Research Promotion and Operation Policies

KRISHNA INSTITUTE OF MEDICAL SCIENCES
"DEEMED UNIVERSITY", KARAD

Research Promotion and Operation Policies

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From the Desk of Vice-Chancellor

Higher education system in health sciences is witnessing a sea of change in the current times. The old 'Teacher centric' knowledge imparting methodology is being replaced by 'Learner centric ideology. In these changing times, the entire education system is revolving around technology and innovation in which Research is the buzz word. To stay afloat, we need to honor more than ever the famous dictum, 'Publish or Perish'

Krishna Institute of Medical sciences Deemed University is one of the vibrant institutes. However, to strongly promote research at the campus, we need to develop a team of trained, committed and enthusiastic faculty and researchers who could instill adequate research interest among the learners at all levels. An initiative in that direction has been taken up a few years back and now is the time to strengthen it further.

Directorate of Research at the university has identified multiple research promotional avenues and has taken steps to streamline the entire assembly line to facilitate smooth conduct of research to culminate in to quality research publications and intellectual property benefitting both, the individual researcher and the university as a whole.

Let us coin and respect a new phrase, '**Research or Regress'**

I hope that this treatise will be useful for one and all and is able to generate adequate research interest in the young budding minds of the learners to contribute towards research and innovation

Dr. (Mrs.) Neelima Malik
Vice- Chancellor

Preface

Research is an integral part of any academic institution or the university. Apart from assuring high standards of academic teaching, Institute of Medical Sciences Deemed University accords primacy to in-house research conducted by its staff and students. The university has created an enabling environment for the conduct of on and off campus research. While, adequate and appropriate infrastructure that includes high end laboratories has been instituted, several avenues have been established in order to promote high quality research. The junior and senior faculty is encouraged by adequately addressing research impediments. In addition to substantial monetary support, the researchers are assured of technical guidance through a dedicated unit in the form of Research Directorate. All efforts are made to inculcate research culture among the postgraduate and undergraduate learners. In order to ensure smooth research operations, a number of policies have been developed which are described in the treatise that follows.

Director of Research

KIMSDU, Karad

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Research Promotion

Research promotion among the staff and students is aggressively pursued at the university by adopting following activities.

- Substantial **Annual budgetary provision** is made by the university to facilitate Research at the campus
- Provision for financial support for research Studies in the form of seed money has been made
- Availability of a dedicated department, **Directorate of Research** through which technical guidance and statistical support is provided to the researchers
- In order to train researchers on appropriate methods for undertaking research, a R**esearch Methodology certificate course** is annually conducted for the new post graduate students
- To ensure quality research, **multiple scrutiny** of all research proposals is undertaken involving in-house and external subject experts
- Adherence to Ethics Principles is ensured by mandatory screening of all human research proposals by the **Institutional Ethics Committee**
- Research work of the PhD and post graduate students is **periodically monitored** to ensure quality research
- Manuscript Review Services are provided to the researchers to bring out **quality publications**
- Researchers are encouraged to publish in the **indexed journals.** Provision for expenditure for such publications is made and the efforts are appreciated by providing monetary incentive

- Researchers are encouraged to apply and obtain **extramural funds**
- The students and staff are encouraged to organize and participate in scientific activities like **Conferences, Workshops, CMEs** with a provision of monetary support
- Staff is encouraged to write **books/monographs.** Provision for expenditure for such publications is made and the efforts are appreciated by providing monetary incentive
- Staff and learners are encouraged and guidance is provided to apply for **patents, patent design, and copy right.** Provision for expenditure for such applications is made and the efforts are appreciated by providing monetary incentive
- The University publishes quarterly Journal (JKIMSU) in which, a limited number of good in-house publications are accommodated
- A large (1125 bedded) **multi- specialty hospital** makes it easy for the researchers to enroll adequate number of participants in their studies and also provides ample research material.
- Latest and **high end diagnostic facilities** in the form of Microbiology, Pathology, Biochemistry laboratories are available at the clinical departments of the hospital for the study participants.
- Following **specialized laboratories** are established to help researchers to carry out technically demanding assays for research purpose

  Molecular Biology & Genetics,

  Lead Referral Laboratory

  Virology laboratories
- Linkages with reputed research institutes (national & international) are developed through which the researchers are encouraged to undertake collaborative research studies and to apply for funds from other funding organizations

- Expertise from these institutes is made available for training, design and conduct of research studies

General Considerations

Research undertaken under the aegis of Krishna Institute of Medical Sciences Deemed University will be governed by following general considerations.

1. All research studies conducted will mandatorily require Institutional Ethics Committee (IEC) / Institutional Animal Ethics Committee (IAEC) approval which has been constituted as per the guide line of Indian Council of Medical Research (ICMR) & The Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA). Dean of faculties will submit a list of proposals, ready for IEC approval, to the Directorate of research on the First of every month. Depending on the lists such received, Research Directorate will schedule IEC meeting and the dates will be communicated to each of the faculties in a week's time.

2. All research proposals will be reviewed and approved by the Protocol review committee before submission to the IEC. Individual faculties except KIMS (SDS, KINS, KIP, Allied Sciences) will arrange for in-house protocol review meetings. Faculties will invite 1-2 external experts for this purpose. KIMS proposals will be reviewed by the protocol review committee established at KIMS in consultation with the Directorate of Research.

3. All faculties will strive hard to ensure good quality proposals of their own as well as of their students. Good proposals will facilitate research publication in good quality journals.

4. It may be noted that as per the UGC guidelines, original papers published in journals indexed in Scopus, Pub Med, Web of Science and Indian Citation Index only will be considered for accreditation by the regulatory bodies (NAAC, UGC)

5. Postgraduate students should be encouraged to publish their Dissertation work as a first author and in time (Before they are passed out of their respective examinations).

6. KIMSDU strongly discourages plagiarism and such cases will be subjected to a strict disciplinary action as recommended by the UGC.

7. Researchers should refer to the list of subject-wise journals uploaded on the UGC website before deciding the journal for publication of their papers (https://wwwugc.ac.in/journallist/)

8. If the existing staff decides to publish Dissertation work of a student who has passed out and left, such publications should be undertaken only on prior (before preparation of Manuscript) approval of the Research Directorate.

9. Each department should send quarterly data (in detail) of departmental research related (NAAC Criteria III) work along with supporting documents (e.g. for publication- a copy of published

paper) to the Directorate of Research at the end of each quarter as per the template provided.

Investigators' guidelines for Ethics Committee approval of the Research Study

All research studies undertaken under the aegis of Krishna Institute of Medical Sciences Deemed University" will mandatorily require Institutional Ethics Committee approval and / or Institutional Animal Ethics Committee approval as the case may be

- **Responsibilities of the Principal Investigator :**
  1. The protocol soft copy & hard copy (as per the format shown in Annexure I A/ I B/ I C) should be submitted to the Research Directorate, KIMSDU in the stipulated time limit given by IEC, prior to the scheduled date of meeting.
  2. The Principal investigator / Co-investigator should present the research protocol in the IEC meeting.
  3. The concerned guides are expected to be well versed with the proposal and should remain present during the protocol review
  4. The PPT presentation should have following slides.
     - **i.** Title of study
       Name of PI
     - **ii.** Introduction in brief (Do not show review of literature)

iii. Need for the study and Novelty

iv. Aim & objectives

v. Materials and methods (type of study, duration of study, study groups, sample size, randomization, Inclusion & exclusion criteria, describe intervention, Investigations etc.

vi. Questionnaire / CRF

vii. Patient information sheet

viii. Informed consent form & Assent form if applicable, in english and also a translated version

5. The PI should be aware that cost of extra investigations should not be borne by the participant. PI should be ready with calculation of total expenditure of required investigations at the time of IEC meeting. He/she should be able to explain the source of fund to meet with the estimated expenditure.

6. The PI should submit the corrected protocol and other documents (as per suggestions given by IEC) in a week's time.

7. The PI should note that IEC certificate is an important document and may be required at the time of thesis submission/Publication. Kindly note that duplicate certificate will not be issued again by IEC

8. The PI should notify any change or deviation in already approved protocol to IEC and get it approved again before implementing it

9. Kindly note that, whether informed consent is required or not, in a particular study will be decided only by the IEC. The protocols of questionnaire based studies also need to be reviewed by the IEC.

10. The actual research work (data collection) can be started only after the protocol is cleared by the IEC.

- **Documents to be submitted to IEC for getting clearance of Ethics Committee for any research protocol :**

  1. Complete research protocol in proper format as per the template - Soft copy & 5 hard copies

  2. Patient information sheet as per the template (Annexure II)

  3. Patient Informed Consent Form and Assent as per the template (Annexure III & IV)

  4. Questionnaires / case record forms if applicable

  5. Any other document asked by the IEC

  Following templates of EC documents are enclosed :

  1. A template of research study proposal write up (Separate for staff, UG/PG student and PhD student)

  2. A template of consent Form

  3. A template of Assent Form *(Assent of the adolescent participants is mandatory in addition to Parent consent)*

  4. A template of Patient Information Sheet

- **Brief on the EC functioning :**

  Submissions:

  Submit in time the study proposal to the Directorate of Research for EC committee review.

Ensure following before submission:

1. The study proposal is modified as per suggestions/comments of the Protocol approval Committee **(HOD / Guide to verify & endorse that the proposal is appropriately modified)**
2. The letter accompanying or the end page of the proposal bears signatures of the student/investigator, Guide and the HOD
3. The patient information sheet & the consent, assent forms are prepared as per the template and are enclosed.
4. The tool (questionnaire) to be used in the study is enclosed
5. That the title of the study as approved by the IEC and your name is verified for correctness **(Title & name of the investigator will appear on the certificate issued)**

Presentation in the EC meeting :

1. Bring at least 6 copies of your study proposal for distribution among the EC members
2. A brief presentation on Title, Aim & Objectives, Material & methods, Consent form, Assent form, Study Tool etc. be made using PPT slides.
3. A slide showing ethics issues in the study and how you plan to address them will be appreciated
4. Load your presentation on the computer before the start of the meeting. Students from one department should make one folder for all presentations of that department
5. One final copy of the proposal will be kept by the EC secretariat for official purpose.

6. Confirm correctness of the title, name of the PI and protocol number (This information will appear on the approval certificate)
7. Guide of the student should make it convenient to be present at the time of presentation

Ethics Committee approval certificate

Certificate of EC approval may be collected from member secretary of the EC committee after one week from the day of the meeting.

(Remember that this approval has a validity of one year and studies extending beyond 1 year need to apply for renewal well in time)

Institutional Animal Ethics Committee (IAEC)

Proposals requiring use of animals for work, will be submitted to the IAEC for approval.

IAEC will function on similar lines as IEC and will issue individual certificates for approved proposals in the name of the Principle Investigator

Policy for providing incentive for publication of Research Papers and Reimbursement of expenditure incurred for publication

I. Intent :

Incentive Policy for publication of Research Papers is formulated for the purpose of creating awareness about importance of quality publication of research and giving impetus to research publications by the staff members of the University.

II. Eligibility :

1. Individual publishing his /her own original research work only is eligible.
2. Faculty publishing research work carried out by the student for obtaining degree will not be entitled for incentive and reimbursement of expenditure made for publication.
3. All the UG, PG & PhD students and members of the teaching faculty at the rank of Research Assistant, Tutor, Junior and Senior Resident, Assistant Professor, Associate Professor, Professor, Faculty Dean and Director and Hon. Vice-Chancellor are eligible for incentive for publication of their own research work.
4. Claims made by the passed out PG and PhD students will be entertained even if they have left the KIMSDU College, provided KIMSDU affiliation is mentioned in the research manuscript.
5. The staff, who has left KIMSDU affiliated college, can claim the incentive provided the manuscript is based on the research work

carried out at the KIMSDU College and the staff was holding position at KIMSDU College at the time of writing and submission of the research paper and KIMSDU affiliation is mentioned .

6. Only the first author is entitled for incentive for the publication.
7. If the existing staff decides to publish Dissertation work of a student who has passed out and left, such publications will be eligible for incentive only if prior (before preparation of Manuscript) approval is obtained from the Research Directorate.
8. Research papers (Original articles) published in journals indexed in Scopus, Pub med, Thomson Reuters (web of Science / Clarivate Analytics) and Indian Citation Index only will be eligible for incentive claims.
9. Short Communication, Case reports, review articles and Letter to Editor are not eligible for incentive claims. However, the amount of publication expenditure will be reimbursed as per the indexing category of the journal.
10. In addition to the incentive for publication, the first author is eligible to claim reimbursement of publication expenditure.

III. Terms of Incentive for Publication of papers :

1. Only Original Articles will be given cash incentives.
2. The cash incentive will vary depending upon the journal in which the original article is published as given in the following table (page-16).

3. The indexing status of the journal at the time of submission of the article will be considered for deciding incentive eligibility.
4. The amount of reimbursement of publication expenditure will be up to maximum of the incentive amount applicable for that article as per the category of the journal.
5. The case reports are not entitled for incentive claims however, expenditure incurred for publication of a case report will be reimbursed as per the incentive policy.

IV. Procedure :

1. An application along with a copy of the article and a proof of date of submission of the article and a copy of IEC approval should be submitted to the Chairman of Research Fund Allotment Committee through proper channel.
2. If cost is incurred for publication of the article the receipt/proof of payment made to the journal should be submitted along with the application through proper channel.
3. The Research Fund Allotment Committee (RFAC) meeting is held every three months where the claims are considered for grant of incentive.
4. A letter of sanction is issued to individuals for approved claims.
5. The Accounts Office will issue individual cheques to the staff members as per the decision of the research fund allocation committee.

V. Criteria :

1. Applications within three months of publication of the article will be considered.
2. The indexing status of the journal at the time of the submission of the article will be considered for deciding the amount of incentive.
3. After receiving sanction letter from RFAC, investigator will have to apply to the Finance officer for release of funds.

