye protection (goggles, face shield, engineering controls such as laminar flow hoods and splash shields), Masks (required when using goggles). All laboratory employees must use PPE if there is a potential for exposure to blood or other potentially infectious material through any route (e.g. skin, eyes, other mucous membranes). Personnel must use the proper personal protective devices when handling corrosive, flammable, biohazardous, and carcinogenic substances. PPE should be made available to laboratory visitors, as applicable.

The external assessments of the clinical laboratories should be frequently carried out with the internal audits was detailed by the resource person. The laboratory's monitoring of the QM program must include an internal auditing program. Internal audits involve an individual or a group of laboratory personnel performing a self-assessment comprised of a comprehensive comparison of the actual practices within the laboratory against the laboratory's policies and procedures (personnel files, training documentation, QC performance, review of SOPs). These audits may also compare the laboratory's practices against a standard set of guidelines and/or standard.

After taking the feedback and queries from the participants, the program was ended up with closing ceremony.

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Dr. Kailas D. Datkhile (M.Sc. Ph.D.)
Senior Research Officer,
Department of Molecular Biology and Genetics,
KIMSDU, Karad-415539

Good Clinical Laboratory Practice (GCLP) Workshop 2016

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Good Clinical Laboratory Practice (GCLP) Workshop 2016

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GCP Training Workshop, 16th to 17th August 2017

The objective of this training was to provide an educational and reference tool for anyone interested in, or intending to become or already actively engaged in, clinical research by providing the necessary background and insight into the reasons for the requirements of GCP and their efficient application

Partnering organizations and institutes

1) National AIDS Research Institute

Following were the speakers at the workshop

- Dr. Kishor Kumar is Post Doctorate in Statistics and a senior clinical research professional with more 30 years of experience in drug development. Has been instrumental in developing the analysis and reporting services in Biotech, Pharma, CRO and leading Academic & Research Institutions (ICMR, WHO, IAVI). In his last role as the practice leader in Cognizant, he developed the team to be one of the largest team in biostatistics and programming globally (as a Full Service Outsourcing model).
  He is well-versed in applications of advanced biostatistical techniques for multi-phase, multi-therapeutic clinical trials including Adaptive Trials, Pharmaco-epidemiology studies. He is a visiting faculty and examiner to leading institutes and invited speaker at many national and international conferences. He was also actively involved in multiple data standards consortium.

- Dr Seema Sahay is Academic Editor –PlOS One from 2015. She was Junior Research Fellow, Indian Council of Medical Research, Department of Anthropology, Delhi (1985-1989). She received Fogarty Fellow, Leadership program for the Women's Global Health Scholars program, University of California, San Francisco, USA (2007-2008) and Scholarship for Microbicide Conference, India (2008). She was invited and joined as member of Editorial Board of 'Journal of the International AIDS Society' (2010-2012). She was Member, Editorial Board IJAR in 2013. She was Invited speaker on talk entitled, "ARV-based HIV prevention in Practice: Social and Behavioral Aspects" of '20th International AIDS Conference (AIDS 2014), Melbourne, Australia in 2014.

- Dr Sanjay Mehendale is Director Research at PD Hinduja Hospital and Medical Research Center Mumbai, India . He was Additional Director General and Scientist H at Indian Council of Medical Research (ICMR), New Delhi Area, India from Sep 2016. He served as Director and Scientist G at National Institute of Epidemiology [NIE, ICMR], Chennai from Dec 2010 – Oct 2016. He has completed his MBBS, MD from B. J. Medical College in the year 1983.

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- Dr Manisha Ghate has served at various positions of Scientist B (1995-2000), Scientist C (2000-2005), Scientist D (2005-2010), Scientist E (2010-2015) and Scientist F since 2015 at ICMR – National AIDS Research Institute Pune.

The following principles of GCP and GPP were discussed.

1) Clinical trials are conducted aiming at obtaining evidence regarding efficacy and safety of products that, in addition to non-clinical evidence and quality data should support their registration by a regulatory authority. Ethical principles based primarily on the Declaration of Helsinki should be the basis for the approval and conduction of clinical trials. Three basic ethical principles of equal moral force, namely respect for persons, beneficence and justice, permeate all the GCP principles enumerated below

2) Clinical trials should be conducted only if the anticipated benefits for the individual trial subject and society clearly outweigh the risks involved;

3) Although the benefit of the results of the clinical trial to science and society are important and should be taken into account, the most important considerations are those related to the rights, safety and wellbeing of the trial subjects;

4) A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/independent ethics committee (IEC) approval/favorable opinion;

5) Approval of clinical trials of investigational products should be supported by adequate non-clinical and, when applicable, clinical information;

6) Clinical trials should be scientifically sound, and described in a clear, detailed protocol;

7) Freely given informed consent should be obtained from every subject prior to clinical trials participation; 2.7 Qualified physicians (or, if appropriate, qualified dentists) should be responsible for the medical care of trial subjects, and for any medical decision made on their behalf;

8) These professionals should be adequately qualified by education, training and experience to perform their tasks regarding the trial and trial subjects;

9) Recording, handling, and storage of all clinical trial information should be appropriate to allow accurate trial reporting, interpretation and verification;

10) The confidentiality of records that could identify subjects should be protected respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s);

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11) Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP), and should be used in accordance with the approved protocol;

12) Systems with procedures that assure the quality of every aspect of the trial should be implemented.

13) Structure and Responsibilities of the Ethics Committee, composition of IRB, functions and operations on should be done

Dr. Sujata V. Patil.

Associate Professor in
Dept. of Community Medicine
[illegible] Institute of Medical Sciences

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Workshop On GCP from 16th to 17th August 2017

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GCP Training

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REPORT OF CDE PROGRAMME

- **Topic of CDE:** "Workshop on Research Grant writing - Essentials of research protocol"
- **Venue:** Lecture Hall No-3, Faculty of physiotherapy, KIMSDU, Karad
- **Date:** 20/09/2017 **Time:** 10.00 pm to 12.00 am.
- **Organizers:** Faculty of physiotherapy, KIMSDU, Karad
- **Number of Delegates Participated:** 130
- **Speaker:** Dr. Supriya Patil, Professor of Department of Community Medicine.

Event plan/ report:

Faculty of physiotherapy conducted "Workshop on Research Grant writing - Essentials of research protocol" for Medical, dental and physiotherapy faculty and students. The workshop and lectures were delivered by Dr. Supriya Patil, Professor of Department of Community Medicine, KIMS, KIMSDU, Karad.

The CDE program was conducted on 20th Sept 2017. A total of 130 participants attended the program. This session focused thoroughly on the different components of the research protocol. The research protocol is a science and art of describing intended outcomes, practices, process and procedures of a research study. The resource person deliberated on how components of the research protocol vary depending on the discipline and objectives of the study. The expert faculty successfully explained 12 main components of a research protocol; • Abstract • Literature review or background • Research question follows PICOTS and FINER frameworks. Research outcomes • Study design and research approach • Data extraction or collection methods • Data management policies • Statistical

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procedures● Risks to subjects● Threats to validity; ● Works cited; ● Appendices. She stated the importance of understanding the steps to develop a research protocol to conduct study appropriately and obtain reliable results. The program was very informative and interactive. The workshop ended with the valedictory function where in certificate, as token of appreciation a Memento was presented to the Guest speaker.

Pre & Post- test result:

Advanced learning gain as calculated by the formula

ALG= post test – Pre test score/total score x 100

All the Questionnaire's were scored, analyzed and Advanced learning gain was calculated for each learner. The sample copy of the questionnaire with the calculation is attached with the report. We obtained a 60% ALG from the analysis.

Dr. A. R. Risbud
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Department of Oral and Maxillofacial Surgery
Faculty of Dental Sciences
K.I.M.S.D.U.
Malkapur, Tal. Karad Dist. Satara
Karad - 415 110

Workshop on Research Grant writing -Essentials of research protocol

Add. Director of Research
KIMSDU, Karad

Workshop on writing research protocol

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KIMSDU, Karad

Report of Workshop in Research Methodology 2017

Krishna Institute of Medical Sciences Deemed University, Karad scheduled workshop in research methodology for post graduate students from faculty of Medicine, Nursing, Dental and Physiotherapy and also for Ph. D. students as well as for interested faculty members.

Workshop was conducted as per scheduled programme (Attached time table for the workshop) from 3rd to 7th Oct 2017. Workshop was conducted for 5 days. Everyday irrespective of lunch break, lecture/discussion session were conducted for 6hrs. The total hours of lectures delivered /discussion were 30 hours.

Total 123 delegates attended the workshop out of that 69 from medical 18 from dental, 17 from physiotherapy, 13 from nursing, 2 Ph. D. students and 3 faculty members .

Workshop began with inaugural programme. In welcome address Dr. Mrs. Supriya Patil explained about the importance of this workshop as well as plan for the same. Dr. A. K. Pratinidhi our former Director of Research was Chief Guest. In her speech stressed upon need of research. Dr. Arun R. Risbud Director of Research explained in detail about the expectations from this workshop. Subsequently topics covered were need of research study, designs, framing of research question, basic statistics, sample size & statistical software's.

This year as a part of this workshop one session on ICT was included. Also this year we included aluminous of Krishna Institute of Medical Sciences as resource person. He delivered lecture on how to write thesis best practices which was appreciated by all the delegates.

Writing of research proposal was covered on 2nd day of workshop and subsequently group activity for preparation of research protocol was given to five groups (2 - Medical, 1 - Nursing, 1 - Dental, 1 -Physiotherapy) on last day one representative from each group presented the protocol which was assessed by Judges Dr. A. K. Pratinidhi and Dr. P. M. Durgawale. Winner & runner up groups were awarded with trophy at the time of valedictory function.

All the sessions were interactive, informative and good quality. Topics were covered by resource persons from NARI Pune, other renowned teaching institutes and KIMSDU. Pre-post test, feedback evaluation will be completed within 2 weeks. Maharashtra medical council has given two credit points. Certificates will be given to delegates who have satisfactorily completed the workshop.

I am very much thankful to Dr. Arun Risbud sir for his encouragement, guidance and support. I extend my sincere thanks to all resource persons as well as all staff members from research office KIMSDU, because of their co-operation and help smooth conduction of workshop was possible. I thank Miss. Archana Madam Assist. Registrar for her help in MMC credit points.

Dr. A. R. Risbud
Director of Research
KIMSDU, Karad

Dr. Supriya S. Patil

Workshop on Research Methodology 2017

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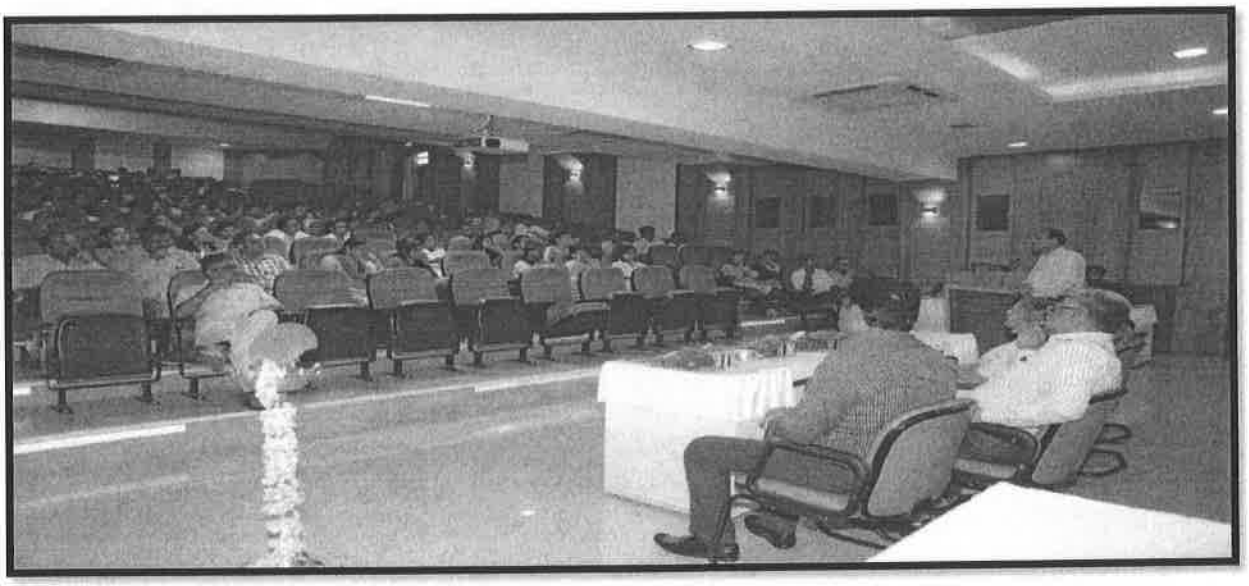
KIMSDU, Karad

Workshop on Research Methodology 2017

Add. Director of Research
KIMSDU, Karad

Workshop on Research Methodology 2017

Workshop on Research Methodology 2017



Add. Director of Research
KIMSDU, Karad

Overview of Good Clinical Laboratory Practice (GCLP) Workshop

Krishna Institute of Medical Sciences, Deemed to be University, Karad has successfully conducted the two days workshop on good clinical laboratory practices in collaboration with National Institute of Virology (NIV, Pune) and National AIDS Research Institute (NARI, Pune), on 24th & 25th October, 2017. This workshop was conducted in the S1 hall, of the Krishna Institute of Medical Sciences and hands on training was performed in Department of Molecular Bioogy and Genetics. This programme was inaugurated in the auspicious hands of Honorable Vice Chancellor Dr. Neelima Malik, Registrar Dr. M. V. Ghorpade and their august presence of Director of Research, Dr. Kavita S. Lole, Scientist F, National Institute of Virology, Dr. Sara S. Cherian, Scientist F and Dr. Varsha Potdar, Scientist D from National Institute of Virology, Pune and Deans of different faculties and head of departments of KIMSDU, Karad. Dr. Kavita S. Lole, Senior Scientist ,National Institute of Virology delivered and overview lecture on overview of good clinical laboratory practices after the orientation address of the workshop by Director of Research, Krishna Institute of Medical Sciences, Deemed to be University, Karad. Thirty delegates from all the different medical testing laboratories of Biochemistry, Microbiology, Pathology and Molecular Biology and Genetics of Krishna Institute of Medical Sciences along with different faculties of various colleges have participated in the workshop. The participants were illustrated the quality document preparation based on international standard document ISO:15189: 2012.

In summary, the resource persons highlighted the major areas of the good clinical laboratory practice standards such as specimen collection, chain-of-custody, and shipping instructions, instrumentation and analytical methods to be used, reference ranges, referral laboratory information, and transmission of results, external quality assurance, validation of test methods, reporting of results, retention of records to be applied to all laboratories performing testing include safety, diagnostic, and endpoint laboratory assays. Safety assays are those tests that are performed to both monitor potential adverse events and to verify the study participants' continued satisfaction of study inclusion/exclusion criteria, as appropriate, for each protocol.

The importance laboratory management was explained by Dr. Kavita S. Lole, Scientist F from NIV, Pune which included following points;

Dr. A. R. Risbud
Director of Research
KIMSDU, Karad

Responsibility of laboratory management and laboratory staff thorough documentation of the structure of the organization and the respective job descriptions and qualifications, as well as an ongoing documentation of an individual's professional experience, training, and skill-assessment.