Incentive Policy for Publications of Original Research Paper

Sr. No.	**Type of Publication**	**Incentive in INR**
	Original Research paper	
1	**Non indexed Journal**	3500
2	**Indexed journal with Impact factor (By Thomson Reuters) < 1**	
A	Journal Indexed in World Health Organization (HINARI) International Committee of Medical Journal Editors (ICMJE) World Wide Science Organizations (WWSO) Directory of Open Access Journals (DOAJ)	5000
B	Journal Indexed in Index Copernicus	7500
C	Journal Indexed in Scopus/ Pub Med	10000
3	**Indexed Journal with impact factor (By Thomson Reuters) more than one and up to three**	
A	Journal indexed in other than Scopus /Pub Med	17500
B	Journal indexed in Scopus /Pub Med	20000
4	**Indexed Journal with impact factor (By Thomson Reuters) three and above**	

A	Journal indexed in other than Scopus /Pub Med	32500
B	Journal indexed in Scopus /Pub Med	35000

Incentive Policy for publications of Books and Monographs

I. Intent :

Incentive Policy for publication of Books and Monographs is formulated for the purpose of creating awareness about importance of publication of Books and Monographs and for promotion of publication of Books and Monographs by the staff members of the University.

II. Eligibility :

1. All members of the teaching faculty at the rank of Assistant Professor, Associate Professor, Full Professor, and Research Assistants, Deans and Directors including Hon'ble Vice Chancellor of Krishna Institute of Medical Sciences Deemed University can write Monographs and Books.
2. They should have written and submitted the Book/Monograph to the publisher while holding the staff position at KIMSDU.
3. Only the first author is entitled for incentive for publication.

III. Terms of Incentive for publication of Monograph :

1. Monographs published by the reputed national / international publisher only, will be entitled for incentive

2. First author of the monograph will be given cash incentive.

3. The cash incentive to be given for writing Monograph will be as follows –

Incentive for Publication of Monograph		
Sr. No.	**Type of Publication**	**Incentives (Rs.)**
1	Original Monograph	10,000

IV. Terms of Incentive for publication of Book

1. Book / Book chapter published by the reputed national/ international publisher only, will be entitled for incentive
2. Book/ Book chapter published in-house will not be entitled for incentive however; the expenditure incurred for publication will be borne by the university.

Incentive for Publication of Book/Book Chapter		
Sr. No.	**Type of Publication**	**Incentives (Rs.)**
1	Book	25,000
2	Book Chapter	10,000

3. Procedure :

i) The author/authors are free to get their Monograph/books published from any reputed registered publisher.

ii) The University will provide facilities for In-house publication.

iii) For In-house publication, a hard and a soft copy of the Monograph/Book written by the author/authors should be submitted to the Director of Research along with names of two referees specialized in the concerned subject.

iv) The proposed Monograph / Book will be sent to the referees.

v) After receiving a favorable reply from the referees the Monograph /Book will be published In-house.

vi) Application for International Standard Book Number (ISBN) should be made by the authors to the National Library, New Delhi.

4. Criteria :

- Publication incentive claims, made for publication during the current financial year only, will be considered.
- The incentives will be applicable as per existing policy of incentives.

Incentive Policy for Copyright & Patents

I. Intent :

There are many innovative ideas and modifications in the instruments, procedures for betterment of screening the population, diagnosis and treatment. But copyright and patent applications are often not filed. The incentive policy for Copyright, Patent applications and design & trade mark, therefore, is made to encourage and provide impetus for filling these applications.

These activities come under Intellectual Property rights and are motivated through the committees constituted in the constituent colleges and also through the centralized IPR cell under the control of Directorate of research in which, each constituent college is represented by Hon'ble Vice Chancellor's nominee.

II. Eligibility :

1. All members of Assistant Professor, Associate Professor, Professor, and Research Assistants, Principals, Directors and Hon. Vice Chancellor including PG and PhD students of Krishna Institute of Medical Sciences Deemed University can apply for Copyright, Patent etc.
2. The original idea/innovation should be new and not done by anybody anywhere.
3. It should be related to health sciences or eco-friendly ventures.

III. Terms of Incentives for Copyright & Patents :

1. All the expenditure for application of Copyright, Patent and design & trade mark as well as for preparing prototype will be borne by the University.
2. The cash incentive will be given after getting Copyright / Patent as follows :

Incentive Policy for Patents & Copy Right		
Sr. No.	**Type of Publication**	**Incentives (Rs.)**
1	Patents	
	Application	Institutional support
	On Approval	10000
2	Copyright	
	Application	Institutional support
	On Approval	5000
3	Design	Institutional Support
	On Approval	5000
4	Trade mark	Institutional Support
	On award	5000

IV. General policies :

The Krishna Institute of Medical Sciences Deemed University, Karad will have sole ownership of all intellectual property created by an employee or a student.

The KIMSDU will provide various review and management services for the patentable inventions as well as other intellectual property through IPR cell.

In the instances where, the patent is obtained and licensed and is subsequently transferred to a third party, revenue generated will be shared between the inventor and the University on mutually agreed terms on a case by case basis

V. Procedure :

1. An application of Copyright / Patent and other IPR documents should be submitted along with a soft copy to the Director of Research.
2. Applicant should do goggle search prior to submission of application to the Directorate of Research
3. Examination of existing literature is undertaken by Directorate of Research to confirm that it is innovative.
4. The application will be forwarded to Copyright / Patent lawyer for internet search and finding out newness of the idea.
5. All the necessary forms are filled in, diagrams drawn and application is prepared for submission after taking due signatures.

6. The fees for patent office and lawyer are released by the Account Office.

7. After scrutiny of the application for correctness and completeness the application is submitted online by the lawyer to the Copyright/Patent office in the name of the Registrar of the University. The identity of the innovators is maintained and their signatures as innovators are taken.

8. The Copyright / Patent will be registered in the Copyright / Patent office of India, examined and decision about awarding the patent will be made by the office of commissioner of IPR (Intellectual Property Right)

VI. Criteria :

On award of the Copyright / Patent/ other IPR documents, the inventor will be eligible for cash incentive as per existing criteria of incentive at that time.

Policy for Intellectual Property

PREAMBLE

Richness of a country in today's perspective is defined by its holding of Intellectual property (IP) and therefore universities and research institutions have a fundamental role in socio-economic development. The bases for economic, technological and social mobility as well as for economic growth are the innovation and scientific development. Universities and research institutions are main domains in which scientific development and innovation occur and the IP system is the main mechanism that enables universities and society at large to capture the value of innovation.

It is the objective of the Institute to help Universities and the research institutions to commercialize their knowledge assets and potentially generating additional sources of funding, which may be channeled into, amongst other, further research. Also, partnerships with the private sector and other organizations can assure that academic research outcomes have greater impact, including competitiveness of industry and the regions, establishment of new companies, or addressing a variety of socio-economic challenges.

This policy is further extended to protect the respective interests of all concerned participants by ensuring that the benefit of such property accrue to the public, to the inventor, to the university and to sponsor of

specific research in varying degrees of Protection, monetary return and recognition.

This approach requires support for the entrepreneurial dimension of knowledge transfer, where strategies that leverage IP assets at the same time place emphasis on how academic research and the resultant IP best provide economic, environmental and social benefits for society at large.

Krishna Institute of Medical Sciences Deemed University has a very clear vision in creating new knowledge through scientific research which can reach the masses and impact our society. The knowledge is an intellectual asset and needs protection. Hence, Krishna Institute of Medical Sciences Deemed University has taken the necessary steps to create an Intellectual Property Research (IPR) cell.

This IP policy is foundation of IP management in the University. It:

5 Serves as the starting point for a common understanding about IP, IP rights and incentives for researchers;
6 Establishes the structure for the way the University deals with the ownership and disposition of its IP. As such, it ensures certainty and transparency to reinforce the links between the University and industry and
7 Is fundamental in helping the University to address social commitments, and especially, in ensuring the dissemination of knowledge and technology for the public good.

This **IP Policy** aims to provide a summary of important issues that are essential in an IP policy, including ownership, incentives, confidentiality

and publication, IP management and commercialization, recording and maintenance of IP, and IP-related conflicts of interest. The aim is to promote reflection and critical thinking; to stimulate certainty in terms of IP ownership; to encourage responsible IP commercialization of research results.

ARTICLE 1- PROLOGUE

1.1. Context and University Mission

1.1.1. The core mission of the Krishna Institute of Medical Sciences Deemed University is to create knowledge through scientific research which can reach the masses and impact the society.

1.1.2. The University has commitment to ensure that IP resulting from its research activities is used in accordance with its legal obligations, for the benefit of the University, the Inventors and most importantly society-at-large.

1.2. Impetus of the IP Policy

1.2.1. **Promotion of IP utilization**. The intent of the IP Policy is to facilitate the widespread use of the University's IP through various access modalities.

1.2.2. **IP management**. The IP Policy seeks to set the framework for the translation of the IP arising from the University's Research into products, services and processes. It encourages Staff Members, Learners and Visitors to become Inventors and to identify IP with potential commercial value. It also establishes clear rules and procedures for the management

and Commercialization of such IP generated at the University.

1.2.3. **Balance of interests**. The IP Policy seeks to ensure the legal protection, where applicable; effective management and Commercialization of University IP; while at the same time not impeding with the traditions of education and scholarship, academic freedom, open and timely publications, University sovereignty, and the University's mission serving the public interest.

1.3. Concepts

The University operates under the following concepts:

1.3.1. **Responsible Commercialization**. Where IP arises that has commercial potential as a result of Research, the University intends to make such IP available in a form that will most effectively promote its development and use for economic and social benefit.

1.3.2. **Incentives**. The University shall recognize and reward the Staff Members, Learners and Visitors whose IP generates a demonstrable socio- and/or economic impact.

ARTICLE 2 -DEFINITIONS

Without prejudice to any applicable laws, in this Policy the definitions set out below shall apply:

2.1 **Appointment**. A formal agreement for a Visitor at the University, which is a prerequisite to participate in or conduct

Research, scholarship, creative work, or teaching at the University.

2.2 **Author**. Any person to whom this Policy is applicable, who individually or jointly with others makes a design, a mark or copyrightable work and who meets the criteria for authorship under the IP laws of India.

2.3 **Background IP**. Any pre-existing IP created before the execution of any Research Project, or prior to an Inventor becoming subject to this IP Policy, by virtue of Appointment in the case of a Visitor, employment contract in the case of a Staff Member, or registration in the case of a Learner.

2.4 **Commercialization**. Any form of utilization of IP intended to generate value, which may be in the form of a marketable product, process or service, commercial returns, or other benefit to society. **Commercialize** is similarly defined.

2.5 **Commercialization Institution**. A company that has access to the IP of the University, through any one or more of the available Commercialization modes, to produce new products, processes or services. This can be a spin-off or start-up.

2.6 **Conflict of Commitment (COC)**.Any situation in which an individual Staff Member's or Visitor's primary professional loyalty is not to the University because the time devoted to outside activities adversely affects their capacity to meet their responsibilities as set out in their employment contract of Appointment, respectively.

2.7 **Conflict of Interest (COI)**.Any situation in which real or perceived interests of an individual Staff Member, Visitor or Learner may run counter to the interests of the University or negatively affect their employment or duties.

2.8 **Collaborative Research.** In this category of R&D, would comprise projects that are jointly conceived, planned, and executed by the Institute Personnel, in collaboration and partnership with, the representatives, personnel, and staff of the Sponsor/ Funding Agency/ Industry/ Collaborator, including Inter-University Collaborator(s). Such projects will be characterized by substantial inventive and financial contributions from the Sponsor/ Funding Agency/ Industry/ Collaborator, including Inter- University Collaborator(s). Consequently, the Institute would be amenable to considering joint ownership of the IP, with the corresponding Sponsor/ Funding Agency/ Industry/ Collaborator, including inter institute Collaborator(s).

2.9 **Contract Research**. Contract Research is the kind of Research performed by Institute Personnel, when a Sponsor/ Funding Agency/ Industry sets out a specific problem/ research agenda/scope of work, and the Institute Personnel work on the same, in a "work for hire" mode.

2.10 **Course Materials**. All materials used in, or in connection with, and for the purpose of, teaching an education course through the provision of lectures, tutorials, seminars, workshops, field or

laboratory classes, assessments, practicum and other teaching activities conducted by the University; and all IP in such materials.

2.11 **Enabler**. Any assistants, technicians, and other individuals who have indirectly contributed to the creation/commercialization of IP - and as such may not be listed themselves as an author or inventor in terms of statutory IPRs - but without whose practical contribution the Commercialization would not have been possible.

2.12 **Gross IP Revenue**. All revenue received by the University on Commercialization of University IP before any deductions for IP Expenses, as defined in Article 10.

2.13 **Gross Non-IP Revenue.** All revenue received by the University for Execution of Projects / Scientific or Clinical Work as part of the Research Contract before any cost recovery or deductions for the incurred Expenses, as defined in Article 7.

2.14 **University**. Krishna Institute of Medical Sciences Deemed University.

2.15 **University IP**. IP owned or co-owned by the University.

2.16 **Intellectual Property (IP)**.All outputs of creative Endeavour in any field at the University for which legal rights may be obtained or enforced pursuant to the law. IP may include:

a. literary works, including publications in respect of Research results, and associated materials, including drafts, data sets and laboratory notebooks;

b. teaching and learning materials;

c. other original literary, dramatic, musical or artistic works, sound recordings, films, broadcasts, and typographical arrangements, multimedia works, photographs, drawings, and other works created with the aid of University resources or facilities;

d. databases, tables or compilations, computer software, preparatory design material for a computer program, firmware, courseware, and related material;

e. patentable and non-patentable technical information;

f. designs including layout designs (topographies) of integrated circuits;

g. plant varieties and related information;

h. trade secrets;

i. know-how, information and data associated with the above; and

j. Any other which is not included above.

2.17 **Intellectual Property Rights (IPRs)**.The proprietary rights that may be granted for an invention, mark, design, plant variety, or other type of IP, should the statutory Requirements for protection are met to result in a patent, trade mark, registered design or plant breeders' right, respectively.

2.18 **Invention**. Section 2(1)(j) of Indian Patents Act (2005), defines "invention" as a new product or process involving an inventive step capable of industrial application.

The term "industrial application" refers to capable of industrial

application in relation to an invention means that the invention is capable of being made or used in an industry. One of the pre-requisite of invention is that it should be new i.e. the invention proposed to be patented has not been in the public domain or that it does not form part of the state of the art.

2.19 **Inventor**. Any person to whom this Policy is applicable, who creates, conceives, reduces to practice, authors, or otherwise makes a substantive intellectual contribution to the creation of IP and who meets the definition of 'Inventor', 'author' or 'breeder' as generally implied in the IP laws of India.

2.20 **Investigator.** Staff Members, Learners and Visitors involved in the execution of Project / Scientific or Clinical Work as part of the Research Contract.