The importance of quality policy of the laboratory for ensuring compliance with applicable laws and regulations. Applicable requirements include the following areas: handling radioactive materials, shipping infectious or diagnostic materials, reporting infectious disease testing results, personnel qualifications, retention of specimens and records, hazardous waste disposal, fire codes, medical examiner or coroner jurisdiction, legal testing, acceptance of specimens only from authorized personnel, handling controlled substances, patient consent for testing, confidentiality of test results.

Maintenance of documentation of personal records of the laboratory staff including the following records (in electronic or paper format), orientation and training, experience, education, applicable licensure/certification, competency assessments, continuing education records, Curriculum Vitae (CV, Work-related incident and/or accident records, dates of employment, safety training, attendance at job-related workshops and seminars.

Guidelines were explained to follow for the maintenance and calibration of the equipments.

Staff must keep all equipment clean, avoiding any buildup of dust, dirt, and spills that may adversely affect personnel safety or equipment performance. The laboratory must employ and adhere to documented daily, weekly, and/or monthly routine maintenance plans for all equipment utilized, and record completion of these tasks on the appropriate logs in a timely fashion. Any equipment that is out of service for any reason should be clearly identified as such. For equipment that has no standard frequency or requirement for maintenance and function checks, each laboratory should establish a schedule and procedure that reasonably reflects the workload and specifications of its equipment.

The maintenance and calibration records need to include the following information:

Instrument or Equipment identification ▪ Date and time maintenance/calibration performed ▪ Maintenance activities performed ▪ Results of calibration ▪ Acceptability status of calibration (Pass/fail) ▪ Identity of personnel performing maintenance activity ▪ Any necessary maintenance/calibration follow-up actions taken ▪ Review and approval

Dr. A. R. Risbud
Director of Research
KIMSDU, Karad

The importance of standard operating procedures was discussed in the session. The laboratory must write SOPs in a manner and language that is appropriate to the laboratory personnel conducting the corresponding procedures.

The format of the SOP may include the following: document number, revision number and date, effective date of the document, number of pages, title, to include name of analyte, type of specimen, and method/assay and/or instrumentation, principle and/or purpose, scope, specimen requirements/collection methods, reagents, standards, controls, and media used, instrumentation, calibration procedures, QC, procedural steps, reporting results, reference ranges/critical values, limitations, references, definitions, distribution, approval signatures and dates, document change history etc.

One session was delivered on Test Method Validation and Verification.

Perform External Quality Assurance (EQA) or alternative assessment within 30 days prior to restarting patient testing. • Verify method performance specifications as applicable, within 30 days prior to restarting patient testing. • Assess competency for analysts within 12 months prior to restarting patient testing. • A test is considered to be taken out of production when: (1) patient testing is not offered; and (2) EQA or alternative assessment, as applicable, is suspended.

The standard procedures for the reporting of the test results were illustrated by the resource persons. The laboratory's test report must indicate the following items: • Study-participant's name and/or a unique study-participant identifier. • Date of specimen collection, and if appropriate, time of collection. • Specimen source (e.g., blood, cerebrospinal fluid, urine). • The date and time of specimen receipt into the laboratory. • Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. • The name of the test performed. • The name and address of the laboratory location where the assay was performed. • The identity of the personnel who performed the test(s) • The assay result and, if applicable, the units of measurement or interpretation or both. • Reference ranges along with age and gender of study-participants, if these affect the reference range. • The assay report date. • Time of release of report, if applicable (if not on the report, this information should be readily accessible) • Name of physician of record, or legally authorized person ordering test, as appropriate.

The resource persons also oriented the recent trends in research. After taking the feedback and queries from the participants, the program was ended up with closing ceremony.

Dr. A. R. Risbud
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Dr. Kailas D. Datkhile (M.Sc. Ph.D.)
Senior Research Officer,
Department of Molecular Biology and Genetics,
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Workshop on Good Clinical Laboratory Practice 2017

Workshop on Good Clinical Laboratory Practice 2017

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Report of Workshop on IPR 10th – 11th Jan 2018

Two Days Workshop on "IPR Awareness" conducted from 10/01/2018 to 11/01/2018 by Intellectual Property Rights (IPR) Cell. This workshop was firstly initiated as a stepping stone in the institute to create awareness in IPR. This workshop was organized followed by inauguration programme in the MET Hall. This programme was inaugurated in the auspicious hands of Honorable Chancellor Dr. Vedprakash Mishra and by their august presence of Honorable Vice Chancellor Mrs. Dr. Neelima Malik, Registrar Dr. M. V. Ghorpade, Director of Research Dr. Arun R. Risbud, Additional Director of Research Dr. D. K. Agarwal, Dr. S. T. Mohite and others

Sixty nine participants have attended in the workshop. Mr. Arghya Roy and Ms. Ushoshi Guha were invited as resource persons from Lex Regia, Nagpur. They have delivered several talks on patent and copyrights during workshop. The topics covered in the workshop were: Awareness of IPR and prosecution of patent, copyright, design and trademark applications. In order to make successful for "granted" patent application at earliest, novelty, unique and utility – are the main prerequisites of patent application. So it has created a significant awareness among participants and added more information of IPR in their knowledge of IPR during the workshop. On the last day of workshop in the discussion session, Mr. Roy has discussed about previous patent applications, gave his suggestions after publication of patent application and important tips for improvement in the patent specification. This has developed on awareness for participants and faculties to develop patent drafting and prosecution.

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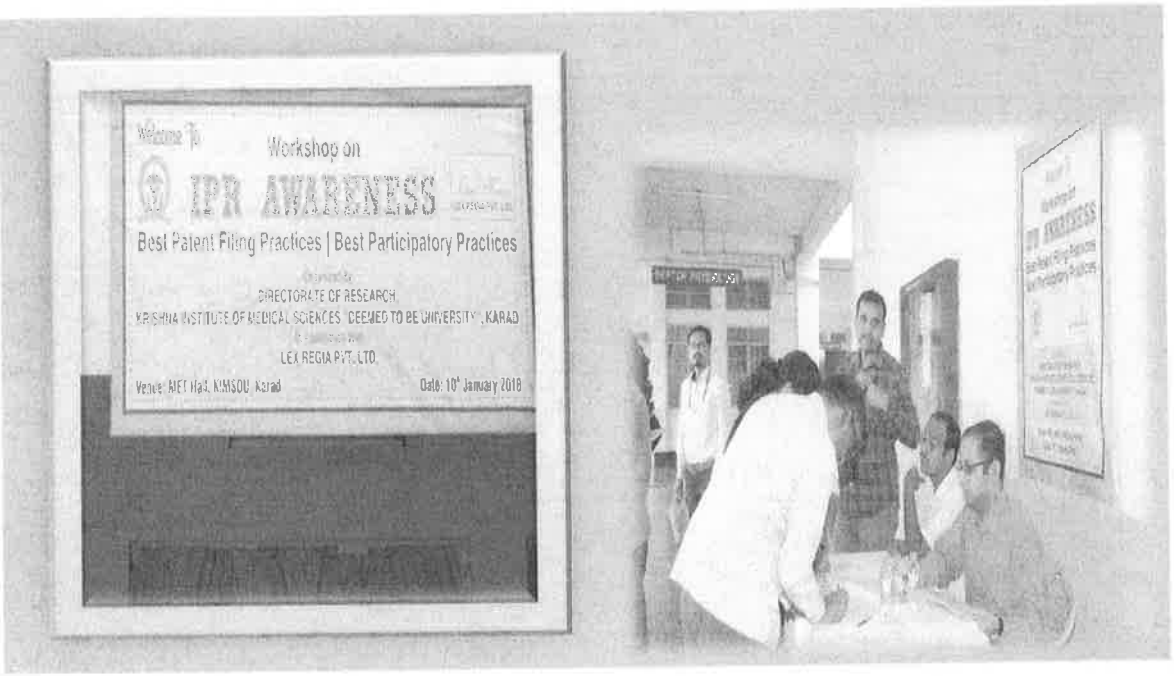
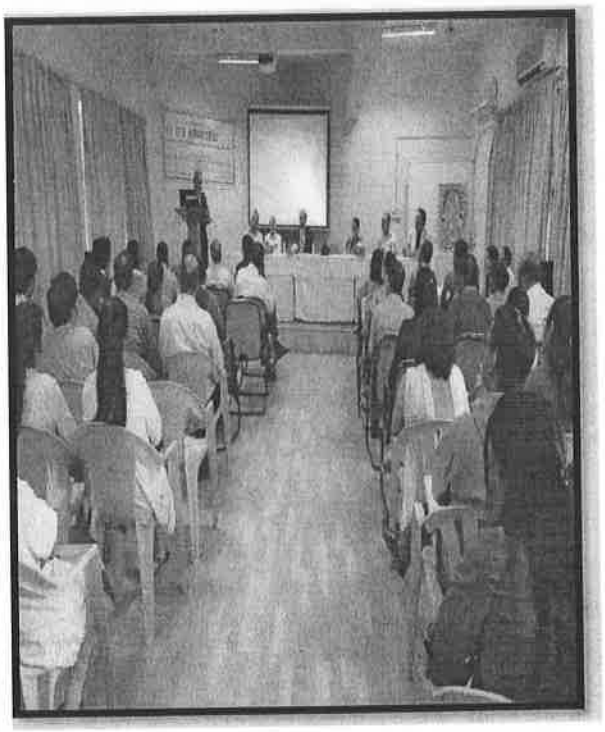
Workshop on IPR Awareness





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Workshop on IPR Awareness

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Workshop on IPR Awareness

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Report of Workshop on IPR 25th – 26th July 2018

Two Days Workshop on "IPR Activities" conducted from 25/07/2018 to 26/07/2018 by Intellectual Property Rights (IPR) Cell. This workshop was organized in the MET Hall. Twenty two concerned participants were enrolled in the workshop. Mr. Arghya Roy and Ms. Ushoshi Guha were invited as resource persons from Lex Regia, Nagpur. They have explained on various IPR activities and follow-up. They have emphasized on the importance of "patent drafting" during workshop. Patent write up and drafting with highlighted topics were shown in the workshop.

On the last day of workshop in media room, Mr. Roy has elaborated how to make draft patent application in the PowerPoint presentation and Ms. Guha has discussed with concerned participants in the preparation of copyright works. This has developed a new dimension for participants and faculties to maximize patent and copyright applications.

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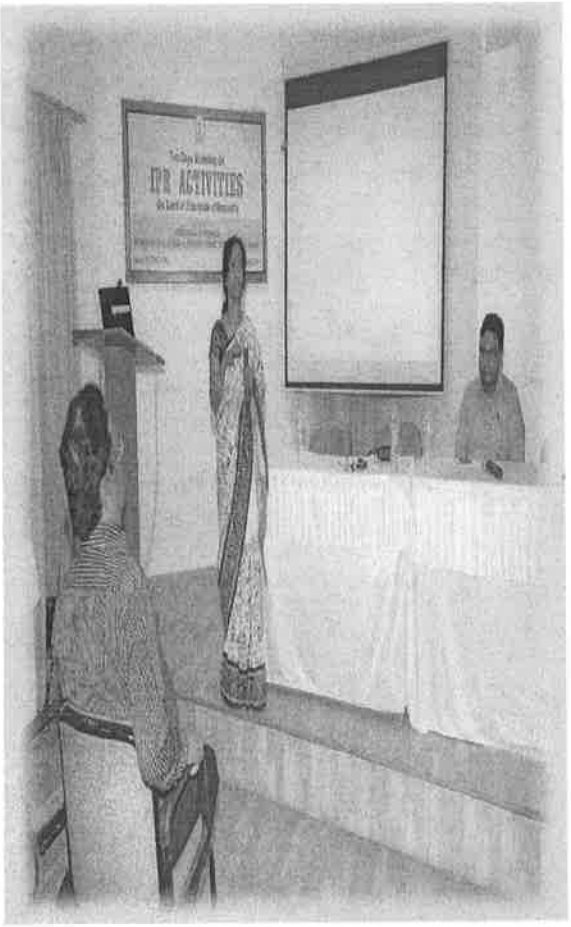
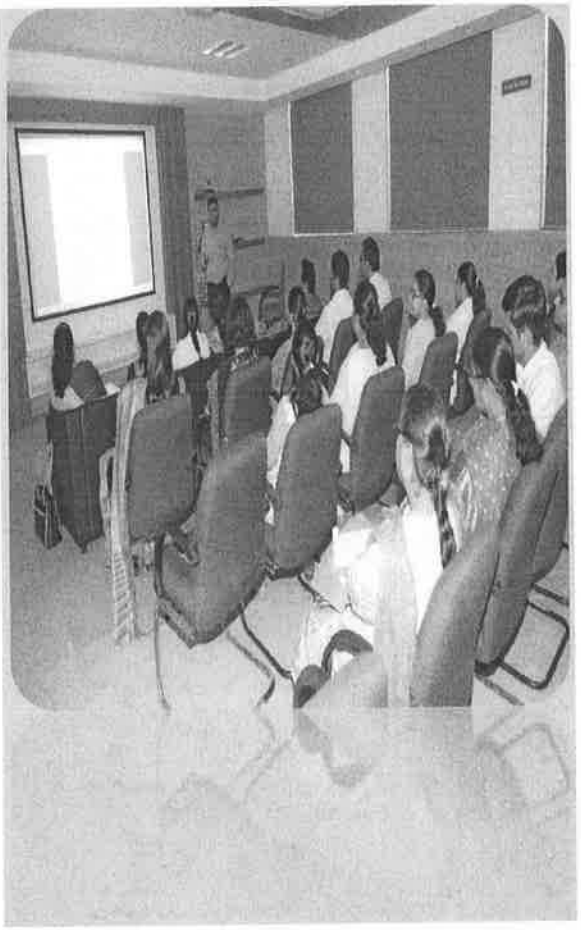
Work Shop on IPR Activities





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Work Shop on IPR Activities

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Report of Workshop of Good Clinical Practices on 30th July, 2018

One Day Workshop on "Good Clinical Practices" was conducted on 30/07/2018 by Research Cell of KIMSDU. This workshop was conducted in the S1 Hall. This programme was inaugurated at the auspicious hands of Honorable Director of Research Dr. Arun R. Risbud, by their august presence of Registrar Dr. M. V. Ghorpade , Dr. Asha Jadhav , Additional Director of Research Dr. D. K. Agarwal, Deans of Constitutes of Colleges and others

Forty Five participants attended the workshop. Dr. Pawandeep Kaur Dhawan (Associate Medical Director, CDSA),Shri. A. B. Ramteke(Former Joint Drugs Controller(India), CDSCO, HQ, New Delhi & Consultant Regulatory Affairs, CDSA),Mr. Anand Pendse(Senior Project Manager, Boehringer Ingelheim),Ms. Poonam Saini(Clinical Specialist Manager, Quintiles),Dr. Anand Kawade(Consultant, Paediatric Research, KEM Hospital Research Centre, Pune.),Dr. Gayatri Vishwakarma (Biostatistician, CDSA) were invited as resource persons from Pune. They delivered lectures on SOPs of GCP during workshop. The topics covered in the workshop were: Risk Identification, Benefit-Risk Assessment, Review by Independent Ethics Committee and Independent Review Board Records, Confidentiality/Privacy. So it has created a significant awareness among participants and added more information of GCP in their knowledge of during the workshop. At end of workshop in the discussion session, has discussed about previous technical queries regarding GCP.

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Dr. Sujata V. Patil.
Associate Professor in
Dept. of Community Medicine
Krishna Institute of Medical Sciences, D.U.
KARAD

Workshop on Good Clinical Practices

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Workshop on Good Clinical Practices

Workshop on Good Clinical Practices

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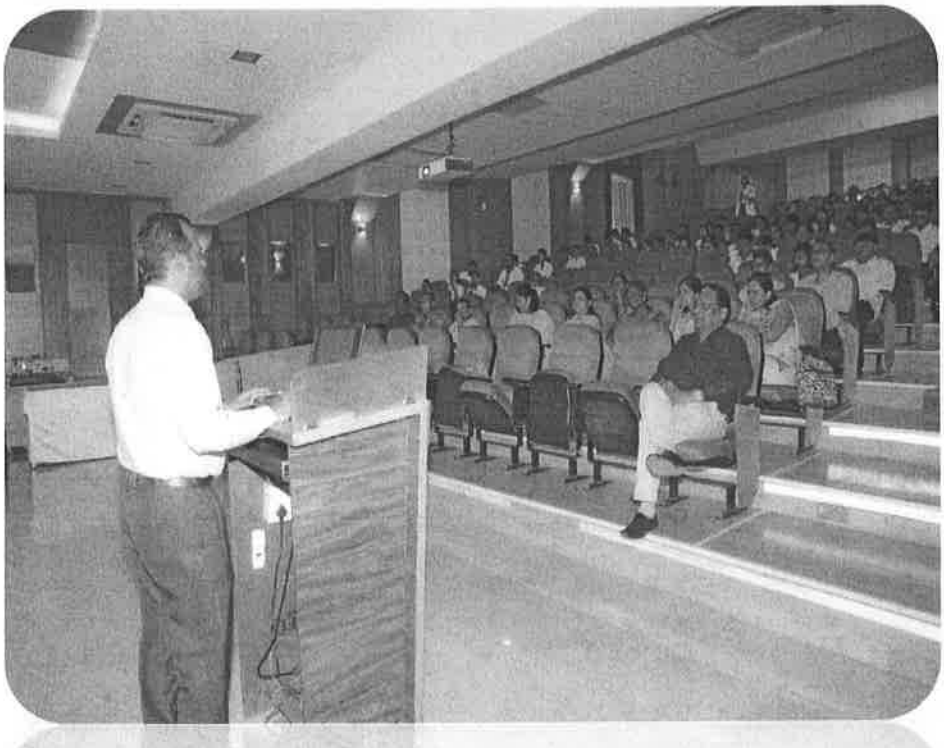
Workshop on Good Clinical Practices



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KIMSDU, Karad

Overview of Good Clinical Laboratory Practice (GCLP) Workshop

Krishna Institute of Medical Sciences, Deemed to be University, Karad has successfully conducted the two days workshop on good clinical laboratory practices in collaboration with National Institute of Virology (NIV, Pune) and National AIDS Research Institute (NARI, Pune) , on 17th & 18th August, 2018. This workshop was conducted in the S1 hall, of the Krishna Institute of Medical Sciences and hands on training was performed in Department of Molecular Biology and Genetics. This programme was inaugurated in the auspicious hands of Honorable Vice Chancellor Dr. Neelima Malik, Registrar Dr. M. V. Ghorpade and their august presence of Director of Research, Dr. Varsha Potdar, Senior Scientist and Head, Influenza group from National Institute of Virology, Pune, Dr. Sangeeta Kulkarni, Quality Manager from National AIDS Research Institute, Pune and Deans of different faculties and head of departments of KIMSDU, Karad. Dr. Varsha Potdar, Head, Influenza group National Institute of Virology delivered and overview lecture on overview of good clinical laboratory practices after the orientation address of the workshop by Director of Research, Krishna Institute of Medical Sciences, Deemed to be University, Karad. Twenty delegates from all the different medical testing laboratories of Biochemistry, Microbiology, Pathology and Molecular Biology and Genetics of Krishna Institute of Medical Sciences have participated in a workshop. In summary lecture Dr. Varsha Potdar explained an overview on good clinical laboratory practices including laboratory organization, personnel involved in laboratory testing and the laboratory facilities including equipment calibration and maintenance, use of standard operating procedures, Preparation of documents as per the international standards. Dr. Sangeeta Kulkarni highlighted laboratory documentation, Sample collection practices, sample transportation, sample management and laboratory waste management in all clinical laboratories as well as molecular and genetic testing laboratories. The quality system procedures were illustrated and guided to follow the same to the participants in their routine clinical practices to fulfill and improve the clinical investigations. The laboratory personnel were trained for the good laboratory practices starting from sample collection and processing of the samples to the reporting of the results of all the clinical investigations following international standards for the laboratory practices. The

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participants were illustrated the quality document preparation based on international standard document ISO:15189: 2012.

Various points were discussed in the workshop on the following headings; Management requirements and technical requirements

The standard procedures as per the requirement of ISO: 15189: 2012 were explained by the resource persons. First of all the quality policy and quality objectives of the clinical testing laboratories were discussed to introduce good laboratory practices in the clinical laboratories. The purpose of quality policy document was explained to generate reliable test results for all the clinical tests conducted in all the medical laboratories. The staff was explained regarding the purpose of adequate and prompt and polite services to the patients attending the clinical laboratories for the services.

Management requirements included:

- Quality System Management: The resource person highlighted the quality management to implement the Quality System in conformance as per the ISO 15189:2012 requirements and continually improve its effectiveness in the clinical laboratory testing.
- Control of quality documents: The need of maintenance of the quality documents including defined Quality Policy and Quality Objectives, Quality System Procedures, Standard Operative Procedures, Sample Collection documents, Safety documents, Patient records, Internal record documents, external quality control documents and other external origin documents was explained by the resource person.
- Examination of sample testing by referral laboratories,
- Evaluation of services and supplies
- Identification and resolution of the complaints in laboratory testing
- Identification and correction of non conformities in technical and managerial requirements
- Corrective and preventive actions for continual improvement,
- Evaluation and control of records
- Review of the documentation to the management of the Institute: The need of the management review to be frequently conducting in regular manner to run the laboratory set up with the permissions of the management.

Technical requirements included:

Dr. A. R. Risbud
Director of Research
KIMSDU, Karad

- Selection, purchase of equipment, chemicals, reagents and consumables required of the testing: The standard procedures to be formulated and maintained for the selection of reagents, kits chemicals, consumables and equipments for the proper test to be conducted.
- Selection of procedures: The purpose of selection of the procedures for the clinical testing as the major task for the initiating of the test and continuously improve the laboratory practices was highlighted by the resource persons.
- Quality indicators of the Testing laboratories (Preanalytical, analytical and post analytical): The necessity of defining quality indicators to monitor and evaluate performance throughout critical aspects of pre- examination, examination and post-examination processes was explained to the participants to monitor the objectives, methodology, interpretation, limits, action plan and duration of measurement. Also, the periodic review of quality indicators for the continual improvement of the laboratory procedures to fulfill the users of the laboratories.
- Laboratory Risk management: The importance of the risk assessment in the potential failures in working procedures and potential failures on examination results as they affect patient safety, modifies processes to reduce or eliminate identified risks and document decisions and actions taken.

The importance of management review was also explained to the participants. The major parameters of the management review explained were based on:

- The periodic review of requests and suitability of procedures and sample requirements.
- Assessment of feedback including complaints and other relevant factors from clinicians, patients and other parties
- Internal audits
- Risk management
- Quality indicators for monitoring the laboratory's contribution to patient care.
- Reviews by external organizations
- Results of participation in interlaboratory comparison program
- Monitoring and resolution of complaints
- Identification and control of nonconformities
- Results of continuous improvement including current status of corrective and preventive actions
- Follow up actions from previous management reviews

Dr. A. R. Risbud
Director of Research
KIMSDU, Karad

- Recommendations for improvement in technical requirements
- The resource persons also oriented the recent trends in research. After taking the feedback and queries from the participants, the program was ended up with closing ceremony.

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Senior Research Officer,
Department of Molecular Biology and Genetics,
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Good Clinical Laboratory Practice 2018

Add. Director of Research
KIMSDU, Karad

Research Methodology 8th to 12th October 2018

Directorate of Research, Krishna Institute of Medical Sciences, "Deemed To Be University", Karad scheduled Workshop in Research Methodology for Postgraduate Students from Faculty of Medicine, Nursing, Dental, Physiotherapy, and for Ph.D. Students.

Workshop was conducted as per the scheduled programme (Attached time table for the workshop) from 8th to 12th October 2018. The Research Methodology Workshop was conducted for 5 full days, every day irrespective of lunch break, lecture/discussion sessions were conducted for 6 hours. The total hours of lectures delivered/discussions in 5 days were 30 hours. Total 173 delegates participated in workshop. Out of that 72 were from Medical, 20 from Dental, 15 from Physiotherapy, 24 from Nursing, and 42 were Ph.D. students.

Workshop began with inaugural programme on 8th October 2018. Dr. A. K. Pratinidhi Former Director of Research was the Chief guest. In the welcome address Dr. Supriya Patil, Dean Academics, KIMS explained about importance and plan of workshop as well as rules and regulations. Dr. A. R. Risbud, Director Research, KIMSDU emphasised importance of methodology while conducting the research project. Dr. Asha K. Pratinidhi stressed on original work and need of quality research. Dr. S. V. Kakade Associate Professor proposed vote of thanks

Subsequently topics covered were need of research, selection of research topics, framing research questions, objectives, presentation of data, types of data, study designs, writing research proposal, sample size, sampling techniques, statistical tests, writing of thesis best practises, software's in statistics and ethics in medical research. In ICT session internet of medical things for healthcare application and role of mechanical engineering in medical profession topics were covered.

In addition to in-house faculties experts from different teaching institutes and National AIDS Research Institute were invited as resource persons. All the sessions were informative and interactive. There was active participation from delegates. ALG was 60.7%.

Group activity was given to 5 groups which included 2 from medical and 1 from Nursing, Dental and Physiotherapy faculty. Presentation work was assessed by Dr. A. K. Pratinidhi and Dr. P. M. Durgawale, HOD, Community Medicine. Winner and runner up groups were felicitated during valedictory function. Four credit points were granted by Maharashtra Medical Council. Soft copy of workshop and certificates were distributed to delegates as well as resource persons.

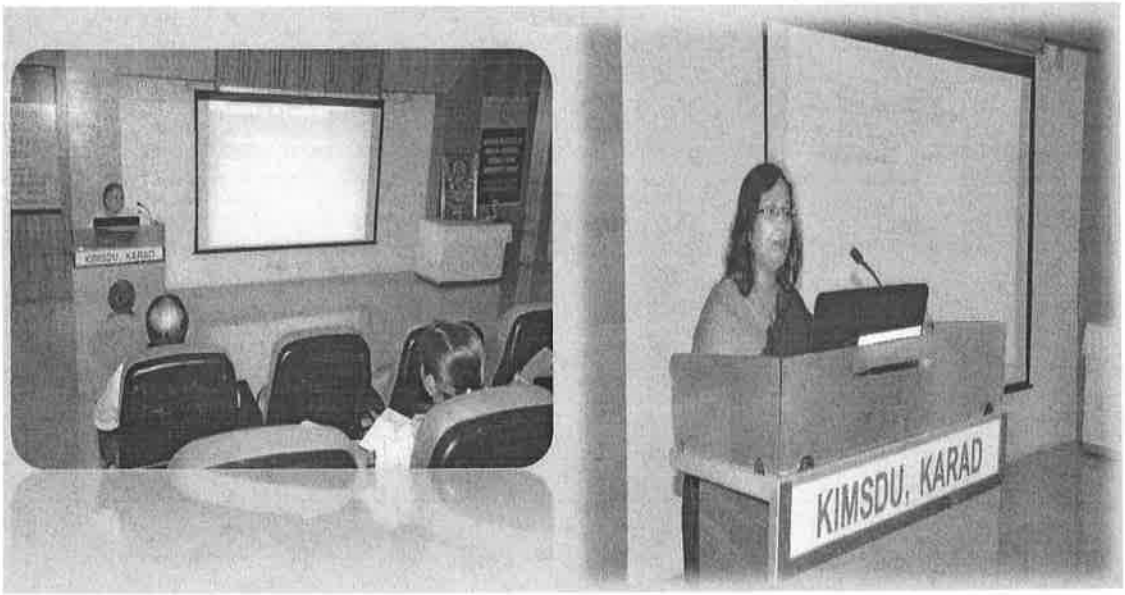
I am very much thankful to Dr. Arun Risbud sir for his encouragement, guidance and support. I extend my sincere thanks to all resource persons as well as all staff members from research office, KIMSDU, because of their co-operation and help smooth conduction of workshop was possible. I thank Miss. Archana Madam Assist. Academic Registrar for her help in MMC Credit points.

Dr. A. R. Risbud
Director of Research
KIMSDU, Karad

Sspatil
Dr. Supriya. S. Patil

Research Methodology Workshop 8th to 12th October 2018

Research Methodology Workshop 2018



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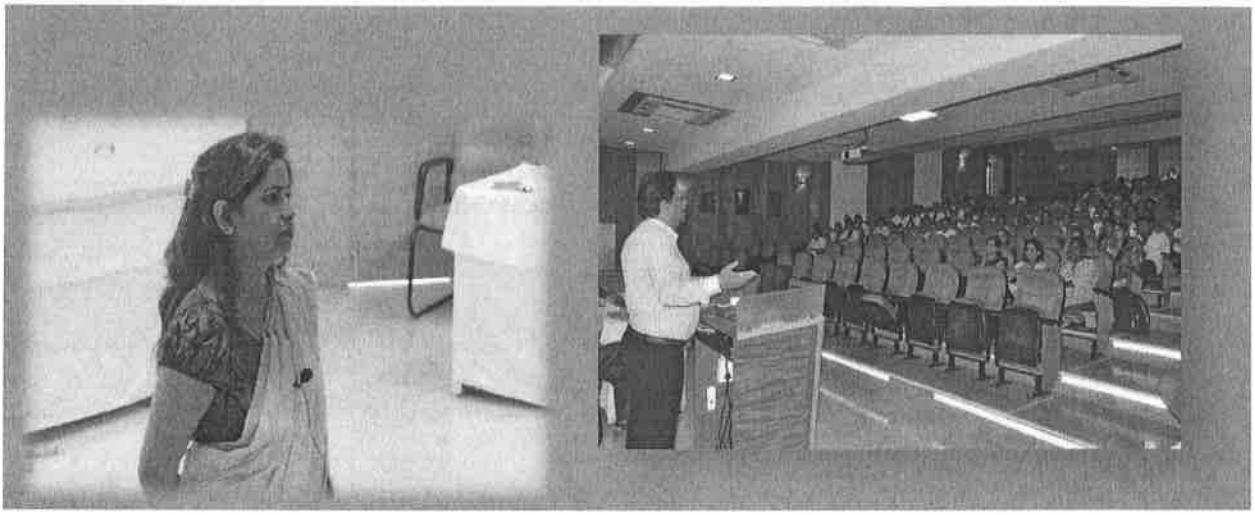
RESEARCH METHODOLOGY WORKSHOP 2018



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KIMSDU, Karad

REPORT OF CDE PROGRAMME

- **CDE TOPIC: : "Workshop on Research Grant writing"**
- **SPEAKER : DR. D. A. Gadkari**
- **VENUE** : Lecture Hall No-3, Faculty of Nursing, KIMSDU, Karad
- **DATE** : 15/10/2018 **TIME:** 10.30 am to 1.00 pm.
- **ORGANIZERS:** Faculty of Nursing, KIMSDU, Karad
- **DELEGATES Participated:** 120.
- **REPORT:** Faculty of Nursing conducted a workshop program on "Research Grant writing for health care professionals and students of KIMSDU Karad. The speaker, Dr. D. A Gadkari, is a well-known Ex-Director National Institute of Virology from Pune. Dr.Shivkumar K.M, Master of the Ceremony, introduced the guest speaker. Dr. V. R. Mohite, Principal of faculty of Nursing, felicitated Dr. D.A gadkari with a floral bouquet.