2.21 **Innovation**. An Invention that has been implemented, or put to actual, practical use, that results in better products, processes, or services. Such Innovations result in new products, processes, or services that result in better solutions that meet new requirements, unarticulated needs, or existing market needs. The basic difference between an invention and an innovation is that the former is a laboratory creation, whereas an innovation is its actual application in the field.

2.22 **IP Disclosure Form**. The form as prescribed by the university to be completed by Inventors and submitted to IPR cell with all relevant documents.

2.23 **IP Expenses**. All expenses incurred by the University in the

management and Commercialization of IP for which Gross IP Revenue has been received.

IPR cell committee is the body within the University set up in terms of Article 4.1, which is responsible for overseeing the drafting, implementation, monitoring and evolution of the Policy, and for providing strategic oversight of the IPR.

2.24 **IP Research cell (IPR)**.The administrative unit established in terms of Article 4.2, responsible for day-to-day management of all IP-related activities of the University.

2.25 **Net IP Revenue**. Gross IP Revenue less IP Expenses.

2.26 **Policy.** Krishna Institute of Medical Sciences (Deemed to be University) Intellectual Property Policy.

2.27 **Project Expenses.** All expenses incurred by the University in the management and execution of Research Contract for which Gross non-IP Revenue has been received.

2.28 **Public Disclosure**. The communication of information, relating to IP, to external parties. Public Disclosure includes, but is not limited to, disclosure in written or oral form; communication by email; posting on a web blog; disclosure in a news report, press release or interview; publication in a journal, abstract, poster, or report; presentation at a conference; examination of a thesis; demonstration of an Invention at a trade show; or the industrial application of an Invention.

2.29 **Public Domain**. The freely accessible public realm in which works that are not protected by IPRs, either because the rights

have been forfeited or because the rights have been expired, are thereby held by the public at large and available for all to use without permission from the Inventor or owner.

2.30 **Research**. Any creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications. It comprises three activities: basic research, applied research and experimental development.

2.31 **Research Contract**. Any type of agreement between the University and an external party or research sponsor, concerning Research, which could result in IP being created at the University. This shall include, but is not limited to, all sponsorships, donor ships and collaborations with the external party or research sponsor and can also be referred to as Contract R&D and or Contract Research.

2.32 **Research Project**. Any project that forms the basis of Research undertaken by the University and includes projects undertaken by a Learner, under the supervision of a Staff Member or a Visitor, as part of a research degree program.

2.33 **Scholarly Works**. All copyright works which are the outputs of academic Staff Members, Learners or Visitors, including Research, creative and other outputs in area(s) of his/her expertise. It does not include Course Materials and computer software and databases**.**

2.34 **Sponsor/ Funding Agency/ Industry.** These terms, used interchangeably in this IP Policy document, refer to the entity that funds the R&D work that is proposed to be carried out by the Institute. In addition, in the case of Collaborative R&D work carried out by the Institute and the Industry, the latter shall also make substantial inventive contributions, in tandem with the financial contributions made by it.

2.35 **Faculty Member**. Any person who is under a contract of employment with the University including academic, research, technical, administrative and adjunct staff, whether full-time or part-time or on a temporary basis.

2.36 **Learner**. Any Learner registered for an approved course at the University.

2.37 **Utilization.** Holistic use of the University's resources which include but are not limited to facilities, equipment, human resources or funds. Not included is routine use of libraries and/or office space or the IP has been written or developed in the personal (unpaid) time of the Inventor.

2.38 **Trade Secrecy**. Confidential information not publicly available that has commercial value because of its confidential nature, and which the owner has taken reasonable efforts to keep secret.

2.39 **Visitor**. Any person who is neither a Staff Member nor a Learner of the University who engages in work at the University, including visiting professors, adjunct and conjoint

professors, teachers, researchers, scholars and volunteers; and who concludes an Appointment agreement with the University.

ARTICLE 3 – SCOPE

3.1. **IP**. This Policy applies to all IP generated at the University, particularly by Faculty Members, Learners and Visitors.

3.2. **Background IP**. After commencing employment, enrolment or an appointment, Staff Members, Learners and Visitors must declare any existing IP they wish to exclude from the application of this Policy due to creation prior to their employment, enrolment or appointment at the University.

3.3. **Applicability**. This Policy applies to all Staff Members, Learners and Visitors who participate in a research project or produce scholarly works. Rights and obligations under this Policy shall survive any termination of employment, enrolment or Appointment at the University.

3.4. **Binding effect of the Policy**. This Policy constitutes an understanding that is binding on the University, Staff Members, Learners and Visitors, once adopted by the Board of Management (BOM) of the University, on the following grounds:

3.4.1. **Staff Members**. The University shall ensure that the employment contract or other agreement establishing any type of employment relationship between the University and Staff Members includes a provision

placing Staff Members under the scope of this Policy.

3.4.2. **Learners participating in a Research Project**. The University shall ensure that Learners participating in a Research Project sign an agreement before commencing the project, to the effect that they have read and will comply with the provisions of this Policy, according to Article 5.2.5.

3.4.3. **Visitors**. The University shall ensure that Visitors sign an Appointment agreement before commencing any activity at the University. Such agreement shall place the Visitor under the scope of this Policy and shall make reference to this Policy, a copy of which will be made available to the Visitor.

3.4.4. **Informed consent**. This Policy shall be included on the University's website. In addition, a reference to this Policy shall be made in the academic catalogues or their equivalent. Said reference shall be in sufficient detail to enable the full text of the Policy to be easily accessed.

ARTICLE 4–EXECUTION AND OPERATION

4.1 IP Research Cell Committee

4.1.1 **Purpose**. The University shall establish an IPR Cell

Committee to oversee the implementation and evolution of this Policy and provide strategic guidance to the University (according to Article 4.2 below).

4.1.2 **Composition**. The IPR Cell Committee shall consist of members as identified by the Registrar and chaired by the Vice Chancellor or their designated other.

4.1.3 **Responsibilities**. The IPR Cell Committee is the ultimate decision making body in the determination of an IP management and Commercialization strategy for a particular IP.

4.1.4 **Meetings**. The IPR Cell Committee shall establish regular meetings and also be available for Emergent meetings.

4.2 The IPR Cell (IPR)

5.1.1 **Purpose**. The University has established an IP Research Cell (IPR) to assist the University in managing and commercializing its IP in a form that will most effectively promote its development and use for economic and social benefit.

5.1.2 **Responsibilities**. The responsibilities of the IPR Shall include, but are not limited to:

3.1.2.1.1 Outreach/awareness to Inventors;

3.1.2.1.2 Relationship management with Inventors;

3.1.2.1.3 IP management;

3.1.2.1.4 Technology marketing and IP contract negotiation;

3.1.2.1.5 IP contract management; and

3.1.2.1.6 IP costs and revenue distribution

ARTICLE 5 -OWNERSHIP OF IP AND its usage

6.1 IP Created by Staff Members

5.1.1 **University ownership**. The University owns all IP created by a Staff Member:

5.1.1.1 in the course and scope of his/her employment; or

5.1.1.2 Making Substantial Use of the University's resources.

5.1.2 **Staff Member ownership**. Staff Members will own/co-own the IP they have created when such IP:

5.1.2.1 Is outside the course and scope of their employment and without Substantial use of the University's resources;

5.1.2.2 Vests in Scholarly Works (see Article 5.5);

5.1.2.3 Other IPRs, as required by national law, or for which the University cannot or does not wish to claim ownership and the University has communicated such in writing.

5.1.3 **IP emanating from Research Agreements**. Where there is no substantial use of the University's resources or if the Contract R&D Project is completely funded by the Sponsor/ Funding Agency/ Industry/ Collaborator, to cover all direct and indirect costs, as well as all operating costs and overheads for the independent

(out- sourced) execution of the Contract R&D, the terms of the research contract will regulate ownership of IP created by staff members in the course of a Research project that forms part of a research contract, as set out in article 7.

5.1.4 **Appointment of Staff Members another University**. Those staff members who hold an honorary or other academic or research appointment at another University (Host University) should bring to the attention to the University of the Host University, including its IPR Cell committee.

5.1.5 **His/her obligations in terms of this Policy, prior to the tenure at the Host University.** To the extent that the Host University's IP Policy makes a claim on IP created by the Staff Member pursuant to such appointment, the Staff Member shall ensure that the Host University negotiates a suitable IP arrangement with the University.

6.2 IP Created by Learners

5.2.1 **Learner ownership**. IP created by a Learner in the course of study at the University (including theses, dissertations and other Scholarly Works) will be owned by the Learner. This is in contrast to IP created by a Learner in a Research Project, as per Article 5.2.3 below.

5.2.2 **Theses or dissertations.** The Learner must submit his/her final thesis or dissertation to the university repository and the Learner must grant a royalty-free license to the university to reproduce his/her thesis or dissertation and to distribute copies thereof to the public.

5.2.3 **University ownership**. IP resulting from a Learner's research project shall be owned by the university in the following circumstances:

5.2.3.1 if the IP is created by making Substantial Use of the University's resources (excluding supervision) and there is re-imbursement agreement concluded between the University and the Learner; or

5.2.3.2 If the Research carried out by the Learner forms part of the University's Research Projects.

5.2.4 IP emanating from Research Agreements**. The terms of the Research** Contract **shall regulate the ownership of IP created by a Learner in the course of such Research Contract, as set out in Article8.**

5.2.5 University ownership responsibilities**. If the University is the owner of IP** created **by a Learner, in terms of Article 5.2.3 or Article 5.2.4, and hence created in terms of a Research Project or Research Contract, respectively, the University shall:**

5.2.5.1 provide the Learner with an explanation of the

reasons for the assignment of IP rights to the University;

5.2.5.2 advise the Learner to seek independent advice regarding the assignment;

5.2.5.3 obtain a deed of assignment from the Learner for all IPRs emanating from the Learner's Research Contract or Research Project, where relevant, in return for revenue sharing as provided for in Article 10; and

5.2.5.4 Withdraw the Learner from the Research Project or Research Contract if a Learner elects not to assign the relevant IPRs to the University.

6.3 IP Created by Visitors

5.3.1 **University ownership**. Unless otherwise agreed to in writing by the University and the Visitor's home University prior to the tenure at the University, Visitors are required to assign to the University any IP:

5.3.1.1 Created in the course and scope of their Appointment at the University; or

5.3.1.2 Created by making Substantial Use of the University's resources.

5.3.2 **University IP**. On departure from the University, a visitor must sign and submit to IPRC an IP disclosure form disclosing any IP created, as per Article 5.3.1, whilst at the University.

6.4 Special Rules for Course Materials

5.4.1 **University ownership**. The University will own the IP in Course Materials created by a Staff Member or a Visitor, with the exclusion of Course Material that is created from or for Open Educational Resources, in accordance with Article 5.6.1.

5.4.2 **Licensed by the University**. The University grants the Inventors of Course Materials a royalty-free, non-exclusive license to use the Course Materials created by them for teaching and Research purposes at the University.

6.5 Special Rules for Scholarly Works

5.5.1 **Publication**. The University recognizes and endorses the rights of Staff Members, Learners and Visitors to publish their Scholarly Works, provided that any Scholarly Work which may disclose any possible University IP shall first be cleared by IPRC after having an opportunity to protect such University IP according to Article 8.

5.5.2 **University repository**. Staff Members, Learners and Visitors should Endeavour to obtain publishers' permission to include published Scholarly Works in the University repository whether as a published edition or in pre-publication form.

5.5.3 Licensed to the University. Staff Members, Learners and

Visitors shall grant to the University a non-exclusive, royalty free license to use their Scholarly Works for the University's administrative, promotional, Research and teaching purposes.

6.6 Public Domain

5.6.1 **Public Domain**. University IP forms part of the Public Domain in the following circumstances:

5.6.1.1 If a Research Contract provides that the Research results be placed into the Public Domain; or

5.6.1.2 If Staff Members or Visitors made use of resources licensed through Open Source or Creative Commons Licenses and the licensing conditions require release of derivatives into the Public Domain.

5.6.2 **Release into the public domain**. The University will release IP into the Public Domain in the following circumstances:

5.6.2.1 Where it is deemed to be in the public interest;

5.6.2.2 If the IP has low commercial or other development potential and low prospects of fostering the development of new products or services; or

5.6.2.3 If deemed necessary by the University.

ARTICLE 6– PUBLICATION,NON-DISCLOSURE AND TRADE SECRETS

6.1. **Right of publication**. The University encourages and supports the right of Inventors to decide if and when to publish their

Research results, in accordance with Article 5.5 Above.

6.2. **Non-disclosure for IP protection**. In conjunction with the right of publication, Inventors should be aware that premature Public Disclosure may result in loss of IP protection rights. Therefore, they are strongly encouraged to make all reasonable efforts to identify any protectable IP as early as possible, according to Article8, and shall consult IPRC before making any Public Disclosure of potential University IP.

6.3. **Trade Secrets**. The University may nominate certain confidential information as a Trade Secret, owned by the University. In that event, all Inventors will be compelled to maintain secrecy of the Trade Secret and to follow the direction for management of the Trade Secret by IPRC.

ARTICLE 7–RESEARCH AGREEMENTS

7.1. **Authority**. Staff Members, Learners and Visitors shall not have the right to enter into a Research Contract with external parties on behalf of the University unless they are authorized to do so by an official representative of the University. Any substantial use of University resources by any external party, which includes but not limited to the use of University infrastructure and manpower, requires a formal Research Contract to be signed.

7.2. **Due conscientiousness**. Persons acting for and on behalf of

the University shall exercise all due conscientiousness and consult IPR Cell when negotiating and signing Agreements that may affect the University's IPRs.

7.3. **Ownership and rights to use**. Subject to any provisions in law to the contrary, ownership and rights to use shall be agreed upon with the external entity, in accordance with the guidelines outlined in the IP Policy of the University.

7.4. **Government rules**. Research Agreements shall comply with any applicable law and/or Government regulations and/or rules, which may be applicable to Research undertaken by the University, in particular, as far as it relates to the ownership of IP resulting from such Research.

7.5. **Approval**. Proposed Research Agreement and other legal statements concerning the University's IPRs shall comply with the provisions of this Policy. Any variance from this Policy must be approved by the Vice Chancellor.

7.6. **Basic Principles**. The IP clauses in all Research Agreements shall be governed by the following basic principles:

7.6.1. **Concluded from the outset**. A Research Contract must be executed in writing and signed by the University and the external party (is)/sponsor(s) prior to the commencement of any Research Project and, as appropriate and without limitation, must contain terms relating to ownership, management and use of IP arising from the Research Project as well as any Background IP.