  In the morning session, Dr. Gadkari explained about medical research grant writing in very simple but effective way. After the lecture he answered the queries related to the topic. The lecture was followed by lunch break.

  After the lunch break, second session primarily focused on importance of methodology planning in research writing. The lecture also clarified the seriousness of plagiarism in medical research and how it can be avoided during grant and article writingThe resource person elaborated about the strategies that can be used for avoiding the plagiarism – explaining about the importance of paraphrasing, using a quote for direct sentence citing appropriately, and use of available plagiarism checker software.

Dr. A. R. Risbud
Director of Research
KIMSDU, Karad

Pre-Test & Post Test Results

Before and after the lecture, Pre-test & Post-test was conducted respectively.

The Pre-Test score : 46%.

The Post-Test score : 89%

Absolute Learning Gain= Post Test- Pre Test/ 100%- Pre Test

= 89-46/ 100-46= 43/54

= 79.62%.

At the end of CDE programme, certificates were distributed to the participants by the Speaker, Dr Gadkari. Then, Dr Arun Risbud, presented Momento & certificate to the guest speaker & thanked him for his wonderful lecture. Dr. Pranob Sanyal gave vote of thanks & declared the end of CDE Programme.

Dr. A. R. Risbud
Director of Research
KIMSDU, Karad

Oral and Maxillofacial Surgery
Dental Sciences
KIMSDU
Karad - 415 110.

Report of Workshop of IPR on 17th – 18th Jan 2019

Two Days Workshop on "Patent Filing Procedure" conducted from 17/01/2019 to 18/01/2019 by Intellectual Property Rights (IPR) Cell. This workshop was organized followed by inauguration programme in the media room. This programme was inaugurated in the auspicious hands of Honorable Vice Chancellor Dr. Neelima Malik and by their august presence of Registrar Dr. M. V. Ghorpade, Additional Director of Research Dr. D. K. Agarwal and deans from constituent faculties

Thirty eight participants, who were faculties from constituent colleges, have attended in the workshop. Mr. Suneet Sabale, Mr. Vinayak Khobrekar, Ms. Amruta Kulkarni and Ms. Saumya Shukla were invited as resource persons from Brainiac IP Solutions, Pune. Mr. Suneet Sabale has delivered several talks on patent and Amruta Kulkarni has talked on copyrights during workshop. The topics covered in the workshop were: Filing patent procedure, patent prosecution, copyright, design and trademark applications. In order to make successful patent application, PCT application is useful to speed up the patent examination.

On the last day of workshop in the discussion session, Mr. Suneet Sabale has discussed about patent applications, gave his important tips for improvement in the patent specification. Patent search demo has demonstrated in the ICT lab at Central Library, KIMS, Karad.

Dr. A. R. Risbud
Director of Research
KIMSDU, Karad

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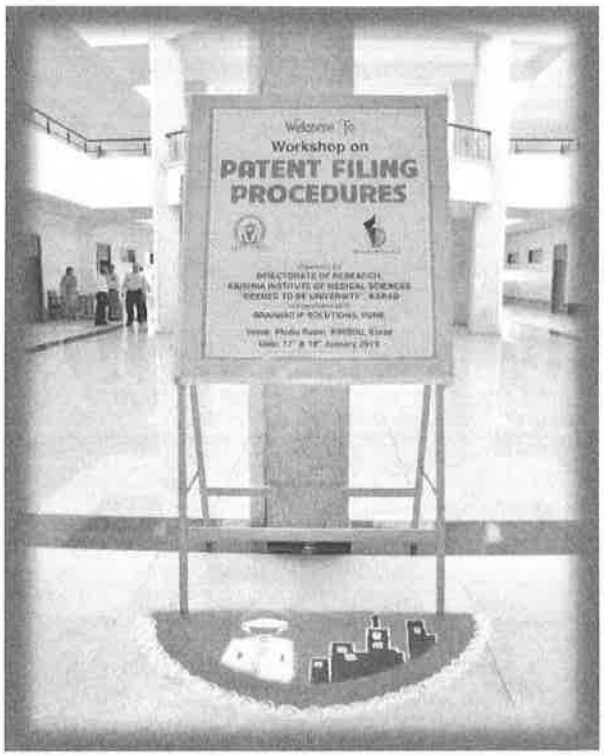
KIMSDU, Karad

Workshop on Patent Filing Procedure



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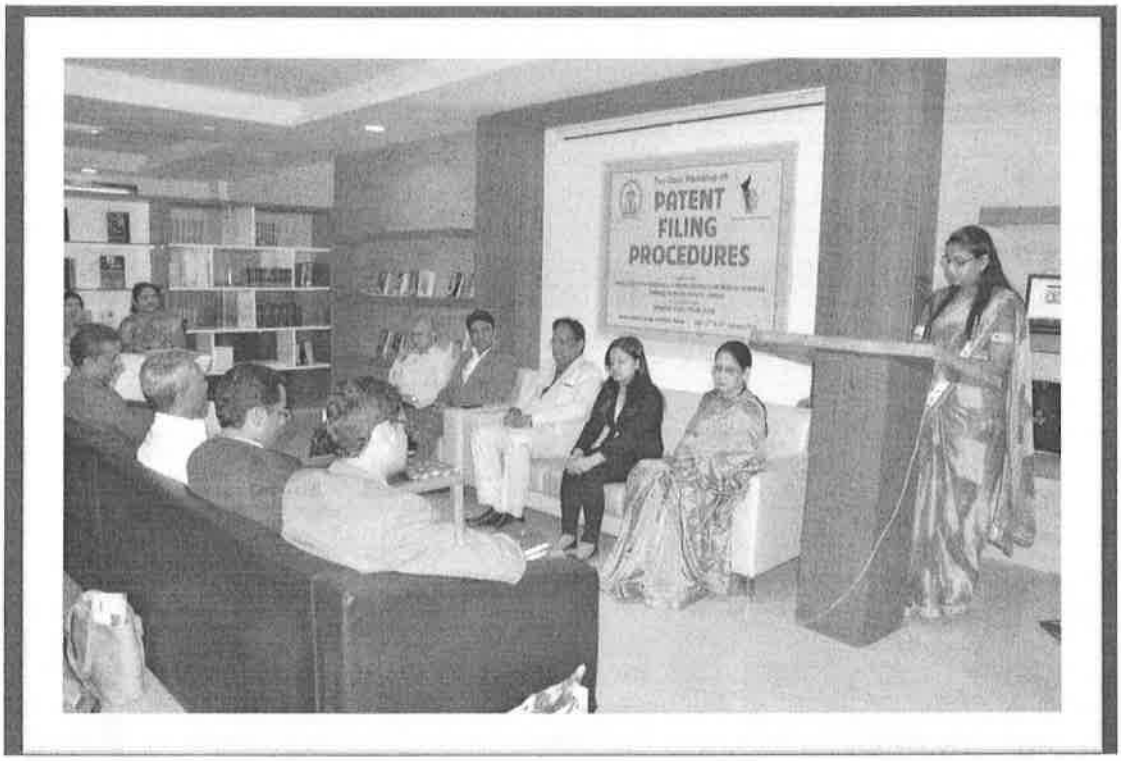
WORKSHOP ON PATENT FILING PROCEDURE



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Report of Workshop of IPR on 16th April 2019

One Day Workshop on "Patent Drafting, Filing, Commercialization and Copyrights" conducted from 16/04/2019 by Intellectual Property Rights (IPR) Cell. This workshop was organized in the S1 Hall. This workshop was organized followed by inauguration programme in the S1 hall, KIMS. This programme was inaugurated in the auspicious hands of Honorable Chancellor Dr. Vedprakash Mishra and their august presence of Honorable Vice Chancellor Dr. Neelima Malik, Registrar Dr. M. V. Ghorpade, Additional Director of Research Dr. D. K. Agarwal and deans from constituent faculties.

Eighty one participants who were faculties as well as students from constituent colleges, enrolled in the workshop. Mr. Suneet Sabale was invited as resource person from Brainiac IP Solutions, Pune. He has explained on various IPR activities and follow-up. The detailed explanation in "how to make draft patent application" in the presentation with many illustrations was delivered by him. The importance of "patent drafting, filing and commercialization" have emphasized during workshop. Patent write up and drafting with highlighted topics were shown in the workshop. This has developed a new curiosity for participants and faculties to maximize patent and copyright applications.

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Overview of Good Clinical Laboratory Practice (GCLP) Workshop

Krishna Institute of Medical Sciences, Deemed to be University, Karad has successfully conducted the two days workshop on good clinical laboratory practices in collaboration with National Institute of Virology (NIV, Pune) and National AIDS Research Institute (NARI, Pune) , on 13th & 14th May, 2019. This workshop was ordered by inauguration programme in the S1 hall, of the Krishna Institute of Medical Sciences. This programme was inaugurated in the auspicious hands of Honorable Chancellor Dr. Suresh J. Bhosale, Registrar Dr. M. V. Ghorpade and their august presence of Director of Research, Dr. Varsha Potdar and Dr. Pragya Yadav from NIV, Pune, Dr. Sangeeta Kulkarni from NARI, Pune and Deans of constituent faculties and head of departments of KIMSDU, Karad. Dr. Varsha Potdar, Head, Influenza group National Institute of Virology delivered and overview lecture on goals, objectives and introduction on good clinical laboratory practices after the orientation address of the workshop by Director of Research, KIMSDU, Karad. Twenty eight delegates from all the Clinical laboratories of Biochemistry, Microbiology, Pathology and Department of Molecular Biology and Genetics of Krishna Institute of Medical Sciences have participated in a workshop. In summary lecture Dr. Varsha Potdar explainced an overview on good clinical laboratory practices including laboratory organization and the laboratory facilities including equipment calibration and maintenance, use of standard operating procedures. Dr. Pragya Yadav demonstrated proper uses of Personal Protection Equipments, donning and doffing of PPE, waste management of PPE. Dr. Sangeeta Kulkarni highlighted laboratory documentation, sample management and laboratory waste management. Thereafter different distinguished speakers elaborated on good clinical laboratory practices in Biochemistry, Pathology, and Microbiology and Molecular diagnostics. The quality system procedures were illustrated and guided to follow the same to the participants in their routine clinical practices to fulfill and improve the clinical investigations. The laboratory personnel were trained for the good laboratory practices starting from sample collection and processing of the samples to the reporting of the results of all the clinical investigations following international standards for the laboratory practices.

Various points were discussed in the workshop on the following headings; Management requirements and technical requirements

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The standard procedures as per the requirement of ISO: 15189: 2012 were explained by the resource persons. First of all the quality policy and quality objectives of the clinical testing laboratories were discussed to introduce good laboratory practices in the clinical laboratories. The purpose of quality policy document was explained to generate reliable test results for all the clinical tests conducted in all the medical laboratories. The staff was explained regarding the purpose of adequate and prompt and polite services to the patients attending the clinical laboratories for the services.

Quality System Management: The resource person highlighted the quality management to implement the Quality System in conformance as per the ISO 15189:2012 requirements and continually improve its effectiveness in the clinical laboratory testing.

Control of quality documents: The need of maintenance of the quality documents including defined Quality Policy and Quality Objectives, Quality System Procedures, Standard Operative Procedures, Sample Collection documents, Safety documents, Patient records, Internal record documents, external quality control documents and other external origin documents was explained by the resource person.

Identification and resolution of the complaints in laboratory testing, Identification and correction of non conformities in technical and managerial requirements, Corrective and preventive actions for continual improvement,, Evaluation and control of records

Review of the documentation to the management of the Institute: The need of the management review to be frequently conducting in regular manner to run the laboratory set up with the permissions of the management.

Technical requirements included:

- Selection, purchase of equipment, chemicals, reagents and consumables required of the testing: The standard procedures to be formulated and maintained for the selection of reagents, kits chemicals, consumables and equipments for the proper test to be conducted.
- Selection of procedures: The purpose of selection of the procedures for the clinical testing as the major task for the initiating of the test and continuously improve the laboratory practices was highlighted by the resource persons.
- Quality indicators of the Testing laboratories (Pre-analytical, analytical and post analytical):
- The necessity of defining quality indicators to monitor and evaluate performance throughout critical aspects of pre- examination, examination and post-examination processes was

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explained to the participants to monitor the objectives, methodology, interpretation, limits, action plan and duration of measurement. Also the periodic review of quality indicators for the continual improvement of the laboratory procedures to fulfill the users of the laboratories.

- Laboratory Risk management: The importance of the risk assessment in the potential failures in working procedures and potential failures on examination results as they affect patient safety, modifies processes to reduce or eliminate identified risks and document decisions and actions taken.

The importance of management review was also explained to the participants. The major parameters of the management review explained were based on:

The periodic review of requests and suitability of procedures and sample requirements, assessment of feedback including complaints and other relevant factors from clinicians, patients and other parties, Internal audits, Risk management, Quality indicators for monitoring the laboratory's contribution to patient care, Reviews by external organizations, Results of participation in inter-laboratory comparison program, Monitoring and resolution of complaints Identification and control of nonconformities, Results of continuous improvement including current status of corrective and preventive actions, follow up actions from previous management reviews, Recommendations for improvement in technical requirements.

At the end one session was entirely dedicated for recent trends in research in various disciplines where clinical practices involved. The program was ended up with closing ceremony.

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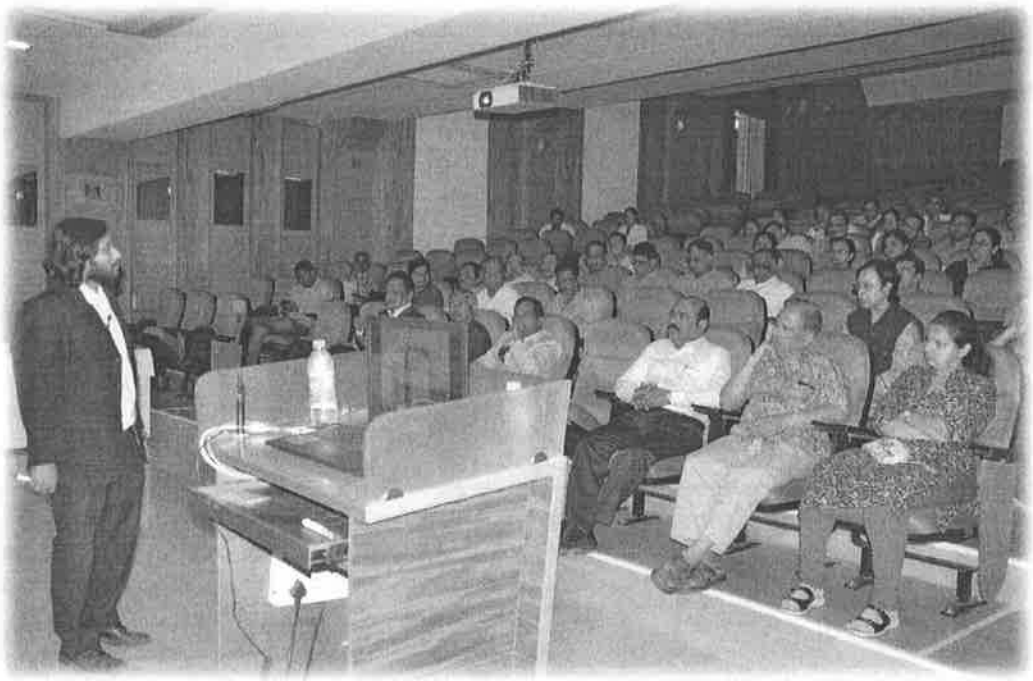
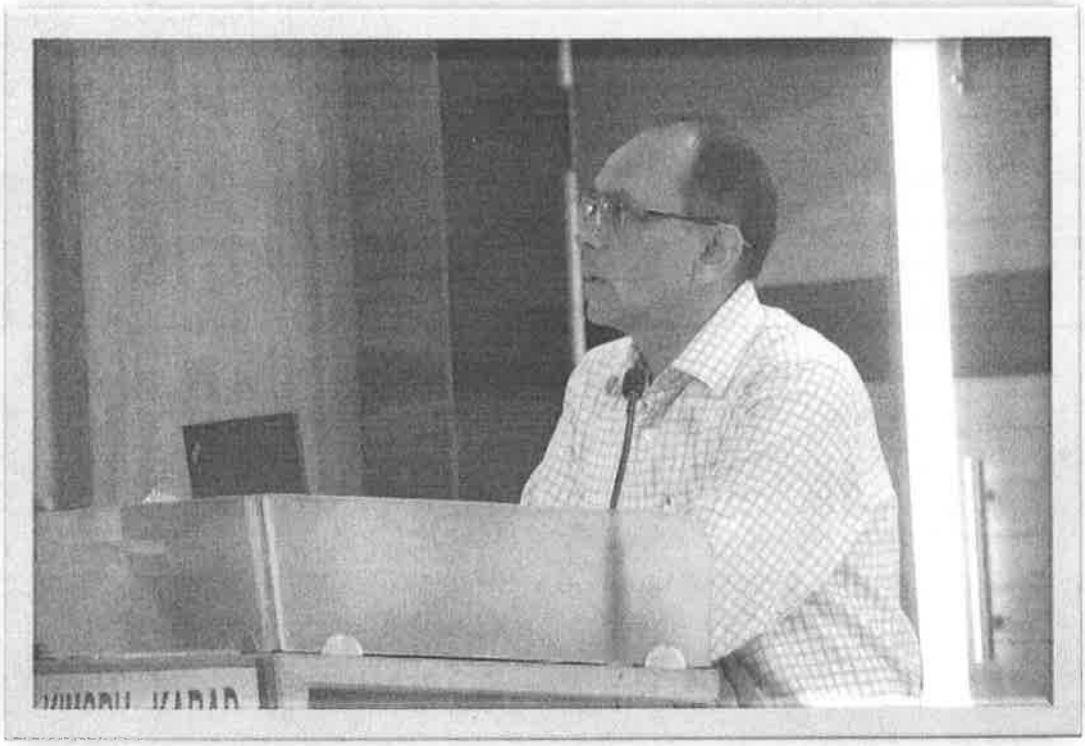
Dr. Kailas D. Datkhile (M.Sc. Ph.D.)
Senior Research Officer,
Department of Molecular Biology and Genetics,
KIMSDU, Karad-415539



Good Clinical Laboratory Practice (GCLP) Workshop



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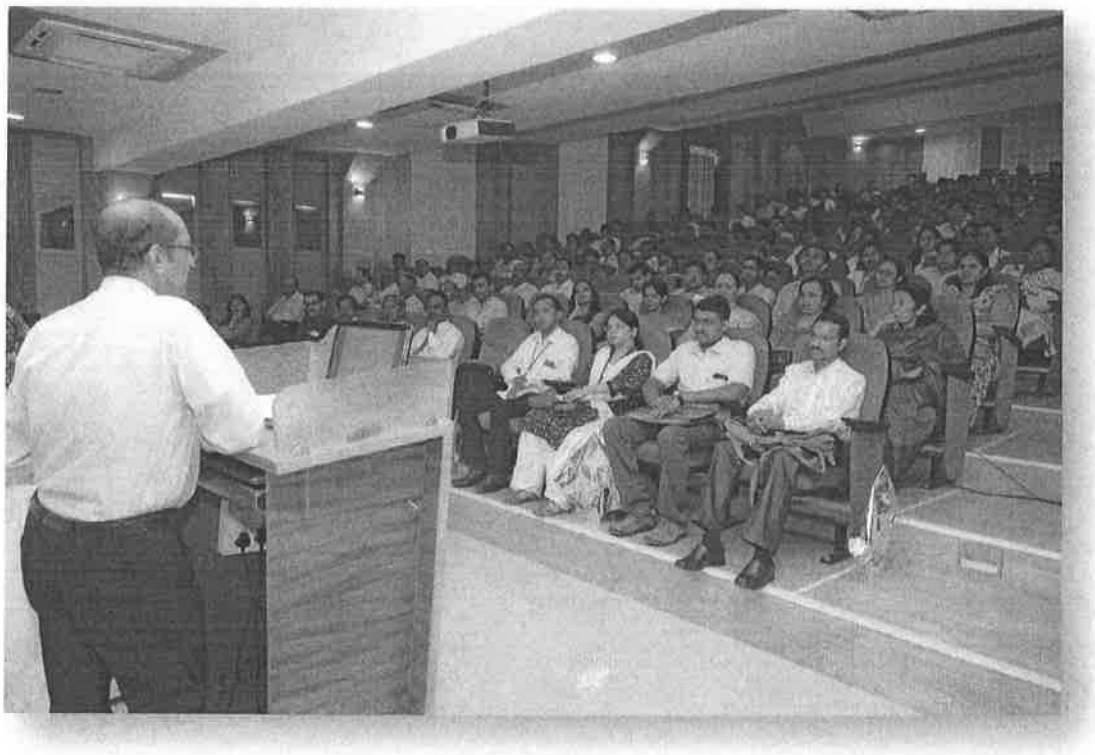
Good Clinical Laboratory Practice (GCLP) Workshop



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Report of Workshop on IPR 23rd July 2019

One Day Workshop on "Formatting, Designing and Drafting of Patents and Copyright" conducted on 23rd July 2019 by Intellectual Property Rights (IPR) Cell. This workshop was organized in the MET Hall. Fifty two concerned participants were enrolled in the workshop. Mr. Arghya Roy and Ms. Ushoshi Guha were invited as resource persons from Lex Regia, Nagpur. They have explained on various IPR activities and follow-up. They have highlighted on formatting, designing and drafting of patents and copyrights during workshop. Mr. Roy has elaborated how to make draft patent application in his presentation and Ms. Guha has discussed with participants in the preparation of copyright works. This has developed a new dimension for participants and faculties to maximize patent and copyright applications.

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Workshop on "Formatting, Designing and Drafting of Patents and Copyright"

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GCP Training Workshop , 4th to 5th September 2019

Partnering organizations and institutes – KIMSDU,Karad

Partnering organizations and institutes- National AIDS Research Institute (NARI), Pune

Following were the speakers at the workshop

- Dr Seema Sahay is Academic Editor –PlOS One from 2015. She was Junior Research Fellow, Indian Council of Medical Research, Department of Anthropology, Delhi (1985-1989). She received Fogarty Fellow, Leadership program for the Women's Global Health Scholars program, University of California, San Francisco, USA (2007-2008) and Scholarship for Microbicide Conference, India (2008). She was invited and joined as member of Editorial Board of 'Journal of the International AIDS Society' (2010-2012). She was Member, Editorial Board IJAR in 2013. She was Invited speaker on talk entitled, "ARV-based HIV prevention in Practice: Social and Behavioral Aspects" of '20th International AIDS Conference (AIDS 2014), Melbourne, Australia in 2014.

- Dr Manisha Ghate has served at various positions of Scientist B (1995-2000), Scientist C (2000-2005), Scientist D (2005-2010), Scientist E (2010-2015) and Scientist F since 2015 at ICMR – National AIDS Research Institute Pune.

- Dr. Shilpa Pratinidhi is Professor and Head of Biochemistry, MIMER Medical College, Talegaon Dabhade, Pune, India., India Professor SKNMC and GH since 2011. She completed her MD in Biochemistry in the year 2002.

The principles and the benchmarks underlying GPP were discussed.

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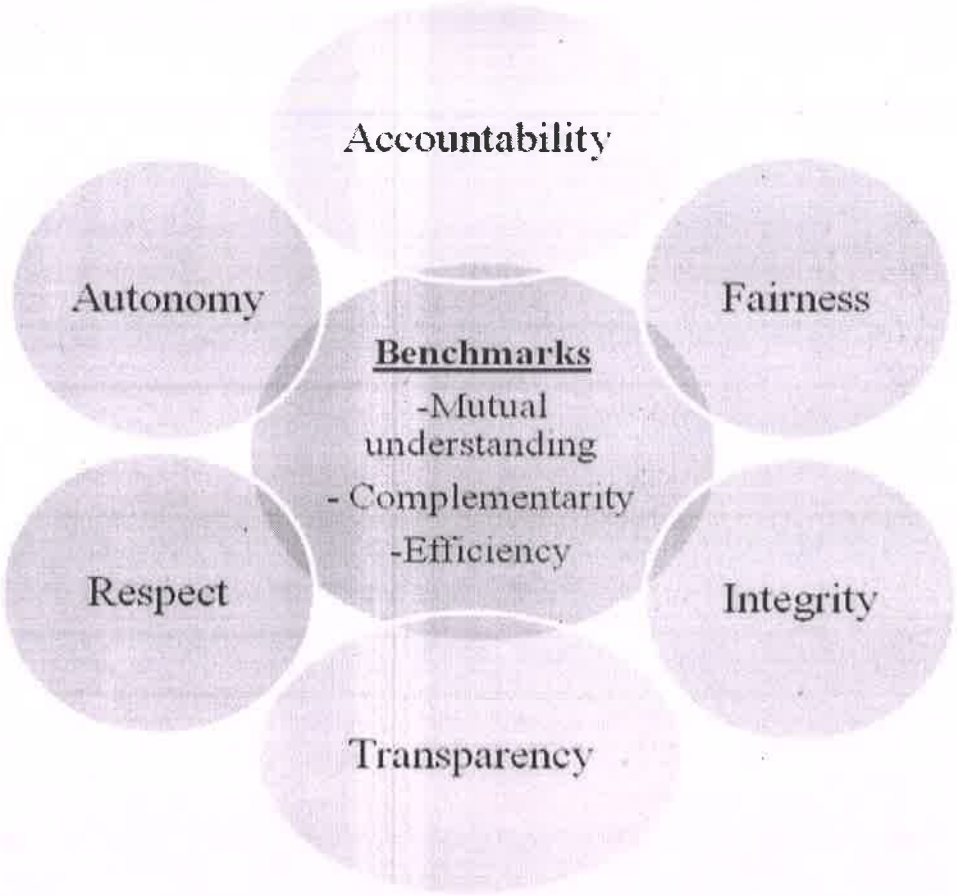
Dr. Sujata V. Patil
Associate Professor in
Dept. of Community Medicine
Krishna Institute of Medical Sciences



1) Respect: The notion of respect implies a special relationship based on acknowledgment, attention, and value

2) Fairness: In the context of stakeholder engagement, fairness refers to the way stakeholders treat and negotiate with each other. The notion of 'fair dealings' emphasizes the honest acknowledgment of one's interests and motivations to ensure that there is no active or passive deception when negotiating with other parties

3) Integrity: In its most general sense, integrity refers to choosing actions that are consistent with one's value system and living up to commitments and promises – on the terms that they were made and with reliability

4) Transparency: t bringing to the open one's interests and motivations in that trial. Transparency requires operating in such a way that it is easy for parties to understand each others' interests; to see what actions are being planned or performed; and to understand the relevant lines of authority and accountability

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5) Accountability: , accountability is often construed as the duty of research teams towards funders to ensure the responsible stewardship of resources and the successful conduct of the project. In the context of stakeholder engagement, the principle of accountability should be understood more broadly as a bidirectional commitment to thinking through the justification for one's actions

6) Autonomy: Autonomy in the context stakeholder engagement describes the stakeholders' privilege both to have input into a proposed research project and to initiate activities that may not be directly supported by trial funders, sponsors, or research teams.