7.6.2. **Background IP**. All University Background IP must be properly recorded and declared prior to the commencement of a Research Contract and belongs to the University. Similarly, Background IP of the external party/sponsor belongs to such party or sponsor. Use of such Background IP requires express written permission.

7.6.3. **Foreground IP** (**IP arising from the Research Contract)**. IP generated pursuant to a Research Contract by Staff Members, Learners or Visitors shall be governed in terms of the above provisions relating to IP generated by these parties. The general rule is that such IP shall be owned by the University.

7.6.4. **Co-owned Foreground IP**

a. **Terms for co-ownership**. Co-ownership of IP generated pursuant to a Research Contract shall be in accordance with national legislative provisions, failing which, or as mutually agreed contractually. The University may consider joint ownership of the IP, with the corresponding Sponsor/ Funding Agency/ Industry in case of Collaborative R&D.

b. **Costs for protecting and maintaining co-owned IP**. The costs for protecting and maintaining any IPRs shall be shared between the University and the external party(ies)/sponsor(s) in accordance with the percentage of IP ownership; or as mutually agreed contractually.

7.6.5. **Serendipitous IP**. Any IP created during the course of the Research Contract which falls outside of scope of the Research Contract shall be owned by the University or the external party(ies)/sponsor(s) which developed such IP, unless agreed contractually otherwise in the Research Contract.

7.6.6. **Right of first refusal to the IP**. The Research Contract may include provisions giving the external party(ies)/sponsors, a right of first refusal to Commercialize the IP emanating from the Research Contract, through a license or joint venture arrangement or assignment.

7.6.7. **Publication delay**. It is the strict policy of the University to allow Inventors freedom to publish their work. However, the University acknowledges that delays in publication for the purpose of initiating statutory protection Of the IP is often necessary. In this regard, the University will agree, on a case-by-case basis, to a contractual delay in publication by Inventors.

7.6.8. **Use of the IP for Research and teaching**. In instances, where the University IP is licensed exclusively or assigned as part of the Research Contract, all efforts should be made to secure a royalty-free license for use of the IP for on-going Research and teaching purposes.

7.7. **Agreement Research Policy.** All Research Agreements must be executed and performed in compliance with the University's regulations and this IP Policy.

7.8. **Exceptions to the Policy**. In certain cases, it may be necessary and/or beneficial to the University to enter into a Research Contract that contains exceptions to the provisions of this Policy. Any such exceptions require prior, written approval from the Vice Chancellor.

7.9. **Sharing of Non-IP Revenue**

7.9.1.**General.** In case University receives any non-IP related revenue and/or other returns, monetary or otherwise, through the execution of the Research Agreements, the investigator(s) executing such a project/work will be entitled to a portion of the revenue as detailed in 7.9.3.Staff Members, Learners and Visitors (investigators) shall not have the right to raise invoices

and/or collect revenues for the execution of Research Agreements.

7.9.2. **Calculation of revenues for distribution**. Calculation of Gross Non-IP Revenue, Project Expenses, and Net Non-IP Revenue shall be in accordance with the following rules:

7.9.2.1. **Calculation of Gross Non-IP Revenue**. "Gross Non-IP Revenue" is defined as *all revenue received by the University for Execution of Projects / Scientific or Clinical Work as part of the Research Contract before any cost recovery or deductions for the incurred Expenses* and includes, but is not limited to, consultation and evaluation fees received, and direct sale of products or services.

7.9.2.2. **Project Expenses**. "Project Expenses" is defined as *all expenses incurred by the University in the management and execution of Research Contract for which Gross non-IP Revenue has been received* and includes, but is not limited to, those expenses that relate to usage charges of the instruments and facilities, purchase of new equipment and consumables specifically for the execution of the particular Research Contract, institutional overheads and general administrative costs.

7.9.2.3. **Calculation of Net Non-IP Revenue**. The University shall maintain accurate and transparent documentation of Project Expenses incurred for a particular Research Contract and shall be entitled to cover all Project Expenses it has incurred, as set out in 7.9.2.2 above.

The "Net Non-IP Revenue" is calculated as the Gross non-IP Revenue less Project Expenses.

7.9.3.**Sharing of revenues – Investigator(s)**

7.9.3.1. **Standard Investigator's share**.
60% of the Net non-IP Revenue will be allocated to the Investigator. Where there is more than one Investigator, the Investigators are entitled to an equal or *pro rata* share, based on contribution (as mutually agreeable between the University and the Investigators), except where there is a prior written agreement between all the Investigators to the contrary.

7.9.3.2. **Payment**. Payment to the Investigators will be made by the University on a periodic basis as agreed in writing, but no later than twelve months after receipt of the Gross non-IP Revenue by the University.

7.9.3.3. **Taxes**. The University may, if so obliged by national tax laws, make any applicable tax deductions before making payments to the Investigators.

7.9.3.5. **Entitlement**. The entitlement to an Investigator's share of Net non-IP Revenue shall survive any resignation/termination of employment.

7.9.3.6. **Banking details**. The onus is upon each Investigator to ensure that the University has their current banking details for the purpose of revenue sharing. The University will keep the relevant revenue amounts in reserve for a maximum period of 2 (two) years after which all rights of Investigators to receive such payments will be forfeited. If the University pays an amount into an incorrect account as a result of information supplied to it being outdated or incorrect, the University will not have any further

obligation or liability in respect of such payment, which will be deemed to have been duly and properly made.

7.9.3.7. **Sharing of revenues – University**. The University's share of Net non-IP Revenue is distributed internally as follows:

20% towards development of research infrastructure; 20% towards maintenance of research facilities and equipment.

ARTICLE 8 – DECISION BY THE IPRC

8.1. Responsibility to Disclose IP

8.1.1. **Recording**. Inventors shall keep appropriate records of their Research in accordance with the University's applicable policy procedures and make reasonable efforts to ensure that only those individuals within the University who have a need to have access to such records for the performance of their duties are granted such access. No other person should be involved.

8.1.2. **IP Disclosure**. Where an Inventor identifies potential IP resulting from his/her Research or that of his/her team, he/she shall disclose such potential IP to IPRC promptly by means of an IP Disclosure Form in a prescribed format.

8.1.3. **Complete disclosure**. Inventors must provide to IPRC such full, complete and accurate information as IPRC may require enabling it to sufficiently assess the technical and related features and functions, ownership, commercial potential and IP protection that might be applicable to such IP. Upon complete disclosure, the IP Disclosure will be registered and assigned a reference number and IPRC will share this reference

number with the Inventors to inform that the IP Disclosure has been formally received by the University.

8.2. Inventor ship and Ownership

8.2.1. **Inventor ship**. Inventors shall, upon request, sign the appropriate legal documents provided by IPRC that attest to Inventor ship. Where there is more than one Inventor, and there is a dispute as to the contribution to Inventor ship, IPRC shall in consultation with the Inventors, assist in the determination of the percentage IP Inventor ship, failing which it shall be assumed that there was an equal undivided contribution.

8.2.2 **Ownership.** Once Inventor ship has been determined, the Inventors shall be required to formally assign any right, title or interest they may have in that IP to the University in the form of a contract that specifies the rights that will accrue to the Inventor(s) and the University and the obligations they will have to assist the University with the Commercialization of that IP. Article 9.3 will apply.

8.3. Decision as to IP Protection and Commercialization

8.3.1. **Evaluation and recommendation**. IPRC will analyze the information disclosed in the IP Disclosure within usually 30-60 days of formal receipt. The analysis will include: whether or not the subject matter is protectable as IP; an assessment of economic feasibility or marketability; and determination of any rights of external parties, such as a funder or collaborator. After evaluation, IPRC will prepare a Preliminary report with findings that will help the University to decide if it will proceed with IP protection and Commercialization. IPRC shall share the preliminary report with the Inventor(s) and seek their input for his/her say if any.

8.3.2. **Decision to protect/Commercialize**. The University will decide,

as soon as reasonably practicable, whether or not it wishes to protect and/or commercialize the IP. IPRC will use all reasonable efforts to notify the Inventor(s) of the University's decision within usually 60-90 days of formal receipt of the IP Disclosure. IPRC will also make a determination in relation to the validity of any claim made by a Staff Member, a Visitor or a Learner that they are the true Inventor(s) of that IP and in relation to their rights under this Policy.

8.4. University elects not to protect /commercialize the IP

8.4.1. **IP abandoned or not commercialized**. The University reserves the right not to protect or Commercialize IP that it feels if after consultation with the Inventors:

a. There is no reasonable prospect of commercial success;
b. It is not in the best interest of the University; or
c. It is not in the public interest.

8.4.2 **Transfer of Ownership**. In the event the University decides not to pursue IP protection and/or Commercialization, it will take steps to return said IPRs to the Inventor(s), contingent on any other superseding contract rights of external party (is)/sponsor(s).

8.4.3. **Written notification**. If the University is unable to or decides not to protect or commercialize the University IP, it should notify the relevant Inventor(s) of its decision in writing and in a time bound manner.

8.4.4. **No prejudice to IP protection**. The Inventor(s) should receive the written notification in a time bound manner which will felicitate the relevant Inventor(s) to take any further steps to ensure the protection of IP, should they so desire.

8.4.5. **Assignment**. If the Inventor elects to take assignment of the IP, the University shall ensure that a deed of assignment is executed without delay.

8.4.6. **Terms and conditions**. If the University assigns IPRs to the Inventor in terms of this Article 8.4.5, the assignment may be subject to one or more of the following terms and conditions:

a. That upon Commercialization, the University be compensated for any expenditure it may have incurred in connection with the protection and/or Commercialization of such IP; and/or
b. That the University be granted a non-exclusive, royalty-free license to use the IP for Research and teaching purposes.

AARTICLE 9 -COMMERCIALIZATION OF IP

9.1. **Determination of the Commercialization Strategy**. Within usually 8-12 months of the decision to protect or Commercialize the IP under Article 8.3.2,the University will determine, with input from the Inventors, the most appropriate Commercialization strategy.

9.2. **Assistance to IPRC**. Inventors of IP which has been selected for IP protection and Commercialization by the University must provide IPRC with all reasonable support in the assessment, protection (including preventing premature disclosure and execution of any documents including deeds of assignment and deeds attesting to Inventor ship), and Commercialization of the IP.

9.3. **Sovereignty and Cooperation**. The University shall have the sole discretion regarding the Commercialization of IP owned by it. Notwithstanding, the University will ensure that reasonable efforts are made to keep the Inventors informed and, where appropriate, involved in the Commercialization of the IP to which they contributed. The Commercialization of University IP will be planned, executed, and monitored by IPRC.

9.4. **Commercialization Pathways**. Modes of IP Commercialization may include:

a. license, either exclusive or non-exclusive, and variations thereof;
b. assignment (sale)for lump sum fees or
c. assignment (sale) to Inventor led company against equity and IP Expenses (as per 10.2.2.2);
d. formation of a Commercialization Entity/ Startup to which the IP is licensed or assigned in terms of this Policy;
e. non-profit use or donation;
f. joint ventures;
g. royalty free access on humanitarian or other grounds; or
h. Various combinations of the above.

9.5. **Guidelines**. Regardless of the mode of IP Commercialization, the transaction will be executed in a contract which:

a. protects the interests of the University, its Staff Members, Learners and Visitors;
b. retains rights for the University to use the IP for educational and research purposes;
c. assures that the IP will be utilized in a manner which will serve the public good;
d. assures that the IP will be developed and brought to the marketplace as useful goods and services; and
e. Prohibits its use in any illegal or unethical manner.

The University will endeavor to Commercialize IP in a manner that encourages and fosters entrepreneurship by Staff Members and others and which supports Commercialization Entities**.**

AARTICLE 10 -INCENTIVES AND DISTRIBUTION OF REVENUES

10.1. The University's Incentive Structure

10.1.1. **Purpose and scope**. The University, in the interest of promoting knowledge transfer, will give due consideration to incentives to researchers to foster Research that has socio-economic impact; such incentives for all IPR component shall be governed by Research Promotion and Operation Policies as prescribed at Sr. Nos. 6 on Page nos. 16 to 18 and subject to modification from time to time by Board Of Management of the university.

10.2. Sharing of Revenues

10.2.1. **General**. The University will award Inventors/Enablers in the sharing of monetary benefits that may accrue to the University from the Commercialization of University IP.

10.2.2. **Calculation of revenues for distribution**. Calculation of Gross IP Revenue, IP Expenses, and Net IP Revenue shall be in accordance with the following rules:

10.2.2.1. **Calculation of Gross IP Revenue**. "Gross IP Revenue" is defined in Article 2 as "*all revenue received by the University for Commercialization of University IP before any cost recovery or deductions for IP Expenses*" and includes, but is not limited to, outright sale of IP, option payments received, license fees received, evaluation fees received, upfront and milestone payments received, royalty payments received, share of profits received, dividends received, shares/stake received, commissions, income through disposal of equity, and direct sale of products or services.

10.2.2.2. **IP Expenses**. "IP Expenses" is defined in Article 2 as"*all expenses incurred by the University in the management of IP for which Gross IP Revenue has been received*" and includes, but is not limited to, those expenses that relate to (i) the University's expenses incurred by payment to external entities for

securing, maintaining and enforcing IP protection, such as patenting and litigation expenses; (ii) costs incurred by the University in the licensing/assignment of IP, including marketing costs, contract negotiation and drafting costs; but not including staff time or general administrative costs.

10.2.2.3. **Calculation of Net IP Revenue**. IPRC shall maintain accurate and transparent documentation of IP Expenses incurred for a particular IP and shall be entitled to cover all IP Expenses it has incurred, as set out in10.2.2.2 above. The "Net IP Revenue" is calculated as the Gross IP Revenue less IP Expenses.

10.2.2.4. **Co-owned IP**. Where the IP is co-owned by the University and an outside organization, the Gross IP Revenue received by the University will be shared in accordance with a pre-determined formula as per a contractual arrangement. Thereafter, the Gross IP Revenue received by the University and the Net IP Revenue will be determined, and revenues will be shared in accordance with section 10.2.3.1 and 10.2.3.2 below.

10.2.3. **Sharing of revenues – Inventors/Enablers**

10.2.3.1. **Standard Inventor's share**

60% of the Net IP Revenue will be allocated to the Inventor. Where there is more than one Inventor, the Inventors are entitled to an equal or *pro rata* share, based on contribution (as mutually agreeable between the University and the Inventors), except where there is a prior written agreement between all the Inventors to the contrary.