A historical background of the reasons and the importance of GCP were discussed –

1. Increased Ethical Awareness
2. Improved Trial Methods
3. Clinical Trial Concept Better Understood
4. Public/Political Concern over Safety Aspects
5. Frauds and Accidents during Trials
6. Growing Research and Development Costs
7. Increasing Competition
8. Mutual Recognition of Data

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Dr. Sujata V. Patil.
Associate Professor in
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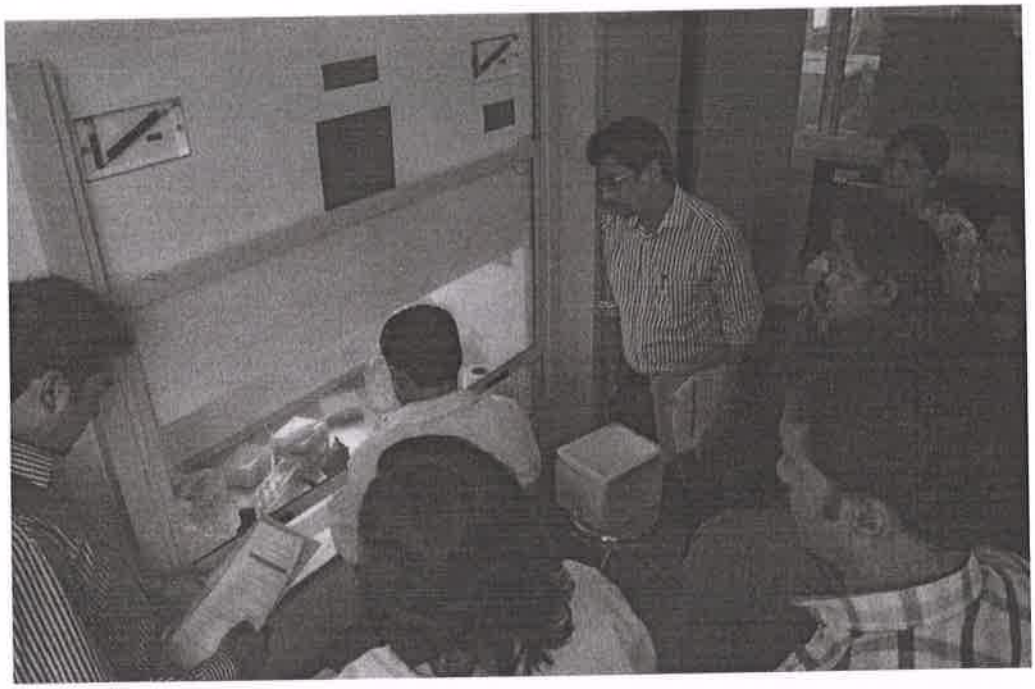
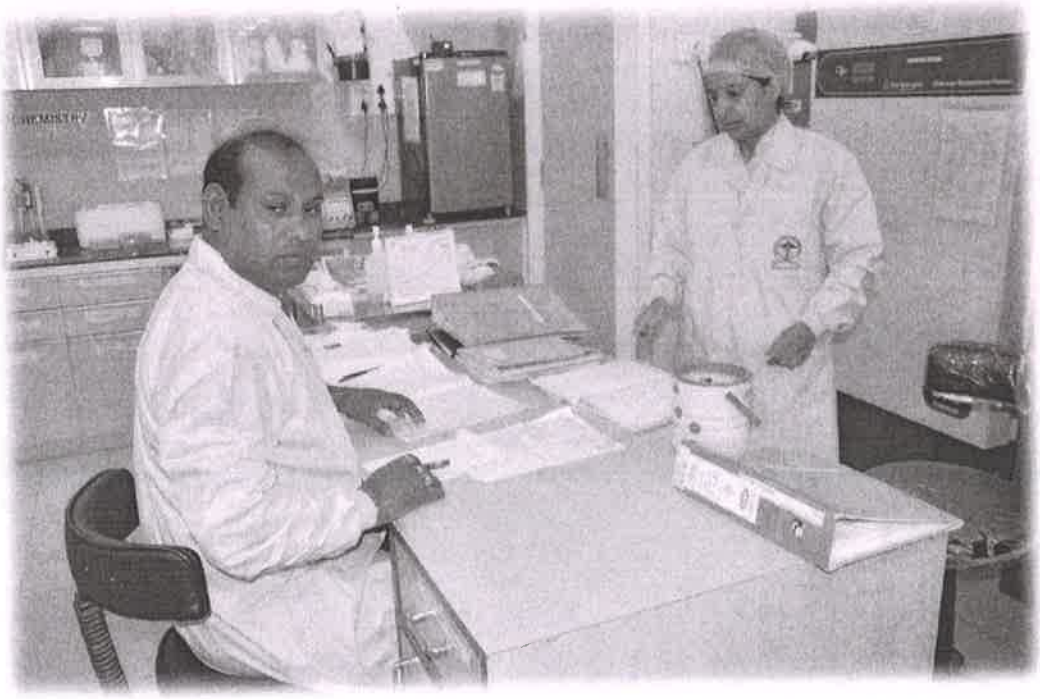
Krishna Institute of Medical Sciences, D.U
KARAD.

GCP Training Workshop on 4th to 5th September 2019



GCP Training on 4th to 5th September 2019



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REPORT OF PROGRAM

Workshop on Research Grant writing

Conducted by:- School of Dental Sciences, KIMS "Deemed to be University", Karad.

Topic: How to write Research Grant

Faculty: - Dr Gyanendra (Associate Professor, Dept. of pedodontics & preventive Dentistry, Maulana Azad Dental College)

Venue: Lecture Hall III, School of Dental Sciences, KIMS "Deemed to be University".

Date: 10:00 a.m – 1.00 pm on 21st November 2019

No. of Participants: - 124

Event plan/ report:

India is a country with huge possibilities in the field of health-related research. Despite the possibilities of different kinds of health-related research and the presence of many health professionals involved in various fields, there is a lag in the scientific publication from those areas. One of the major contributing factors for having no or less publication is due to a lack of proper training, underdeveloped research culture, lack of knowledge of scientific writing such as manuscript writing and grant writing. With this background, a workshop was organized with the national resource person with the aim to improve the present knowledge on scientific writing in health researchers and to build the concept of academic writing to the new researchers.

A total of 124 delegates were present that included undergraduate, postgraduate and staff of School of Dental Sciences, KIMS "Deemed to be University", Karad. The speaker shared his expertise on various important issues related to manuscript writing and grant writing. This session was focused thoroughly on the different components of the research protocol. The research protocol is a science and art of describing intended outcomes, practices, process and procedures of a research study. The resource person deliberated on how components of the research protocol vary depending on the discipline and objectives of the study. Our results showed that most of the participants were satisfied with the venue where the workshop was organized and the topics/contents covered during the workshop.

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Pre and post tests were distributed before and after the session. A positive outcome was achieved with a pre test average score of 38% and post test average score of 94%. An ***Advanced Learning Gain (ALG) of 56%***was achieved. An excellent feedback was achieved from all the beneficiary listeners that attended the workshop

Workshop on Research Grant writing

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Director of Research
KIMSDU, Karad

Dept of Oral and Maxillofacial Surgery
Faculty of Dental Sciences
K.I.M.S.D.U.
Malkapur, Tal. Karad, Dist. Satara
Karad - 415 110

Report of Workshop in Research Methodology 2019

Krishna Institute of Medical Sciences Deemed University, Karad scheduled workshop in research methodology for post graduate students from faculty of Medicine, Nursing, Dental and Physiotherapy and also for Ph. D. students as well as for interested faculty members.

Workshop was conducted as per scheduled programme (Attached time table for the workshop) from 25th Dec 2019. Workshop was conducted for 5 days. Everyday irrespective of lunch break, lecture/discussion session were conducted for 6hrs. The total hours of lectures delivered /discussion were 30 hours.

Total 134 delegates attended the workshop out of that 69 from medical 20 from dental, 14 from physiotherapy, 23 from nursing, 2 Ph. D. students and 06 faculty members .

Workshop began with inaugural programme. In welcome address Dr. Mrs. Supriya Patil explained about the importance of this workshop as well as plan for the same. Dr. A. K. Pratinidhi our former Director of Research was Chief Guest. In her speech stressed upon need of research. Dr. Arun R. Risbud Director of Research explained in detail about the expectations from this workshop Dr. D.K. Agarwal.Add. Director of Research explained in detail about the Role of IPR in research, Copy right, Patent, Subsequently topics covered were need of research study, designs, framing of research question, basic statistics, sample size & statistical software's.

Writing of research proposal was covered on 2nd day of workshop and subsequently group activity for preparation of research protocol was given to five groups (2 - Medical, 1 - Nursing, 1 - Dental, 1 -Physiotherapy) on last day one representative from each group presented the protocol.

All the sessions were interactive, informative and good quality. Topics were covered by resource persons from NARI Pune, other renowned teaching institutes and KIMSDU. Pre-post test, feedback evaluation will be completed within 2 weeks. Maharashtra medical council has given two credit points. Certificates will be given to delegates who have satisfactorily completed the workshop.

I am very much thankful to Dr. Arun Risbud sir for his encouragement, guidance and support. I extend my sincere thanks to all resource persons as well as all staff members from research office KIMSDU, because of their co-operation and help smooth conduction of workshop was possible. I thank Miss. Archana Madam Assist. Registrar for her help in MMC credit points.

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Dr. Supriya. S. Patil

Research Methodology 2019

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Workshop on Research Methodology 2019

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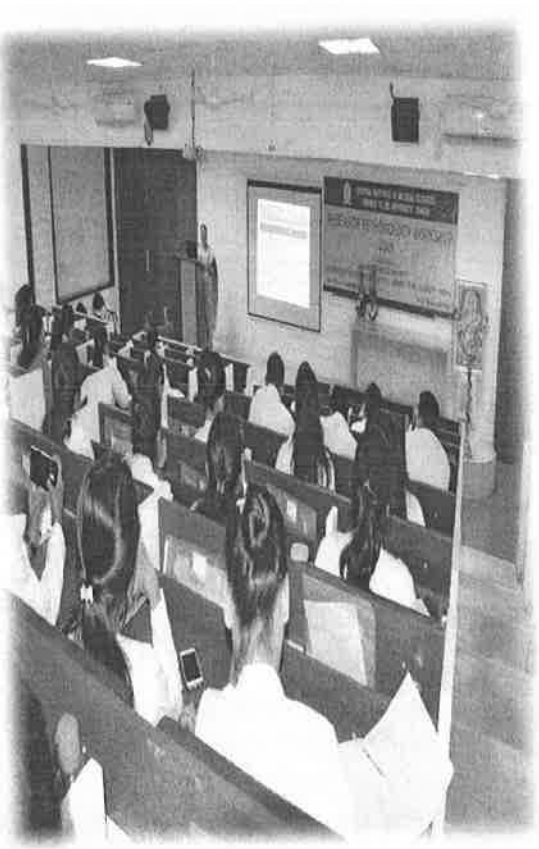
Workshop on Research Methodology 2019



Workshop on Research Methodology 2019

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Report of Workshop of Startup on 8th Jan 2020

One Day Workshop on "Industry Academia Innovation Practices" conducted on 08/01/2020 by Director of Research, KIMSDU under auspices of IQAC. This workshop was organized followed by inauguration programme in the Namaste hall, Annex Building of KIMS. This programme was inaugurated in the auspicious hands of Honorable Chancellor Dr. Suresh J. Bhosale, Honorable Vice Chancellor Dr. Neelima Malik, Registrar Dr. M. V. Ghorpade and their august presence of Additional Director of Research, Mr. Sachin Kumbhoje and Deans of constituent colleges, KIMSDU, Karad.

One hundred and thirteen participants who were faculties and students from constituent colleges have attended in the workshop. Mr. Sachin Kumbhoje has delivered several talks on various topics like how to establish ENRICH StartUp Centre as per AICTE recommendations, to support Innovation & Incubation activities in this Centre, to promote EDC activities under this cell, to arrange interaction with entrepreneurs and create a mentorship scheme for student entrepreneurs, to establish Expert Panel Board & Advisory Board for the Centre, to raise the funds to run the StartUp Centre efficiently, to execute training programs, workshops, events for the Students under StartUp Centre, mentoring and handholding Support to early age StartUp's, to provide funding assistance to StartUp's generated from Centre, Idea Generation to Market Launch, all 6 stage mentoring will be done by us to the StartUp's generated at this StartUp Centre, to design Curriculum Course of 'StartUp: Launching & Sustaining' with the help of Industry-Government-Academic Linkages (StartUp Stream as one of the specialisation, Stated as per policy), to run Business Idea Lab in the Centre and to guide and assist prospective entrepreneurs on various aspects such as preparing project reports, obtaining project approvals, loans and facilities from agencies of support system, information on technologies, etc. Mr. Vishal Daddikar has explained well Pain-points in Healthcare Sector for Idea generation and Mr. Manish Patil has given novel idea on Technology Commercialization for Medical Devices.

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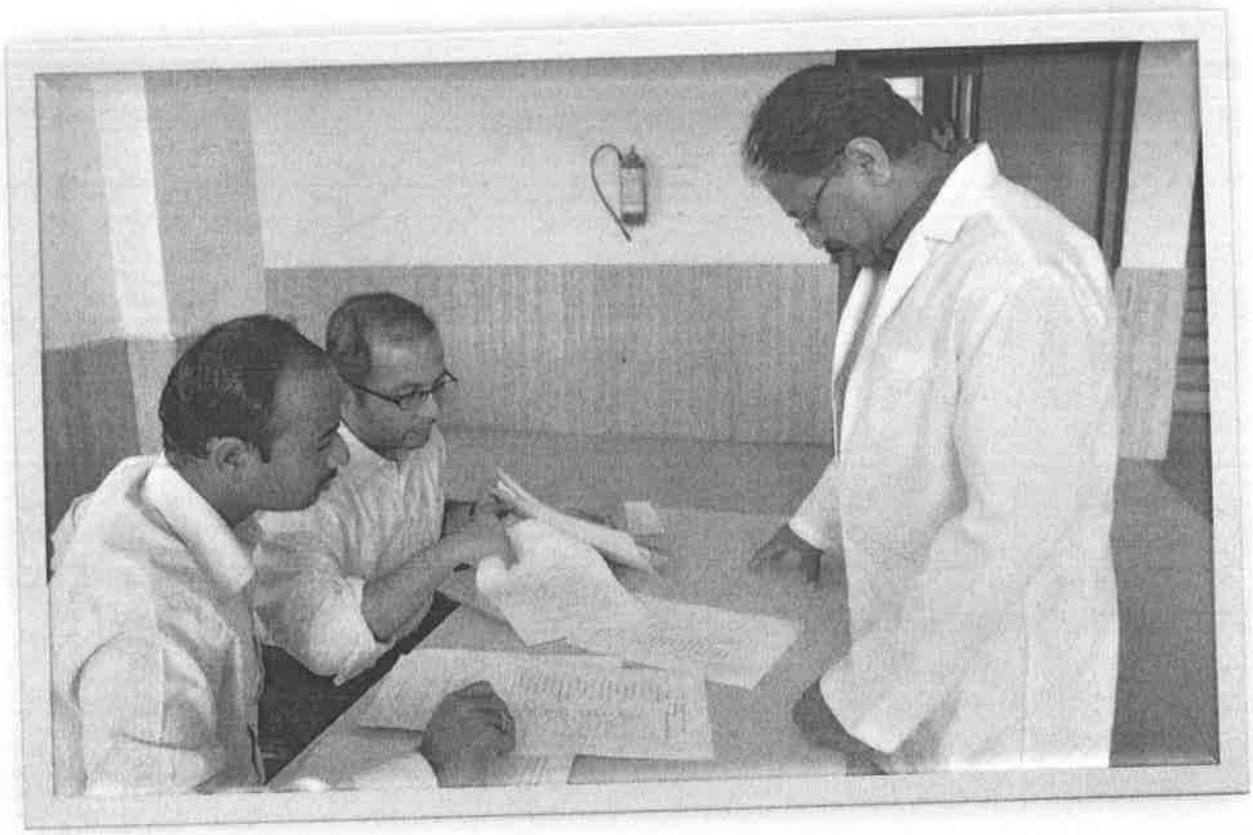
Workshop on Startup 8th Jan 2020



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Inogration of Workshop on Startup 8th Jan 2020

Industry Academia Innovation Practices

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Workshop of Startup on 8th Jan 2020

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Workshop on Startup 8th Jan 2020

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REPORT

Workshop on Research Grant writing

Conducted by: School Of Dental Sciences, KIMSDU, Karad

Objective: To guide the post graduate students and staff of SDS for writing of research Grant.