10.2.3.2. **Standard Enabler's share**

The University may elect to set aside 10% of the Net

IP Revenue for an Enabler. Where there is more than one Enabler, the Enablers are entitled to an equal or *pro rata* share, based on practical contribution, except where there is a prior written agreement between the Enablers and the Inventor(s)/University to the contrary. Where there is no identified enabler, this share will belong to the University.

10.2.3.3. **Disputes**. In the event of a dispute or uncertainty regarding the Inventors'/Enablers' share of the Gross or Net IP Revenue from a specific IP, the issue shall be brought for resolution to the IPR Cell Committee in which case the decision of the IPRC shall be final and binding.

10.2.3.4. **Payment**. Payment to the Inventors/Enablers will be made by the University on a periodic basis as agreed in writing, but no later than twelve months after receipt of the Gross IP Revenue by the University.

10.2.3.5. **Taxes**. The University may, if so obliged by national tax laws, make any applicable tax deductions before making payments to the Inventors/ Enablers.

10.2.3.6. **Entitlement**. Inventors/Enablers and their heirs will be entitled to IP revenue sharing for as long as the University receives Gross IP Revenues from Commercialization of the University IP. The entitlement to all Inventor's/Enabler's share of Net IP Revenue shall survive any resignation/termination of employment.

10.2.3.7. **Banking details**. The onus is upon each Inventor/Enabler to ensure that the University has their current banking details for the purpose of revenue sharing. The University will keep the relevant IP revenue amounts in reserve for a maximum period of 3 (three) years after which all rights of

Inventors/Enablers to receive such payments will be forfeited. If the University pays an amount into an incorrect account as a result of information supplied to it being outdated or incorrect, the University will not have any further obligation or liability in respect of such payment, which will be deemed to have been duly and properly made.

10.2.4. **Sharing of revenues – University**. The University's share of Net IP Revenue is distributed internally as follows:

In case of allocation of Enabler's Share 5% to IPRC; 5% to University overheads. In case of no identifiable Enablers

10.3. Other Incentives

10.3.1. **General.** As a default position, the University will refrain from accepting non- monetary benefits for the Commercialization of its IP or from offering incentives other than revenue sharing, unless they are in addition to the revenue sharing as per 10.2.3.1 and 10.2.3.2, as appropriate. The University will thus give consideration, on a case-by-case basis, to the provision of other incentives, where monetary benefits (revenues) are not available or where the Inventor/Enabler elects to choose other benefits *in lieu of* revenue sharing, which may only be realized in due course. Other incentives will include, but are not limited to, the incentives described in Article 10.3.2. – 10.3.4.

10.3.2. **Growth, development and acknowledgement**. A framework for growth and development of the Inventor/Enabler in their professional and personal capacity shall be developed including (i) recognition of IP generation and Commercialization

performance in appraisal procedures; and (ii) opportunities for enterprise development or capacity development through, for example, specific training opportunities, sabbaticals, and local and international exchanges in their relevant Research field or in their area of interest.

10.3.3. **Research funds**. The University will actively, though its IPRC, promote, source and/or facilitate collaborative arrangements with industry partners to secure funding for further Research for the Inventors/Enablers.

10.3.4. **Inventor/Enabler receiving shares in a Commercialization Entity or other licensee**.

10.3.4.1. In the case where an Inventor/Enabler is granted equity in a Commercialization Entity that licenses the University IP which the Inventor/Enabler has created, such Inventor's/Enabler's portion will be adjusted accordingly, taking into account the shares held in the company by the Inventor/ Enabler. All other Inventors/Enablers will be rewarded in accordance with the formula in Article 10.2.3.1 or 10.2.3.2.

10.3.4.2. Where the University, either directly or indirectly, receives shares in a licensee company, which company may be a Commercialization Entity, as consideration for an IP license, the University,

- may hold, either directly or indirectly, all the shares until liquidation, at which time the income will be considered Gross IP Revenue and the Inventors/Enablers will receive their share according to the revenue sharing formula in Article 10.2.3.1 or 10.2.3.2.
- Or take steps such that the Inventors/Enablers will be issued their licensee company shares in the revenue sharing proportions, at the time the shares are issued to the University by the licensee.

10.3.4.3. Notwithstanding the benefit sharing in respect of shares in terms of this Article 10.3.4, the Inventors/Enablers will still be entitled to their share of any other revenues under the IP license.

10.4. Contact Details

10.4.1. **Contact details**. The onus is upon each Inventor/Enabler to ensure that the University is in receipt of their current address details for the purpose of revenue sharing. Unless contrary to law, should the University be unable to locate the Inventors/Enablers through reasonable efforts, in order to effect payment of the revenue share amount, and a period of two years has passed since an initial attempt, then the portion owed to that Inventor/Enabler or his/her heirs will be paid to the University's central fund to be used to support Research and innovation activities.

A
ARTICLE 11 - IP PORTFOLIO MAINTENANCE

11.1. **Recording and monitoring**. IPRC shall maintain records of the University's IP in an appropriate form and in sufficient detail. It shall monitor the deadlines for the payment obligations related to the maintenance or annuity fees of protected IP, and shall, within a reasonable time, inform the person or department designated to make such payments.

11.2. **Accounting**. IPRC shall maintain income/expense accounting records on each IP so that revenue sharing allocations can be calculated.

ARTICLE 12 -DISPUTE

12.1. **Violation.** Breach of the provisions of this Policy shall be

dealt with under the normal procedures of the University, and in accordance with the relevant provisions of laws and regulations in force.

12.2. **Dispute Resolution**

12.2.1. Any internal disputes or questions of interpretation arising under this Policy must in the first instance be referred to IPRC for consideration and mediation by the IPR Committee.

12.2.2. If the matter cannot be resolved by the IPRC and IPR Cell Committee within two months, then the dispute or question of interpretation must be referred to the Vice Chancellor for mediation.

12.2.3. The Vice Chancellor may at their sole discretion refer the matter to University's Executive Committee and/or an independent committee for arbitration as final arbiter of any disputed issues or for final determination.

12.3. **Appeal**. Individuals covered by this Policy shall have the right to appeal the application of any aspect of this Policy to the IPR Cell Committee.

ARTICLE 13 - AMENDMENT

13.1. **Revision**. This Policy may be amended at any time by a decision of the IPR Cell Committee. In this case:

a. all IP disclosed on or *after* the effective date of such amendment shall be governed by the Policy as amended; and
b. all IP disclosed *prior* to the effective date of the amendment shall be governed by the Policy prior to such amendment, provided that the provisions of the Policy (as amended) shall apply to all IP licensed or otherwise Commercialized on or after the effective date of any such amendment regardless of when the IP is disclosed.

Policy for Startup

ARTICLE 1- INTRODUCTION

1.1. Context and the University Mission

1.1.1. The core mission of the Krishna Institute of Medical Sciences Deemed University, Karad is to encourage the interdisciplinary research so as to generate a meaningful outcome for the community and nation.

1.1.2. To identify the effects of entrepreneurship in identifying and solving scientific and technical challenges and to acknowledge the role of startups in commercializing the Intellectual Property (IPR) resulting from its research activities.

1.1.3. The University will strive hard to encourage its staff and learners to take up entrepreneurship and prioritize the commercialization of its IPR in such a manner that will foster entrepreneurship by faculty and other stakeholders.

1.2. Purpose of the Startup Policy

1.2.1. **Promotion of Entrepreneurship**. The Startup Policy intends to encourage an entrepreneurial ecosystem which fosters co-creation by involving learners, faculty and professionals from multiple disciplines. Also, it lays down guidelines for the involvement of the University's staff and learners.

1.2.2. **Entrepreneurship management**. The Startup Policy seeks to set the framework for the involvement of the University's Staff and Learners in Commercializing University's Research into products, services and processes. It encourages staff members, learners and visitors to become entrepreneurs. It also establishes clear rules and procedures for the creation/participant Ration of Staff and Student-led Startups which may or may not be based on the University IPR.

1.2.3. **Entrepreneurs IPR guidance**. The Technology Incubator established in the University campus will provide the entrepreneurship with the necessary guidance, IPR mentors and infrastructure support to nurture their ideas and help to translate them into successful startups.

1.2.4. **Balance of interests**. The Startup Policy seeks to emphasize that the primary commitment of time and intellectual contributions of an employee should be on the education, research and other obligations of the University and their primary professional obligation is to act in the best interests of the University. Therefore, all the Staff Members, Learners and the Visitors of the University must take care to avoid any cases of Conflict of Interest (COI) and Conflict of Commitment (COC).

1.2.5.

ARTICLE 2 -DEFINITIONS

The following definitions set out in this policy shall apply without prejudice to any applicable laws:

2.1. **Appointment**. A formal agreement for a Visitor at the University, which is a prerequisite to paretic IPR ate in or conduct Research, scholars IPR, creative work, or teaching at the University.

2.2. **Author**. Any person to whom this Policy is applicable, who individually or jointly with others makes a design, a mark or copyrightable work and who meets the criteria for authors IPR under the IPR laws of India.

2.3. **Conflict of Commitment (COC)**. Any situation in which an individual Staff Member's or Visitor's primary professional loyalty is not to the University because the time devoted to outside activities adversely affects their capacity to meet their responsibilities as set out in their employment agreement of Appointment, respectively.

2.4. **Conflict of Interest (COI)**. Any situation in which real or perceived interests of an individual Staff Member, Visitors, Learners, may run counter to the interests of the University or negatively affect their employment or duties.

2.5. **Gross Non-IPR Revenue.** All revenue received by the University for Execution of Projects / Scientific or Clinical Work as part of the Research Agreement before any cost recovery or deductions for the incurred expenses, as defined in Article 7.

2.6. **University**. Krishna Institute of Medical Sciences Deemed University.

2.7. **University IPR**. IPR owned or co-owned by the University.

2.8. **Intellectual Property (IPR)**. All outputs of creative endeavour in any field at the University for which legal rights may be obtained or enforced according to the law. IPR may include:

a. literary works, including publications in respect of Research results, and associated materials, including drafts, data sets and laboratory notebooks;
b. teaching and learning materials;
c. other original literary, dramatic, musical or artistic works, sound recordings, films, broadcasts, and typographical arrangements, multimedia works, photographs, drawings, and other works created with the aid of University resources or facilities;
d. databases, tables or compilations, computer software, preparatory design material for a computer program, firmware, courseware, and related material;
e. patentable and non-patentable technical information;
f. designs including layout designs (topographies) of integrated circuits;
g. plant varieties and related information;
h. trade secrets;
i. know-how, information and data associated with the above; and
j. Any other University-commissioned works not included above.

2.9. **IPR Cell**. The administrative unit established in terms of Article 4.2, responsible for the day-to-day management of all IPR-related activities of the University.

2.10. **Policy**. Krishna Institute of Medical Sciences Deemed University Startup Policy.

Staff Member. Any person who is under a agreement of employment with the University including academic, research, technical, administrative and adjunct staff, whether full-time or part-time or temporarily.

2.11. **Student**. Any student registered for an approved course at the University.

Substantial Use. Extensive use of the University's resources which include but are not limited to facilities, equipment, human resources or funds. Not included is the routine use of libraries and/or office space or the IPR has been written or developed in the personal (unpaid) time of the Inventor.

2.12. **University Incubator.** Krishna Institute of Medical University for Technology Incubation also referred to as Krishna Technology Incubator (KTI) or Incubator or Technology Incubator.

2.13. **Visitor**. Any person who is neither a Staff Member nor a Student of the University who engages in work at the University, including visiting professors, adjunct and conjoint professors, teachers, researchers, scholars and volunteers; and who concludes an appointment agreement with the University.

ARTICLE 3 – SCOPE OF THE POLICY

3.1 **Applicability**. This Policy applies to all Staff Members, Learners

and Visitors who are willing to or may have started a commercialization entity (Company/Startup) which may or may not be based on the University IPR. Rights and obligations under this Policy shall survive any termination of employment, enrolment or Appointment at the University.

3.2 **Binding effect of the Policy**. This Policy constitutes an understanding that is binding on the University, Staff Members, Learners and Visitors, once adopted by the Board of Management (BOM) of the University.

3.3 **Type of Companies**. This University encourages and promotes the following companies.

3.3.1 Companies jointly owned by the Staff Members and Graduating Learners/Alumni.

3.3.2 Companies owned by the Staff Members (one or many) along with possibly others.

3.3.3 Companies owned by the Graduating Learners, Alumni along with possibly others

In such cases, the Staff Members and Learners will be known as founding members of the board of the company.

3.3.4 A company of a specific domain with which the university has signed MoU for the purpose.

The use of the term 'company' in throughout this document refers to the types of companies mentioned above unless specified otherwise.

ARTICLE 4–EXECUTION AND OPERATION

4.1. **Responsibilities**. Vice-Chancellor of the University will be the ultimate decision-making authority in the determination of the permission to the Staff and Student-led Startup.

4.2. **Entrepreneurship Promotion Cell (EPC)**

4.2.1. **Purpose**. The University has established an Entrepreneurship Promotion Cell (EPC) to assist the University in promotion of entrepreneurship and organizing relevant activities like Workshops and other events.

4.2.2. **Responsibilities**. The responsibilities of the EPC shall include, but are not limited to:

- Outreach/awareness;
- Relationship management with potential entrepreneurs;
- Coordinating with the IPMC for IPR licensing;
- Organizing entrepreneurship promotion activities and events

ARTICLE 5–COLLABORATION IN THE COMPANY

5.1 Role of the Staff Members

It is expected that the staff members would be owners of

companies defined in Article 3 and Director on the Board. Also, the staff member may choose to play an operational role as coordinator to make follow up about the progress time to time.

5.1.1 **Startup engagement**. The staff member can choose one of the following options:

5.1.1.1 Take a sabbatical and work full-time in the business.

5.1.1.2 Dedicate up to 4 working days per month for the Startup related activities with due permission from the Registrar of the University.

5.1.2 **Conflict of Interest and Conflict of Commitment**. It should be noted that the staff should take all possible steps to ensure that his/her duties and responsibilities of the University take precedence over all other activities.

5.2 Role of the Learners

During their enrolment, the learners will be allowed to be owners of the companies, as defined in Article 3, be Director on the Board or be employed in a staff member led company. Also, they may be free to play an operational role as coordinator to make follow up about the progress time to time.

5.2.1 **Startup engagement**. Learners will be free to dedicate any time outside their regular academic hours and duties towards their companies. However, if deemed necessary, they may be allowed a special leave towards startup activities subject to approval from the respective department heads and under no

circumstance they will be allowed to avail this leave during the time of their scheduled exams.

5.2.2 **Theses or dissertations**. The learners may be allowed to base their Startup on their theses or dissertation with due approval from their supervisor. All the University regulations related to Theses or dissertation including the University IPR policy will apply.

5.3 Incubation

5.3.1 **University IPR**. If a Staff or a Student intends to base their Startup on the University- owned IPR for which they may or may not be the inventors, they will be required to incubate their company in the University Incubator. Licensing or allocation of the IPR will be governed as per the University IPR Policy.

5.3.2 **No IPR / External IPR**. In case the Staff or Student-led Startup is based on IPR not owned by the University or if no IPR is involved, they may be free to incubate their company either in the University Incubator or outside the University. However, if the company is housed outside the University Incubator, the benefits outlined in Section 5.1.1 and Article 6 and 7 may not be applicable.

ARTICLE 6– USE OF UNIVERSITY RESOURCES AND IPR RIGHTS

6.1 Staff and Learners. The Staff Members and Learners who are the promoters of the Startup housed in the University Incubator may be allowed to use University resources such as labs and other such facilities for their company purposes. Use of any such facilities and resources may not be charged during the incubation period, except for facilities and instruments which are not free for the internal users. To enable free access to the staff and student- led companies, equity may be retained by the University which will also ensure IPR ownership by the company as detailed in section 6.3. The use of space and resources of the University Incubator will be governed as per the norms of the University Incubator.

6.2 Company Employees. The University resources are generally not accessible to anyone who is not associated with the University, either as an employee or a student. Permission from the facility in-charge or department head will be required for involving company employees who are not associated with the University.

6.3 IPR Rights and Ownership. Any IPR developed by the incubated company while using University resources shall be the property of the company. However, before filing such IPR application the permission of KIMSDU is necessary. The company is expected to grant a non-exclusive, royalty-free

license to the University to the IPR generated by the company while using University resources for non-commercial purposes.

ARTICLE 7– UNIVERSITY SUPPORT

7.1 Incorporation. The University may help the staff members and the learners in the form of incorporation fees and guidance for incorporation of the company. This may also include support in form of company's annual maintenance any charges incurred towards its compliance.

7.2 Funding. The University may provide funding support to the companies in the form of grant in aid, seed grant and loan. Equity in the supported companies may be taken up as described in Article 8.

7.3 Mentorship and Guidance. University will provide necessary mentorship and guidance through the Incubator free of cost.

7.4 Special Leaves. Staff Members are expected to ensure the success of their Startups by dedicating efforts and time required. Keeping this in view University will allow Staff to involve in their companies in one of the following ways.

5.4.1 Take a sabbatical and work full-time in the company.

Dedicate up to 4 working days per month for the

Startup related activities with due permission from the Registrar of the University.

7.5 Equity. The University, either directly or through a designated individual or organization, may exercise its discretion in taking up equity in the company in the following cases.

7.5.1 Equity against freedom to use University resources including the IPR.

7.5.2 Equity against incubation.

7.5.3 Equity against seed grants and/or grant in aid.

7.5.4 Equity against loan provided by the University.

For sections 7.4.1, 7.4.2 and 7.4.3 the maximum equity University may take up in the company should not exceed 10%. Equity against any loan provided by the University will be independent of this equity limit.

ARTICLE 8 -DISPUTE

8.1. **Violation.** Any breach of the provisions of this Policy shall be dealt with under the normal procedures of the University, and by following the relevant provisions of laws and regulations in force.

8.2. Dispute Resolution

8.2.1. Any internal disputes or questions of interpretation arising under this Policy must in the first instance be referred to EPC.

8.2.2. If the matter cannot be resolved by the EPC within two months, then the dispute or question of interpretation must be referred to the Vice-Chancellor for mediation.

8.2.3. The Vice-Chancellor may at their sole discretion refer the matter to Board of Management and/or an independent committee for arbitration as the final arbiter of any disputed issues or for final determination.

Financial support for implementation of Research projects

A limited financial support will be provided for the conduct of research studies undertaken by the KIMSDU staff and the students. This support will be provided to meet expenditure incurred for study specific diagnostic tests etc., while implementing the research project. The staff and the students are entitled for this support as shown below. The limit of such fund should be considered while planning the study. A budget with justification be prepared and attached with the protocol.

Research project by the undergraduate student	Up to Rs. 10000/-
Research project by the postgraduate student	Up to Rs. 1,50,000/-
Research project by the staff & PhD student	Up to Rs. 2,50,000/-

Note: PhD projects with budget exceeding the entitled limit of 2.5 Lakhs will be reviewed separately on the basis of type of study, outcome value, number and quality of expected publications, for special sanction of additional funds from the Hon. Vice-Chancellor

- **Procedure :**

  Entitlement:

  KIMSDU staff & students, whose proposal is approved by the protocol committee and the institutional Ethics committee, are entitled to apply.

Application:

Eligible investigator shall apply in the format enclosed, to the office of the Director of Research. After review, an approval letter will be issued to the investigator.

Mode of disbursement of fund:

1. The investigator will not be paid cash for tests done at KIMSDU facilities. Instead, the relevant laboratory/department will provide services for the tests on submission of approval letter which will be used by the departments/laboratories to indent additional reagents/kits etc. from the store.
2. Expenditure made for the tests/ reagents/services purchased from outside will be reimbursed on submission of relevant bills/receipts/invoices in original, to the Department of Research. Due financial procedures such as three quotations need to be followed while identifying external source for services.

Application for Research Study Expenditure Support

Name of the investigator:-

Status of the investigator:-UG student / PG student / PhD student / Faculty with designation

Department & college/institution:-

Number of the study protocol:-

Title of the research study:-

Name, designation & affiliation of the Guide/mentor :-

Date of IEC approval:-

Support requested for:-

1. **Budget of the project:** To be submitted as per the following format. Additional applicable details if any may also be provided

- **Details of the investigations/procedures planned in house**

Sr. No.	Name of investigation / Procedure	Number to be performed	Name of the department	Unit cost	Total cost
1					
2					

- **Details of the reagents/equipment/ planned to be purchased through the store**

Sr. No.	Name of reagent /Kit/ Equipment	Number to be purchased	Unit cost	Total cost
1				
2				

- **Details of the investigations/procedures planned to be outsourced**

Sr. No.	Name of investigation / Procedure	Number to be performed	Unit cost	Total cost
1				
2				

Signature & date of investigator

Certified that the above budget is appropriate & recommended for sanction

Signature & date of Guide

Recommended for sanction

Signature & date of HOD

Short term fellowship for undergraduate students of all faculties

I. Intent :

Short term fellowship is established to inculcate research culture among the undergraduate students. The fellowship is awarded to encourage undergraduate students to understand research methods and to undertake small research study to gain practical experience. STS is a short term studentship offered to undergraduate students of Medicine and Dental faculty by the ICMR. In order to encourage UG students from other faculties, Short term fellowship (STF, KIMSDU) is offered to them on similar terms and conditions by the KIMSDU.

II. Short Term Research Studentship (STS, ICMR) :

a. Eligibility :

Undergraduate students of Medicine and Dental faculty

b. Duration

Total one year (research work 6 months)

Procedure and Terms :

Deserving UG students will be encouraged to participate in the STS fellowship programme of the ICMR. They will be briefed on STS fellowship. Interested Students, in consultation with allotted mentor, will prepare and submit a brief write up describing Title, Rationale, Aim & objectives, Material and Methods, data analysis plan and expected yield. One faculty will mentor only one student. The submitted protocols will undergo a review (by institutional protocol review

committee and Institutional Ethics Committee) and the students will be provided guidance on improvisation of the protocols. IEC approved studies will be undertaken by the students. The Institution will provide the student with all facilities for carrying out research. An amount of up to Rs. 10, 000 will be sanctioned for implementation of the study wherever required. On completion of the study, the student will prepare and submit the report to the ICMR. The student will be awarded stipend of Rs. 10,000 and certificate by the ICMR, only if his/ her report is approved.

Students will be encouraged to publish his/her work in an indexed & reputed journal with him/her being the first author. Publication from such study will attract additional financial incentive as per the university policy.

III. Short Term Research Fellowship (STF, KIMSDU) :

The STF fellowship will be offered to the deserving undergraduate students of all faculties. The Procedure and Terms of the fellowship will be same as that of STS excepting following changes.

1. For STF, One faculty may guide up to two students.
2. The Institution will provide the student with all facilities for carrying out research. An amount of up to Rs. 10,000 will be sanctioned for implementation of the study wherever required.
3. On successful completion of the study, student will submit manuscript for publication in an indexed and a reputed journal with him/her being the first author.

4. A stipend of Rs. 10,000 will be granted after publication of the research paper
5. Both, STS and STF projects will need approvals from protocol review committee and Institutional Ethics Committee as well.
6. The student will be awarded stipend and certificate on successful completion of the project

Policy for Prevention of Plagiarism

Intent:

The University Grants Commission, New Delhi has recommended implementation of technology based mechanism using appropriate software to ensure that the documents such as thesis, dissertation, publication or any other such documents are free of plagiarism at the time of their submission. This policy has been established at the university to create awareness about responsible conduct of research, to promote academic integrity and to prevent misconduct including plagiarism in academic writing among student, faculty, researcher and staff of the university.

As per this policy, all the above mentioned documents generated by the staff and students of the university will be mandatorily subjected to plagiarism verification.

Administration:

The administration of anti plagiarism activity at the University will be managed by the Departmental Academic Integrity Panel (DAIP) as constituted by the Hon'ble Vice Chancellor at faculty level and the

Institutional Academic Integrity Panel (IAIP) of the University, also constituted by the Hon'ble Vice Chancellor as a central body. Composition of DAIP and IAIP are shown in annexure V.

Departmental Academic Integrity Panel (DAIP)

A separate DAIP has been established for each of the six faculties (Medicine, Dental, Nursing, Physiotherapy, Pharmacy and Allied Sciences) of the university. The composition of each of these DAIPs, tenure of the members and the quorum required for the meetings has been shown in the Annexure V

Role of the DAIP

The DAIP shall follow the principles of natural justice while deciding about the allegation of plagiarism against the student, faculty researcher and staff of the faculty

The DAIP shall have the power to assess the level of plagiarism and recommend penalty(ies) accordingly

The DAIP after investigation shall submit its report with the recommendation on penalties to be imposed to the IAIP within a period of 45 days from the date of receipt of complaint/ initiation of the proceedings

Institutional Academic Integrity Panel (IAIP)

An University Academic Integrity Panel has been established at the University. The composition of the IAIP, tenure of the members and the quorum required for the meetings has been shown in the Annexure V

Role of the IAIP

The IAIP shall consider the recommendations of DAIP.

The IAIP shall also investigate cases of plagiarism.

The IAIP shall follow the principles of natural justice while deciding about the allegation of plagiarism against the student, faculty researcher and staff of the University.

The IAIP shall have the power to review the recommendations of DAIP including penalties with due justification.

The IAIP shall send the report after investigation and the recommendation on penalties to be imposed to the Honorable Vice Chancellor within a period of 45 days from the date of receipt of recommendation of DAIP/complaint/ initiation of the proceedings.

The IAIP shall provide a copy of the report to the person(s) against whom inquiry report is submitted

Detection/ Reporting/Handling of Plagiarism

If any member of the academic community suspects with appropriate proof that a case of plagiarism has happened in any document, he or she shall report it to the DAIP. Upon receipt of such a complaint or allegation the DAIP shall investigate the matter and submit its recommendation to the IAIP

Honorable Vice-Chancellor of the university can also take *suomoto* notice of an act of plagiarism and initiate proceedings. Hon'ble VC can also initiate proceedings on the basis of findings of an examiner. All such cases will be investigated by the IAIP

Procedure:

1. All documents such as thesis, dissertation, publication or any other such documents generated by the staff and students of the university will be mandatorily subjected to plagiarism verification.
2. The student shall submit his thesis/dissertation along with the undertaking and a certificate from the supervisor, to the Directorate of Research for plagiarism verification and obtain a 'plagiarism verification certificate' before submission to the examination section.
3. Author shall submit his/her manuscript along with the undertaking to the Directorate of Research for plagiarism verification and obtain a 'plagiarism verification certificate' before submission to the journal for publication
4. Undertaking:

   Every stake holder (students, faculty, researchers and staff) shall have to submit an undertaking indicating that the document which has been prepared is his / her original work. (Template has been provided in Annexure V

   In case where the submitted document is supervised, the supervisor shall also endorse that the document is plagiarism free. (Template has been provided in Annexure V

   Software:
5. A software, will be used for plagiarism verification
6. Exclusion for similarity checks

Following parts of the document will be excluded from similarity check

a) All quoted work reproduced with all necessary permission and / attribution
b) All references, bibliography, table of content, preface and acknowledgements
c) All generic terms, laws, standard symbols and standard equations

Note: The research work carried out by the student, faculty, researcher and staff shall be based on original ideas, which shall include abstract, summary, hypothesis, observations, results, conclusions and recommendations only and shall not have any similarities. It shall exclude a common knowledge or coincidental terms, up to (14) consecutive words.

7. A plagiarism verification certificate will be issued by the Directorate of Research after the document is checked and if the similarity is found to be up to 10 percent.

8. In cases where, the similarity is found to be above 10 percent, the Directorate of Research will send the plagiarism verification report to the concerned DAIP for further processing.

Levels of Plagiarism and Penalties

Levels of plagiarism and the penalties according to severity as defined by the UGC will be determined and implemented as follows:

Penalties in the cases of plagiarism shall be imposed on students pursuing studies at the level of Masters and research programs and on researcher,

faculty and staff of the university only after academic misconduct on the part of the individual has been established without doubt, when all avenues of appeal have been exhausted and individual in question has been provided enough opportunity to defend himself or herself in a fair or transparent manner

A) Levels of plagiarism and level-wise penalties in submission of thesis and dissertation

Levels of plagiarism	**Penalties for submitted Dissertation / Thesis**
Level 0: Similarities up to 10% (minor similarities)	No penalty
Level 1: Similarities above 10% to 40%	Such student shall be asked to submit a revised script within a stipulated time period not exceeding 6 months.
Level 2: Similarities above 40% to 60%	Such student shall be debarred from submitting a revised script for a period of one year
Level 3: Similarities above 60%	Such student registration for that programme shall be cancelled.