Faculty: Dr. Sunali Khanna (President Asian Academy of Oral & Maxillofacial Radiology, Vice President Indian Academy Of Oral & Maxillofacial Radiology, Professor at Nair Hospital Dental College)

Venue: Lecture Hall No. 3

Date & Timing: 16thjanuary 2020,10-1.00 PM

No. of Participants: 120

Event plan/report (Workshop Report):

The participants were under-graduate, post-graduate students and teaching staff of School of Dental Sciences. The workshop was conducted in the Lecture hall 3, School of Dental Sciences, KIMSDU, Karad. The workshop was inaugurated with lamp lightning by Hon'ble Vice Chancellor, Dean of SDS Dr Shashikiran N.D and guest speakers. The speaker for the topic was Dr. Sunali khanna. This workshop highlighted the important aspects of research proposals and how to write grants. In the morning session, Dr. Sunali Khanna delivered a keynote lecture on "Why research proposals are rejected". The resource person in this session provided insight into the different reasons for rejection of a research proposal during grant application. She explained that a research proposal is a document that informs others the proposed piece of research. Unsuitability and poorly designed proposals were described as the primary reasons for the rejection of the research proposal.

In the afternoon session, mini workshop was conducted on "How to write Grant". This session was made interactive by providing a redacted part of the article to all the participants. The preparatory time was provided to the participants followed by interacting with them to construct the possible general and specific objectives of

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KIMSDU, Karad

the study. The comparison was done between the suggested objectives and the authors' objectives mentioned in the study. The speaker discussed the possible methodology for the project based on the suggested objectives of the study. All participants were given a Pre Test and a Post Test questionnaire. The absolute learning gain from the Test was 64.2%.

The valedictory ceremony commenced in the lecture hall 3 with Dr. Kamala K. A delivering the vote of thanks and presenting Dr. Sunali Khanna with a memento as a token of gratitude.

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Director of Research
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Department of Oral and Maxillofacial Surgery
Faculty of Dental Sciences
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Report of Workshop of IPR on 1st Feb 2020

One Day Workshop on "**Workshop on IPR activities & skill to write the patent & related components**" conducted on 01/02/2020 by Intellectual Property Rights (IPR) Cell. This workshop was organized followed by inauguration programme in the N3 hall, Annex Building of KIMS. This programme was inaugurated in the auspicious hands of Honorable Registrar Dr. M. V. Ghorpade and by their august presence of Additional Director of Research Dr. D. K. Agarwal, Dr. Kumari Lipi, Dr. Madhuranjan Vatsa and Dean, Faculty of Allied Sciences, KIMSDU, Karad.

One hundred and fifty participants who were faculties and students from constituent colleges have attended in the workshop. Dr. Kumari Lipi and Dr. Madhuranjan Vatsa were invited as resource persons from IPRSRG, Greater Noida. Dr. Madhuranjan Vatsa has talked on theses and research article write-up during workshop. Dr. Kumari Lipi has delivered several talks on patent. Her topics covered in the workshop were: Filing patent procedure, patent prosecution, copyright, design and trademark applications. In order to make successful patent application, PCT application is useful to speed up the patent examination. Patent filing procedure, Patent process flowchart, difference between applicant and inventor, request for examination, early publication, procedure after examination, concept of provisional and complete specifications, structure of complete specification and its all components, patent drafting: abstract, description, drawings presentation, claims and write-up. International agreements, treaties, conventions, types of patent applications and other important things were explained well.

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Workshop on IPR activities & skill to write the patent & related components

Workshop on IPR activities

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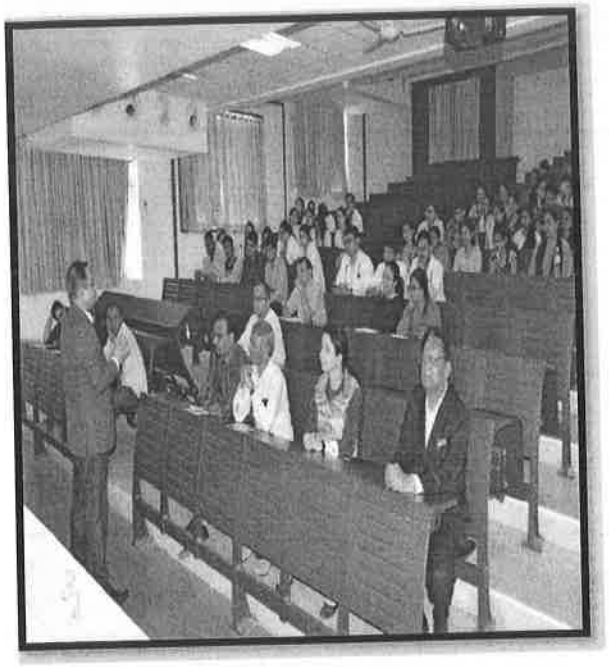
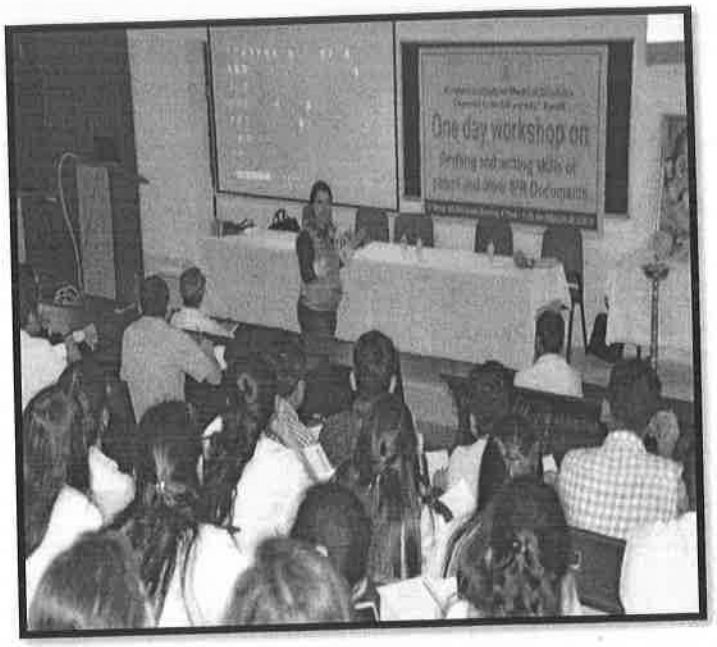
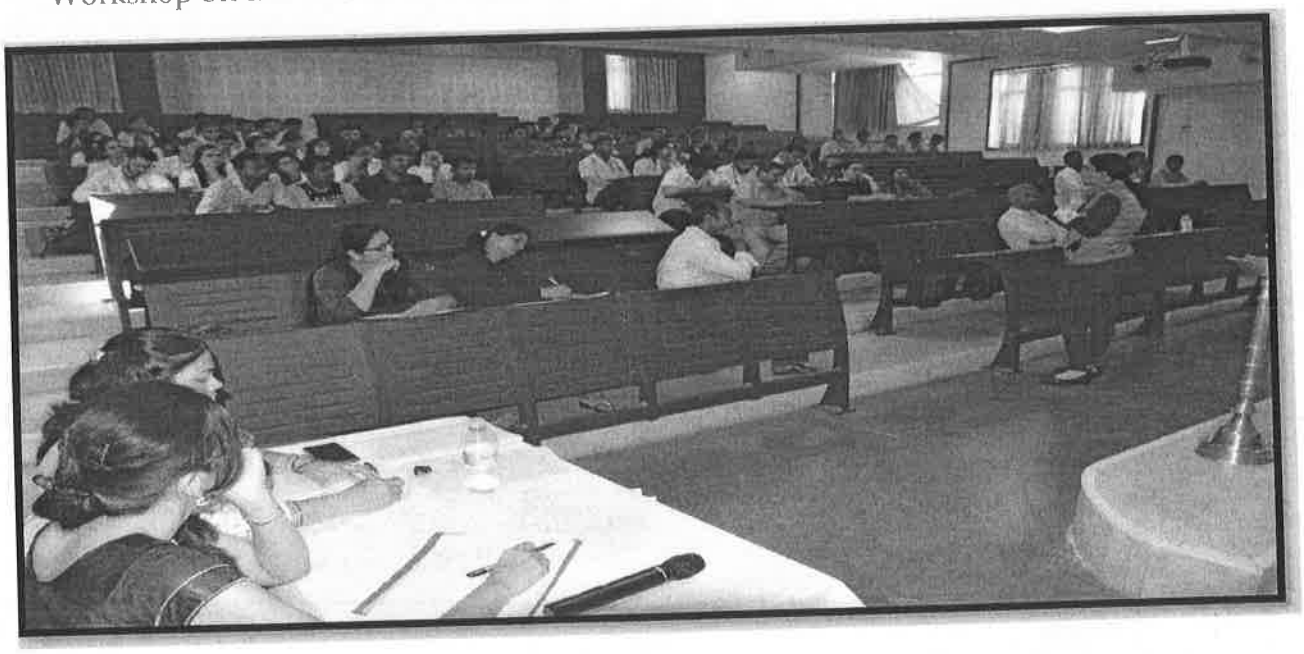




Workshop on IPR activities & skill to write the patent & related components



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GCP Training Workshop, 15th to 16th September 2020

An online meeting consisting of 35 participants was conducted on 15th and 16th September 2020 a by KIMS Deemed to be University, Karad.

Partnering organizations and Institutes

2) National AIDS Research Institute (NARI), Pune

Following were the speakers at the workshop

- Dr. Kishor Kumar is Post Doctorate in Statistics and a senior clinical research professional with more 30 years of experience in drug development. Has been instrumental in developing the analysis and reporting services in Biotech, Pharma, CRO and leading Academic & Research Institutions (ICMR, WHO, IAVI). In his last role as the practice leader in Cognizant, he developed the team to be one of the largest team in biostatistics and programming globally (as a Full Service Outsourcing model).
  He is well-versed in applications of advanced biostatistical techniques for multi-phase, multi-therapeutic clinical trials including Adaptive Trials, Pharmaco-epidemiology studies. He is a visiting faculty and examiner to leading institutes and invited speaker at many national and international conferences. He was also actively involved in multiple data standards consortium.

- Dr Sanjay Mehendale is Director Research at PD Hinduja Hospital and Medical Research Center Mumbai, India since June 2018. He was Additional Director General and Scientist H at Indian Council of Medical Research (ICMR), New Delhi Area, India from Sep 2016 – Feb 2018. He served as Director and Scientist G at National Institute of Epidemiology [NIE, ICMR], Chennai from Dec 2010 – Oct 2016. He has completed his MBBS, MD from B. J. Medical College in the year 1983.

- Dr Sheela Godbole is Scientist F & Head of Division at Indian Council of Medical Research at ICMR-National AIDS Research Institute, Pune since 2017. She held various positions of Scientist E & Head from 2012 to 2017; Scientist D 2008 to 2012; Senior Research Officer 2006 to 1 2008; Research Officer 2001 to 2006; Lady Medical Officer (Part-Time) at ICMR-NARI, Project- Acute Pathogenesis of HIV Infection from 1999 to 2001. She worked as consultant Dermatologist from 1993-2001 and was Hon. Consultant in Skin & STDs at Deendayal Memorial Cancer Hospital, Pune from 1993-1998.

- Suhas Shewale received her MPH from the University of Pune. Her dissertation focused on establishing a community-based network to develop an early detection and response system for disease outbreaks in urban India. Since completing her MPH, she has worked in remote rural areas of India where lack of access to healthcare is prominent. She is currently pursuing her PhD at the National AIDS Research Institute. Her research interests lie in understanding the determinants of access to health care services in rural India and other resource-limited settings.

Lectures were organized on guidelines for good clinical practice, responsibilities of IRB, IEC. Their composition, Functions and Operations

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Also a lecture on the role of investigator, Sponser was included

Clinical trial protocol and protocol amendment was discussed in one lecture

A lecture on Essential documents for the conduct of trial was also included

Second day topics related to Confidentiality, Audit and Finance, record keeping were included

There were total 25 participants

Topics were discussed in and participants were asked to opine and queries were answered

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Dr. Sujata V. Patil
Associate Professor in
Dept. of Community Medicine
Krishna Institute of Medical Sciences, D.U.
KARAD.

National E Workshop on Research Methodology for Nurses

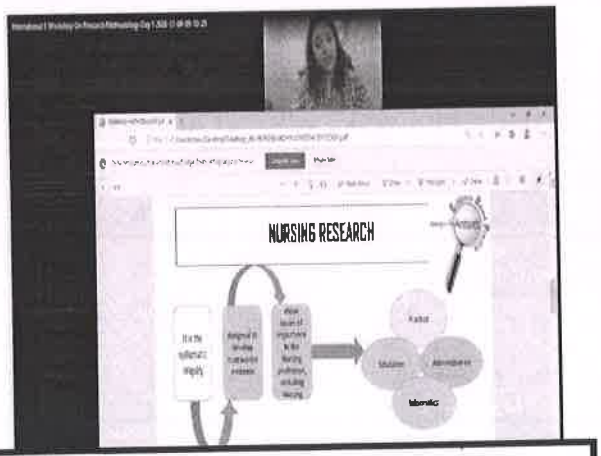
Date: 4th, 5th & 6th November 2020

National E Workshop on Research Methodology for Nurses organized by Krishna Institute of Nursing Sciences, Karad. Workshop was organized under the guidance of DR. Viashali R. Mohite (Workshop-chairperson) and DR. Mahadeo Shinde (Workshop-Coordinator).

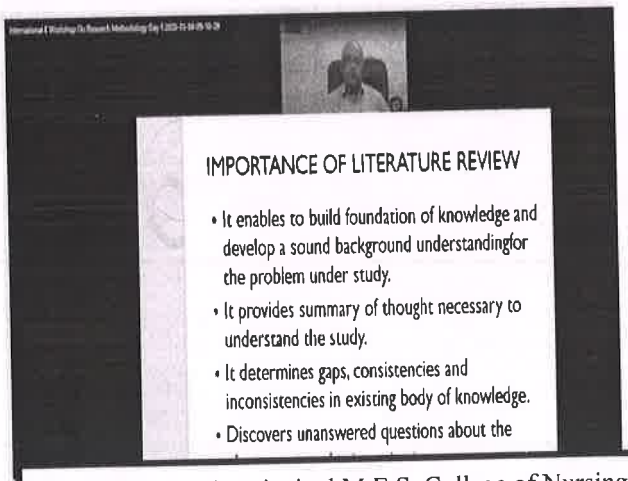
Workshop was designed to enable Participants to develop an understanding of basic concepts of research, research process and statistics. It is further, structured to conduct/ participate in need-based research studies in various settings and utilize the research findings to provide quality nursing care.

Total 810 Participants have registered for the National E Workshop on Research Methodology for Nurses and Pretest link was given to all the registered participants.