Note 1: Penalty on repeated plagiarism- Such student shall be punished for the plagiarism of one level higher than the previous level committed by him/her. In case where plagiarism of highest level is committed then the punishment for the same shall be operative.

Note 2: Penalty in case where the degree/credit has already been obtained- If plagiarism is proved on a date later than the date of award of degree or credit as the case may be then his/her degree or credit shall be put in abeyance for a period recommended by the IAIP and approved by the Head of the Institution.

B) Levels of plagiarism and level-wise penalties in academic and research

Levels of plagiarism	**Penalties for academic and research publications**
Level 0: Similarities up to 10% (minor similarities)	No penalty
Level 1: Similarities above 10% to 40%	(i) Shall be asked to withdraw manuscript
Level 2: Similarities above 40% to 60%	(i) Shall be asked to withdraw manuscript (ii) Shall be denied right to one annual increment (iii) Shall not be allowed to be a supervisor to any new Master's, M. Phil., Ph. D. student/scholar for a period of two years
Level 3: Similarities above 60%	(i) Shall be asked to withdraw manuscript (ii) Shall be denied right to two annual increment (iii) Shall not be allowed to be a supervisor to any new Master's, M. Phil., Ph. D.

	student/scholar for a period of three years

Note 1: Penalty on repeated plagiarism - Shall be asked to withdraw manuscript and shall be punished for the plagiarism of one level higher than the lower level committed by him/her. In case where plagiarism of highest level is committed then the punishment for the same shall be operative. In case level 3 offence is repeated then the disciplinary action including suspension/termination as per service rules shall be taken by the University.

Note 2: Penalty in case where the benefit or credit has already been obtained - If plagiarism is proved on a date later than the date of benefit or credit obtained as the case may be then his/her benefit or credit shall be put in abeyance for a period recommended by IAIP and approved by the Head of the Institution.

Note 3: Heads of Institute shall create a mechanism so as to ensure that each of the paper publication/thesis/dissertation by the student, faculty, researcher or staff is checked for plagiarism at the time of forwarding/submission.

Note 4: If there is any complaint of plagiarism against the Head of Department/Authorities at the institutional level, a suitable action, in line with these regulations, shall be recommended by the IAIP and approved by the Competent Authority.

Note 5: If there is any complaint of plagiarism against any member of DAIP or IAIP, then such member shall excuse himself / herself from the meeting(s) where his/her case is being discussed/investigated.

Note 6: If there is any complaint of plagiarism against any member of DAIP or IAIP, then such member shall excuse himself/herself from the meeting(s) where his/her case is being discussed/investigated

Policy for Attending Conferences / Seminars / CMEs / Workshops / Panel Discussion / Guest Lectures / Orations

I. Intent:

Scientific activities like Conferences / Seminars / CMEs / Workshops / Panel Discussion / Guest Lectures are important as specialists from all over the region / nation / world come together and there is an exchange of scientific information. These scientific activities relate to professional development programme of the University, it therefore encourages attending of various scientific activities.

II. Eligibility:

1. All U.G., P.G. and Ph. D. students, Assistant Professors / Associate Professors as well as Research Assistants, Deans and Directors are eligible to attend the scientific activities.

2. All professors and higher rank of teachers can organize and conduct Regional/National and International Scientific event.

3. All eligible staff members can annually attend following events with prior permission from the Director of Research.

- **a.** One International Scientific activity if organized in India
- **b.** One National scientific activity and
- **c.** One Regional scientific activity
- **d.** For attending additional scientific events, permission will be granted by Hon'ble Vice Chancellor.

Participation in the scientific activity organized outside of India.

4. Faculty can participate in the scientific activity organized outside of India only on prior approval of the Hon. Vice-Chancellor. Such approvals should be obtained at least 3-4 months in advance
5. Faculty can participate in the scientific activity organized outside of India only if he/she is in continuous service of the University for a minimum period of three years.
6. Faculty can participate, once in two years, in the international scientific event organized outside of India only if he / she is the first author and is presenting a paper by oral presentation with a prior permission from the Hon. Vice- Chancellor
7. **Faculty can participate in these events only if such event is organized by a reputed organization / Reputed Society / Reputed Association of Researchers and not by a commercial organisation.**

III. Entitlement:

- **Leave**

  A special casual leave will be granted for the period of activity and travel for such participation.

- **Financial Support**

  a. All eligible staff members who are presenting oral or poster paper or are invited as chairpersons at the National or Regional scientific event as well as International Scientific event organised in India, will

get financial support for attending the scientific activity as per the existing TA/DA admissibility.

b. All staff members of the rank of professor and / or above will get financial support for participation in the conference even when they are not presenting any paper.

c. For attending international scientific event organized outside India, only the faculty who is first author and is presenting a paper by oral presentation can avail the facility of 50% financial support as shown in item ii.

IV. Terms of Financial support for attending Scientific Event:

i. Reimbursement for attending scientific activities conducted in India will be as follows :

- Full registration fees
- Full travel expense as per eligibility of the rank of the staff member.
- Daily allowance @ Rs. 200 per day for the period of scientific activity in addition to the period of travel.
- Cost of accommodation will not be reimbursed
- Reimbursement will be made only on submission of valid receipts

ii. Reimbursement for attending scientific activity conduced outside of India will be as follows :

- 50% of registration fees

- 50% travel by air by economy class
- 50% cost of reasonable accommodation for the period of activity plus two more days.

V. Procedure:

1. The eligible staff members should apply through proper channel at least 15 days in advance of the scientific activity for the event in India through proper channel to the Director of Research, giving all the details including title, duration, place of organization and whether the eligible staff member is presenting a paper by oral or poster presentation or not as well as whether he/she is chairing a session or not.

2. All eligible staff members for attending international scientific event should apply three months in advance through proper channel giving the details of the scientific event and a Xerox copy of the paper along with a Xerox copy of the letter from the organzing secretary /chairman of scientific committee indicating acceptance of paper for oral presentation.

Note: For participation in the event out of India, the concerned individual should not pay for registration, booking tickets, booking accommodation etc. until the university approval has been obtained

3. Reimbursement of registration fee travel and daily allowance admissible to the deputed staff/student as per rule will be given after submission of receipts to the finance officer by the eligible

staff members permitted to attend the scientific activity by the Director of Research.

Policy for conducting National and International Conferences and Workshops / CMEs

I. Intent

Scientific activities like Conferences/Seminars/CMEs/Workshops/Panel Discussion/Guest Lectures are important as specialists from all over the region/nation/world come together and there is an exchange of scientific information. These scientific activities relate to professional development programme of the University. Organisation of such scientific events at the university campus offers additional advantage that a large number of faculty and the students of the university can be benefited by participation. The KIMSDU encourages senior staff to annually organize at least one national and one regional event and an international conference once in two years by each of the disciplines.

II. Terms of Financial support for Conducting Scientific Event:

Financial support will be sanctioned by the Hon. Vice- Chancellor, KIMSDU for organization of scientific event at the university as shown below. Sanctioned amount will be deposited in the conference account in advance from which the organizing secretary will withdraw funds to meet the expenditure.

Scientific Activity	Amount applicable (INR)
International Conference	10 lakhs
National Conference	5 lakhs
Regional Conference	5 lakhs

Interdisciplinary Conference	3 lakhs
Workshop/CMEs	50,000

III. Procedure:

1. For organizing a scientific event, an application by the organizing Chairman / secretary with estimate of budget should reach the Director of Research at least 2 months in advance through proper channel.
2. On recommendation from the Director of Research and approval by the Hon. Vice-Chancellor, the finance officer would release and deposit the grants in the conclave account of the university.
3. The account of the event should be appropriately maintained and audited.
4. Statement of income & expenditure should be submitted to the finance officer with a copy to the office of Director of Research within a period of three months after the event is over.
5. Convenor of the activity (Conference, CME, workshop) should upload details on the dedicated website created by the University, through conference website cCoordinator Ms. Archana Kaulagekar, Assitant Registrar (Academics).
6. The URL of this website is www.conference.kimskarad.in. The link is also provided on the university website – www.kimskarad.in

IV. Criteria:

1. The applications of the staff and students should be duly recommended by the professor and Head of the Department and

Dean of the concerned faculty. Benefit to the Institute by participation of the staff in the event, should be clearly stated for scientific activities where presentation of papers/posters is not undertaken.

2. If the scientific event clashes with some other important function of the university, the special casual leave or deputation will not be sanctioned or cancelled at the eleventh hour.

Policy for providing Consultancy Services

I. Intent :

There are many experts in their own academic field and there are many laboratory facilities available in Krishna Institute of Medical Sciences Deemed University which can help other institutions in improving health care of the population they are catering to. The university encourages the consultancy services of the staff working at Krishna Institute of Medical Sciences Deemed University.

II. Eligibility :

1. All members of the faculty at the Assistant Professor, Associate Professor, Professor, Dean or Director can render consultancy services.

2. All the facilities available at Krishna Institute of Medical Sciences Deemed University can be made available at reasonable cost to other institutions on signing MOU/ Agreement between the two parties.

III. Terms of Consultancy :

Terms for providing consultancy services from Krishna Institute of Medical Sciences Deemed University.

1. The designated authority of the institute, seeking consultancy services, should apply to the Hon. Vice Chancellor of Krishna Institute of Medical Sciences Deemed University to obtain permission for the consultancy services.

2. Staff of Krishna Institute of Medical Sciences Deemed University may provide consultancy services on obtaining due permission from the designated authority.
3. For the purposes of consultancy by the staff members, Deans of the constituent faculties will be the designated authority of Krishna Institute of Medical Sciences Deemed University.
4. For the consultancy of Deans, the Hon. Vice-Chancellor would be the designated authority.
5. For the use of facilities at Krishna Institute of Medical Sciences Deemed University, the Hon. Vice-Chancellor would be the designated authority.

IV. Procedure :

1. The designated authority would contact the concerned staff member and ask his willingness, will see the feasibility of sparing his services for the duration for which the consultancy services are requested.
2. The organization seeking the consultancy services should bear the expenditure of travel of the expert and offer reasonable remuneration for the services and/ or recognize the services which should be clearly mentioned in the letter to the designated authority.
3. The designated authority would give permission if it does not interfere with the working of Krishna Institute of Medical Sciences Deemed University.

4. KIMSDU staff should provide information with details to the Directorate of Research in a timely manner.

V. Criteria :

1. Consultancy services to other institutes should be offered at a time which is mutually convenient.
2. There should not be any loss to Krishna Institute of Medical Sciences Deemed University for offering facilities to other institutions.

Policy for Extension / Outreach Activities

The Institution organizes Community based outreach programs with students and faculty engagement. It aims at reaching the nearby communities specially the underprivileged and needy population.

The institution's social responsibility is being carried out through a wide range of activities addressing the societal needs as well as sensitizing the students and faculty about problems at community based health issues and creation of awareness about healthy way of living participation in community level outreach programs and to help and invoke social responsibility among them. Mutual benefits from such interaction is for both, the community and the students and develop a holistic approach. For carrying out all extension and outreach activities a cell is created comprising of Diretor, Member Secretary and 5 members representing each faculty.

A. Functions :

1. Preparation of time table for routine and special extension activities for every year for the university.
2. Instructions to be given to all teachers responsible for concerned activities –
    - For planning the activity
    - For vehicular arrangements
    - Approaching community leaders/influential persons
    - Giving report of the activities

3. Arrangement for health care of referred cases/card holders as a result of extension activity.

B. Powers :

To ensure regular extension activities as per schedule and to give the students repeat if attendance is not up to 80% level.

C. Objectives :

1. To serve the community by organizing regular need based extension program as a routine.
2. Students and faculty to be encouraged to participate in the program.
3. Celebration of 'health days and weeks' to create awareness and motivate population to change their behavior conducive to good health.
4. Involvement of community leaders and for full participation of the community.
5. To make extension activities integral part of learning and curriculum development.

D. Activities routinely undertaken by Medical / Dental / Physiotherapy / Nursing /Pharmacy and Biotech Colleges :

I. Medical and Nursing Colleges :

1. Specialist visit to adopted PHC's for antenatal, postnatal checkup, Counseling and contraceptive advise.

2. Neonatal and under 5 children's follow up and assessment of nutritional status.
3. Identifications and referrals of high risk pregnancy and neonates.
4. Advice regarding Breast feeding practices and problems.
5. Detection of STI/HIV infection in rural women population.
6. Immunization of mothers and neonates.
7. Counseling services for women seeking MTP/Tubal Ligation/ Contraceptive use.
8. Screening program for Ca-cervix, Ca-Breast including Pap smear, VIA and Cytology.
9. Identification of malnutrition, under nutrition in children at Aanganwadi centres - Rethare Bk & Shenoli and nutrition supplement follow up with parental counseling.
10. Training program under RCH
    a. Training of MO for emergency obst. Services (BEMOC).
    b. Training of ANM for skilled birth attendant (SBA).
    c. Training of ASHA workers.
    d. Training of Aanganwadi workers.
    e. Training of ANM for identification of PIH and Anaemia.
11. Posting of Interns and their training at PHC's
12. Organization of multi diagnostic camps

Number of participating department's are Community Medicine, Surgery, Ortho, Ob/Gynecology, Pediatric, Ophthalmology is decided as per request from the organizers. Beneficiary's record is maintained and 30-50% concession is offered for IPD admissions.

13. School Health camps are organized every year.

14. Special awareness camp's for emerging diseases like Dengue, Swine flue etc. arranged as per the need assessed.

15. Health and awareness programs on social issues are arranged for addressing the issues like Prevention of Female Feticide, Social and Gender Equity, Environmental issues, Cleanliness Drive, Tobacco Alcohol Abuse etc.

16. Extension activities related to National Health Programmes including National Blindness Control Program activities.

17. Blood Donation Camp including awareness and motivation.

18. Any othr activity which is notified by apical statutory body time to time.

19. Any activity which is not defined here and committee feels to be conducted such activities as a part of fulfillment or medico social responsibility can be conducted after due approval by Hon'ble Vice Chancellor.

II. Dental College :

- Mobile dental clinic screening and special camps and awareness program.

III. Physiotherapy College :

- Musculoskeletal Health Camp,
- Camp's for Geriatric group and disabled children camp.