At 9:00am Inauguration programme has started, Inaugural address was given by Dr. D.K. Agarwal, Add. Director of Research, KIMSDU, Karad. After the Inaugural address, the first session was taken by Ms Rachal George, I/C. Registrar, Maharashtra Nursing Council (Mumbai) on Introduction: Scope and Significance in Nursing Research. The next Session on Research Process was delivered by DR. Shabana Anjum, Principal, Jabalpur Institute of Health Science, Jabalpur, Madhyapradesh. At 10:45-11:30am DR. Reeta Lakhani, Principal, College of Nursing, D.Y. Patil University, Nerul, Navi Mumbai has delivered the session the topic was Research Problem/Question. The next session taken by Prof. Milind Kale Principal M.E.S. College of Nursing Lote, Parshuram on Review of Literature. The last session of the first day was taken by Dr. Supriya Patil, Dean Academics, Faculty of Medical Sciences KIMSDU, Karad. Research Approaches and Designs: Quantitative Research.



Rachal George, I/C. Registrar, Maharashtra Nursing Council (Mumbai) delivered the Session on Introduction: Scope and Significance



Prof. Milind Kale Principal M.E.S. College of Nursing delivered the session on Review of Literature.

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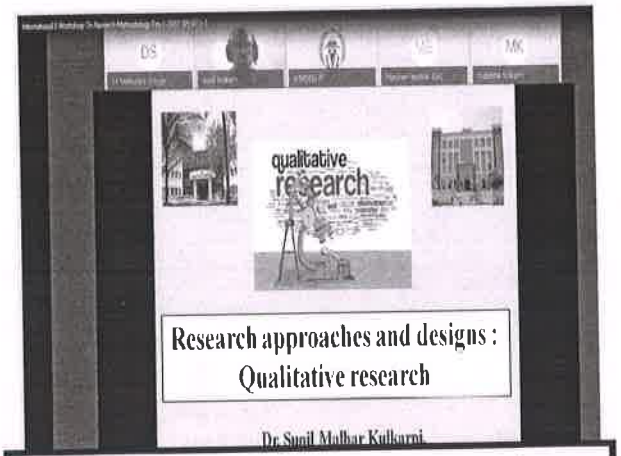
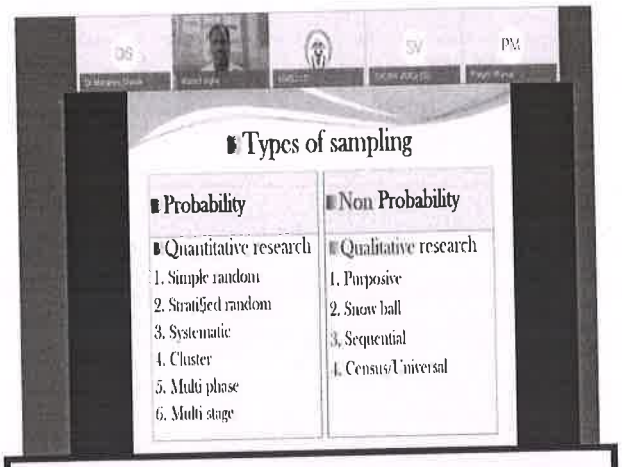
Day-2, 5th November 2020

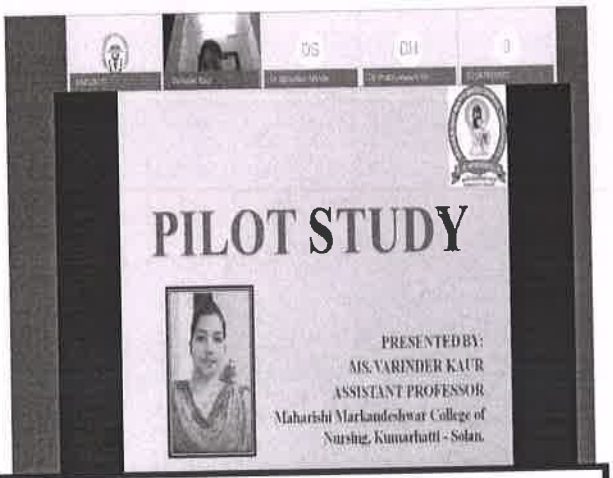
Second day of National E Workshop on Research Methodology for Nurses was started at 9:00am the first session was delivered by DR. Sunil.M. Kulkarni, Prof. College of Nursing. Bharati Vidyapeeth University, Pune on Research Approaches and Designs: Qualitative Research. The second session was taken by DR.T. Shivbalan, Principal, College of Nursing Pravara Institute of Medical Sciences University, Loni on the topic Sampling and Sampling techniques. Next session on Introduction to statistics was delivered by Ms. Trupti Bhosale, Statistician, KIMSDU, Karad and the last session of the day on Pilot study was taken by Ms. Varinder Kaur, Ass. Prof. MMCONMM University, Solan.



DR. Sunil.M. Kulkarni, Prof. College of Nursing. Bharati Vidyapeeth University, delivered the Session on Qualitative Research



DR.T. Shivbalan, Principal, College of Nursing Pravara Institute of Medical Sciences University, Loni on the topic Sampling and Sampling



Ms. Varinder Kaur, Ass. Prof. MMCONMM University, Solan. delivered the Session on Pilot study.

Mrs. Manish C. Gholap Asso. Professor, KINS, Karad While moderating the Workshop.

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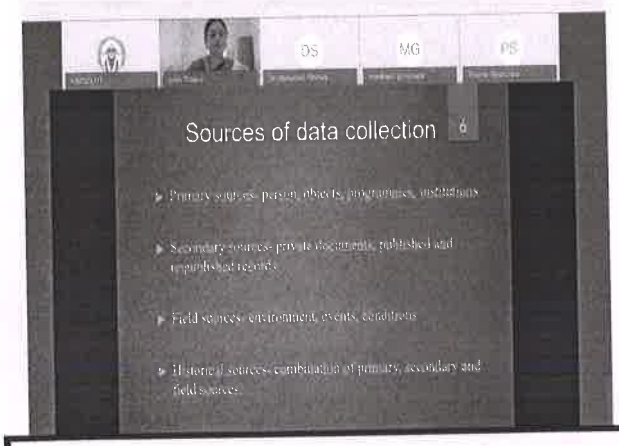
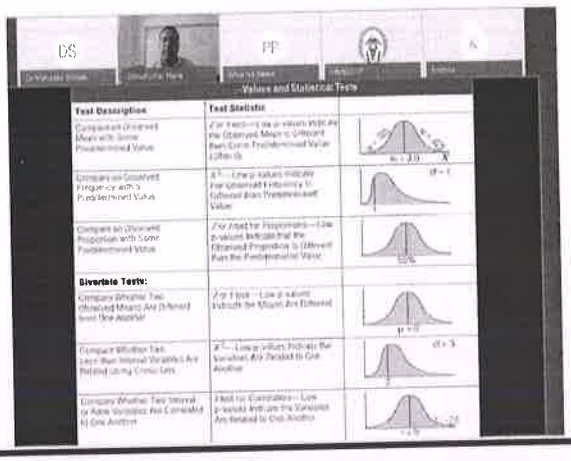
KIMSDU, Karad

Day-3, 6th November 2020

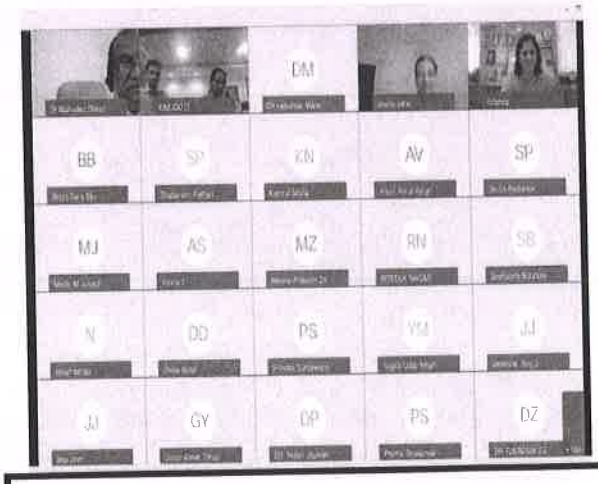
Second day of National E Workshop on Research Methodology for Nurses was started at 9:00am the first session was delivered by Dr Mrs. Jyoti R Thakur, Principal, Gokhale Education Society's Sir Dr. M. S. Gosavi Institute of Nursing Education, Training and Research, Nashik. Dr Mrs. Jyoti R Thakur has taken the topic Methods of data collection. Next session on Analysis of data was taken by Mr. Dhiraj Mane, Statistician, KIMSDU, Karad. The next session was taken by DR. Sneha Pitre Ass. Prof. RAKMHSU College of Nursing, RAS KHAIMAH, UAE. On Communication and utilization of Research. The Next session on Good Academic Research Practices delivered by DR. Vaishali R. Mohite, Dean, Krishna Institute of Nursing Sciences, Karad and the last session of the day on Statistical Packages and its application was delivered by Mr. Mahendra Alate Statistician, KIMSDU, Karad.



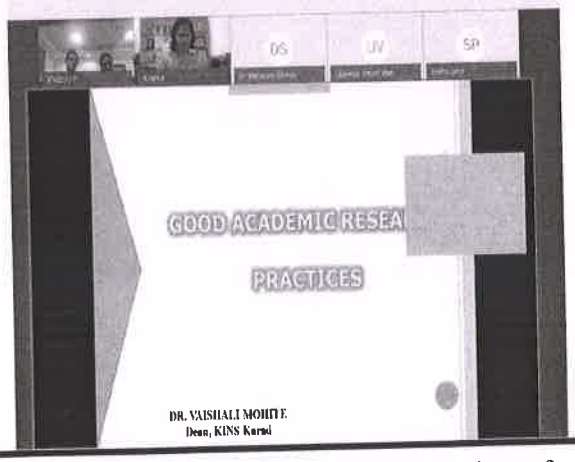
Dr Mrs. Jyoti R Thakur delivered the Session on Methods of data collection



Mr. Dhiraj Mane, Statistician, KIMSDU, Karad delivered the Session on Analysis of data



DR. Sneha Pitre, DR. Vaishali R. Mohite and DR. Mahadeo Shinde while Discussion during the Workshop



DR. Vaishali R. Mohite, Dean, Krishna Institute of Nursing Sciences, Karad delivered the Session on Good Academic Research Practices.

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Director of Research
KIMSDU, Karad

Delegates have given the feedback about Research Methodology workshop, they were happy as they got excellence guidance from experts and then workshop ended with vote of thanks given by Mrs. Swati Ingale, Clinical Instructor, KINS, Karad.

The posttest and feedback link was given to the all the registered participants and after the completion of posttest and feedback E Certificates was awarded to the participants.

Dr. A. R. Risbud
Director of Research
KIMSDU, Karad

Dean
Krishna Institute of Nursing Sciences,
KIMSDU, Karad

Workshop on Good Clinical Practice

Conducted by Department: Department of Paedodontics and Preventive Dentistry. School of Dental Sciences, KIMSDU, Karad

Date and Timing: 4th November, 2020 at 10:00 am

Guest speaker- Dr. Saraswati Naik, Professor, Department of Paedodontics, Bapuji Dental College, Davangere.

Topic: Good Clinical Practice

Objectives: 1.To Aid dental professionals in clinical decision making

2. To optimize patient care

No. of participants: 150(including undergraduate& postgraduate students and staff)

Event plan/report:

A CDE program was conducted by Department of Paedodontics and Preventive dentistry, SDS KIMSDU, Karad on 4th November 2020 on Good Clinical Practice. Lecture was delivered by Dr.SaraswatiNaik, Professor, Department of Paedodontics, Bapuji Dental College, Davangere.

Dr.ShreyaBapat., 3rd year post graduate student of Department of Paedodontics and Preventive Dentistry, welcomed the guests and the audience. Following this, the speaker was introduced by Dr. Swapnil Taur and was felicitated by our principal sir, Dr. Shashikiran N.D. with floral bouquet.

This was followed by an elucidative lecture by Dr.SaraswatiNaik, in which she enlightened us with skills toaid dental professionals in clinical decision making and help incorporate evidence gained through scientific investigation into patient care. Guidelines include recommendation statements intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. After the productive lecture, Dr.Saraswati was honoured with momento and certificate of appreciation by Dr. Shashikiran N.D.To conclude the program, vote of thanks was given by Dr.Savita Hadakar.

Add. Director of Research
KIMSDU, Karad

Workshop on Good Clinical Practice

PRE AND POST TEST RESULTS:

Advanced learning gain (ALG) as per formula=

No. of participants attended pre and post test= 150

Mean of pre test score=$\frac{545}{150} = 3.63$

Mean of post test score=$\frac{1682}{150} = 11.21$

Total score=$\frac{mean\ of\ post\ test - mean\ of\ pre\ test}{no.of\ questions - mean\ of\ pre\ test} * 100$

$=\frac{11.21-3.63}{15-3.63} * 100$

=66.66%

Add. Director of Research
KIMSDU, Karad

To,
Director of Research

KRISHNA INSTITUTE OF MEDICAL SCIENCES "DEEMED TO BE UNIVERSITY"

KRISHNA INSTITUTE OF NURSING SCIENCES, Karad.

REPORT

"Workshop on Research Grant writing"

SPEAKER : Dr. Sudha Reddy

VENUE: Lecture Hall

DATE: 15/10/2018 **TIME:** 10.30 am to 1.00pm.

ORGANIZERS: Faculty of Nursing, KIMSDU, Karad

DELEGATES Participated: 120.

Faculty of Nursing organized a workshop program on "Research Grant writing" for health care professionals and students of KIMSDU Karad. At 9:00am Inauguration programme has started, Inaugural address was given by Dr. D.K. Agarwal, Add. Director of Research, KIMSDU, Karad. After the Inaugural address, the session was started which is taken by Dr. Sudha Reddy Principal, KLE Institute Belgaum, Madam has explained about research grant writing in very simple but effective way. After the lecture she answered the queries related to the topic.

Second session primarily focused on importance of methodology planning in research writing. The lecture also clarified the seriousness of plagiarism in medical research and how it can be avoided during grant and article writing. The resource person elaborated about the strategies that can be used for avoiding the plagiarism – explaining about the importance of paraphrasing, using a quote for direct sentence citing appropriately, and use of available plagiarism checker software.

Delegates have given the feedback about Research Grant writing workshop, they were happy as they got excellence guidance from experts and then workshop ended with vote of thanks given by Mrs. Swati Ingale, Clinical Instructor, KINS, Karad.

Dr. A. R. Risbud
Director of Research
KIMSDU, Karad

Pre-Test & Post Test Results

Before and after the lecture, Pre-test & Post-test was conducted respectively.

The Pre-Test score : 37%

The Post-Test score: 85%

Absolute Learning Gain= Post Test- Pre Test/ 100%- Pre Test

= 85-37/ 100-37= 48/63

= 76.19%.

Dr. A. R. Risbud
Director of Research
KIMSDU, Karad

Dr. (Mrs.) Vaishali R. Mohite

Dean

Krishna Institute of Nursing Sciences, Karad.

DR.(Mrs.) V. R. Mohite
M.Sc.(N) Ph.D. D.Litt.
Dean / Principal
Krishna Institute of Nursing Sciences
Krishna Institute of Medical Sciences
"Deemed To Be University", Karad