E. Program Pattern :

- Individual College has program co-ordinator and team of faculty and students including Interns who participate regularly in the programme activities under NNS & Red Cross.
- Yearly program calendar is made and carried out.
- Involvement of local general practitioners from all pathies is ensured.
- Program is supervised and documented for the purpose of assessment of impact and benefits for the community.

Procedure:

- All the program activities are conducted free of charge.
- University provides the required facilities- Transport, Medicines, staff, students, interns etc.
- Referred patients from the health camp are given 30-50% concessions for IPD treatment up to a period of 1 month. OPD consultations are given free.

- Adopted community is informed about the yearly as well as monthly program. Special emphasis is on community participation and their suggestions for implementation of program. Besides above benefits, regular awareness and prevention programs are organized.

- Any other program or activity is organized if requested by the community, if feasible.

  The community based Health activities program conducted by Medical team of UG/PG students / Interns and faculty provide fruitful linkages and partnership of public and private sector. The community is benefited by way of free / subsidized quality Medical care, with a special focus and emphasis on preventive modalities. The community is encouraged to initiate and participate in all the activities. The outreach programs stand as a sound interface between Public Health, Medical Education and National Health Care Services.

Study / Sabbatical Leave Policy

I Intent:

A study / sabbatical leave reward for KIMSDU faculty will be a leave for the purpose of professional development and enrichment of the faculty members knowledge and for enhancement of his/her skills to further the ability in contributing to objectives of the University.

II Eligibility:

a. Members of the faculty holding the positions of Assistant Professor, Associate Professor or Professors of the University who have completed five years continuous full time service will be eligible for the sabbatical leave.

b. Study / Sabbatical leave can be taken for a period of 1 year at a time and a maximum of up to 3 times.

c. Once a faculty member avails of the leave he/she will not be eligible for the subsequent 7 years.

III Terms of Study / Sabbatical leave:

a. Study / Sabbatical leave will be without pay.

b. The staff who is awarded study / sabbatical leave will have to submit an undertaking that after the end of leave he/she will report to work on the same terms and conditions, and to the same position of employment that he/she had occupied prior to the leave.

c. It is presumed that the staff will return to the same incremental point at which he/she left, unless the experience is of distinct institutional benefit, such as to justify progression.

d. The faculty member granted a study / sabbatical must submit a written report at the conclusion of the leave outlining the activities and achievements of the study / sabbatical as they relate to the plans and objectives stated in the proposal.

e. The University reserves the right to deny a request for a leave, under exceptional circumstances when the services of the staff member are essential for the benefit of the University either for financial or educational reasons, even if the faculty member is eligible and the purpose of the leave is valid.

IV Procedure:

a. A formal letter of intent must be made in writing to the Hon'ble Vice-Chancellor through the HoD and the Dean of the constituent college with a copy to the Registrar of the University.

b. The application should be made six months in advance of the desired academic year for sabbatical.

c. Each application will be judged on its merit and Hon'ble Vice-Chancellor will decide in each case, with reference to the criteria indicated below.

d. Hon'ble Vice-Chancellor will notify the decision to the applicant within one month's time of receipt of the application.

e. The terms of any study / sabbatical leave which is granted will be set by the University and will include an agreed date for confirmation of return to the same post unless specified otherwise.

V. Criteria:

The University will judge applications for study / sabbatical leave against the following criteria:

a. What are the particular circumstances and needs that merit the requirement of study / sabbatical leave for the member of staff concerned?

b. Is the University confident that it can find a satisfactory and cost effective alternative? Is there replacement for the staff member proceeding on study / sabbatical leave?

c. Will it be possible for another member of staff within the department (or the temporary member) to take on the member of staff's workload in its entirety? If not, how great will be the disruption to other staff workload?

d. Is the proposed time for study / sabbatical leave convenient or inconvenient to the University?

Pre-clinical Research

Biomedical research can be sub-classified as basic/pre-clinical research and clinical research. Pre-clinical biomedical research is important for expanding the knowledge of basic biological mechanisms. Pre-clinical research can contribute to the discovery of new medical treatments. Clinical research ranges from clinical laboratory or investigational studies to testing of new clinical procedures, new clinical diagnostic tools and new medicinal products in humans.

Clinical Trials on Medicinal Products

There is a persistent demand, in addition to a great need, to develop new medical treatments that are as effective and safe as, or more effective or safer for specific types of patients than, treatments already on the market. Research also enables discovery of new therapeutic uses for currently available medications, as well as enabling development of innovative treatments for currently untreated conditions. New medicinal products are commonly discovered by means of laboratory research and animal studies before they can be tested in humans – through clinical trials – and eventually used in medical care. Clinical trials are the mandatory bridge between pre-clinical discovery of new medicinal products and their general uses. During the clinical testing period, data are collected to support a subsequent marketing application for the new medicinal product (test article), whether a drug, vaccine, medical device or diagnostic tool. Pre-clinical and clinical developments are carefully monitored under strict

government regulations to ensure that all aspects of the compound have been studied – and that research has used proper trial designs in a high-quality manner, in accordance with international and local human research ethical standards. Clinical testing of the product passes through different phases, from human pharmacology to exploratory research in participants with the target disorder, and eventually large-scale trials where the product's safety and effects are compared to the best current treatment on the market.

Clinical Trial phases

This is the mandatory bridge from preclinical discovery to clinical usage. Thus early phase clinical trials often need more oversight than later phase trials. The highest level of risk arises when the product is first tested in humans (first-into human trials), followed by trials with dose escalation and multiple dosing. Most of these trials are conducted in healthy volunteers, not participants with the target disease. Initial human pharmacology clinical trials, conducted mostly on healthy volunteers, are followed by exploratory trials where the test article is administered on target participant groups for the first time. Proper risk assessment of a trial can be made only with detailed access to the results of previous testing of the product, in animals and humans, as well as details of the target population and knowledge about the characteristics of the test article. Such information should be included in any trial protocol. For trials overseen by a regulatory authority, additional details are documented in a mandatory investigator's brochure. Both the trial protocol and the investigator's brochure for a trial, if present, should be submitted to an EC for review.

CLINICAL TRIAL PLAYERS AND THEIR RESPONSIBILITIES:

There are four major players in the clinical trial arena: the drug regulatory authority, the trial sponsor (sponsor), the clinical researcher (investigator) and the ethics committee (EC). Together the key players work in harmony within a strict pattern of interaction, defining their responsibilities and enabling collection of high-quality trial data in a safe and ethical manner. The sponsor interacts continuously with both the regulatory authority and the investigator before, during and after the trial, while the investigator interacts with the EC generally without involvement from other parties.

a) Drug Regulatory Authority

Each country has its own drug regulatory authority with its own regulations for approving clinical trial protocols and also for conducting clinical trials when testing and approving new medicines and other medicinal products. A clinical trial of a new medicinal product can be overseen by one or several drug regulatory authorities. In addition, the drug regulatory authority has important quality assurance responsibilities in the development of new medicines, as well as the production, distribution, labeling and safety monitoring of medicines, including medicines already registered. There are a number of local and international regulations/guidelines that must be followed when new medicines are developed and tested. Drug regulatory authority in India is Drug Controller General of India (DCGI, India). The regulatory authority interacts with the sponsor and approves the trial protocol that is provided to the investigator. The investigator is responsible for obtaining approval from

the local EC, to identify, recruit and follow the participants and to deliver the study data to the sponsor.

Responsibilities of the regulatory authority (examples):

- Reviewing and approving clinical trial protocols.
- Ensuring that clinical trials comply with national regulations of a country and
- Comply with international guidelines

b) Sponsor

A clinical trial sponsor is an individual, company, institution or organization that takes responsibility for the initiation, management, and financing of a clinical trial. A sponsor can be a pharmaceutical or Biotech Company, a non-profit organization such as a research fund, a government organization or an institution where the trial is to be conducted, or an individual investigator. The sponsor initiates a clinical trial and has a number of responsibilities such as protocol development, financing the trial and quality assurance. The sponsor will seek permission for trial initiation from the drug regulatory authority or authorities if more than one country is involved in conducting the trial. A clinical trial project manager acts as a coordinator among the activities of clinical trials, e.g., protocol development, regulatory applications, auditing, clinical data management, laboratory testing, courier transport and managing monitors. A trial monitor (monitor), or clinical research associate (CRA), is a person employed by a sponsor or by a clinical research organization who acts on a sponsor's behalf and monitors the progress of investigative sites

participating in a clinical trial. The monitor interacts regularly with the investigator and his/her team members, while monitoring the participant informed consent process, participant recruitment rate, test drug presence, protocol compliance and payment schedules. The monitor visits the trial site approximately every month and reports findings to the project manager coordinating the trial.

c) Investigator

Often, there is an investigative team, consisting of the investigator (principal investigator), one or several co-investigators, one or several study nurses (clinical research coordinators, CRCs), and, where necessary, other study support staff. The investigative team can belong to academic medical centers, public hospitals or outpatient clinics, private health care organizations, private practices or commercial research sites. The sponsor identifies a potential principal investigator for the trial and communicates with the investigative team throughout the course of it, usually by way of a project manager and a trial monitor. An investigator is a person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team. A more formal definition of an investigator is "under whose immediate direction the test article is administered or dispensed to, or used involving, a participant, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team."

A co-investigator or sub-investigator is any individual member of the clinical trial team – such as an associate, resident or research fellow – designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions. A clinical research coordinator (CRC) handles most of the administrative responsibilities of a clinical trial, acting as liaison between the investigative site and sponsor, and also reviewing all data and records before a monitor's visit.

Responsibilities of the investigator:
Protecting the rights and well-being of the participants.

- Following GCP and other guidelines.
- Having access to all necessary facilities
- Following the protocol
- Ensuring the clinical trial is reviewed by an EC
- Informing the EC of any adverse events
- Ensuring an ongoing informed consent process for the participants.
- Protecting participants' identity
- Proper handling of all trial medications/supplies
- Reviewing and reporting adverse events during the trial.

d) Ethics Committee

The EC's responsibility is to ensure the protection of the rights, safety, and well-being of potential participants as well as those participants involved

in a trial. The EC provides public assurance of that protection by, among other things, reviewing and approving or rejecting the protocol and ensuring the investigator(s) are suitable to conduct the trial, the facilities are adequate, and the methods and materials to be used in obtaining and documenting informed consent of the trial participants are appropriate.

Responsibilities of the EC:

- Safeguard the rights, safety and well-being of all trial participants; special attention should be paid to trials that may include vulnerable participants, such as children and participants who may have the capacity to make a decision but are unable to exercise that capacity, because prior consent could not be obtained in an emergency situation.
- Review the protocol and associated documents and provide opinions within a reasonable time, documenting its views in writing in a timely manner.
- Consider the qualifications of the investigator for the proposed trial, as documented by a current curriculum vitae and/or by any other relevant documentation the EC requests.
- Conduct continuing review of each ongoing trial at intervals appropriate to the degree of risk to human participants, but at least once a year.
- Reviewing certain types of adverse events and any harm that happens as a result of the trial

Refer to Institutional Ethics Committee's Standard Operating Procedure for additional details.

e) Clinical Trial Services Provider

Outsourcing of tasks related to clinical trials has increased substantially over the past two decades. Today there are thousands of clinical research organization (CROs) acting as service providers worldwide. During the clinical phase, a CRO's services can take the form of project management, trial monitoring and medical statistics work. When a CRO is contracted by a sponsor, it takes on many and sometimes the entire sponsor's trial responsibilities. Central laboratory services have also become an important ingredient of clinical trials, conducting work such as processing blood samples and reading electrocardiograms (ECGs). Sponsors and sometimes also drug regulatory authorities require that one single central laboratory should process all trial blood samples – or in the case of ECGs, read all the ECGs – from study sites

Site Supporting Organization

Another emerging clinical trial organization – a for-profit or non-profit institutional management organization – acts as an interface between the investigator and the sponsor. These organizations often operate from centers commonly called offices of clinical trials or clinical trials centers. The supporting organization assists the sponsor or CRO to identify potential investigators and assists the investigator to estimate the trial budget, prepare the contract, provide GCP training, establish research

pharmacy services and prepare EC applications, and other administrative tasks.

f) Data Safety and Monitoring Committee

A data and safety monitoring board (DSMB) may be established by the sponsor to assess, at intervals, the progress of a clinical trial, safety data and critical efficacy endpoints, and recommend to the sponsor whether to continue, modify or stop a trial. The DSMB usually consists of international clinical research experts, together with representatives of the sponsor and a medical statistician to provide results to the DSMB based on statistical analyses of accumulated data from all sites. The EC can gain much useful information from regular feedback from the DSMB, ensuring that risks to trial participants are kept to a minimum.

Operating procedure for implementation of Clinical trials at the KIMS hospital

Introduction:

The honorable Vice chancellor and the Research Directorate of the KIMS "Deemed to Be University" have undertaken an initiative to promote and enhance clinical trial research at the university. In order to ensure strict compliance to regulatory requirement for conduct of clinical trial, the university has signed a MOU with UCRS, a clinical research organization. UCRS will bring in clinical trials and will ensure compliance of all regulatory issues related to each of the clinical trial undertaken at the KIMS hospital. The site infrastructure such office furniture, Desk top computer, printer and sitting space for UCRS staff will be provided by the KIMSDU. PI, Co-PI and UCRS will jointly ensure documented procedures and oversight mechanism to support clinical trial conduct as per applicable rules and regulations ensuring trial integrity and protection of subject rights, safety and wellbeing. PI & UCRS will ensure appropriate storage and inventory management of investigational product in compliance to applicable rules and regulations. Study specific training of relevant research site staff will be conducted. On completion of the study, PI and UCRS will ensure appropriate storage and retention of trial related documents for the required duration as applicable through a signed MOU with the sponsor.

In order to ensure smooth implementation of clinical trials, following Standard operating procedure (SOP) has been formulated which will be effective with immediate effect.

Request for taking up a clinical trial-

Dr. R. G. Naniwadekar, Medical Administrator, KIMS hospital has been nominated by the Hon. VC as a nodal person for implementation of clinical trials at KIMS hospital.

UCRS will forward request received from the sponsors to undertake clinical trial/ clinical studies. These requests will be communicated by the UCRS to the Hon. VC, Director of Research, Additional Director of Research, Medical Administrator and the Head of the concerned Department depending on the nature of the clinical trial.

Head of the Department and the PI will assess the feasibility of conduct of that trial at KIM's hospital considering the availability of adequate number of participants, infrastructure, expertise etc. The affirmative decision of this assessment and the name of the principle investigator will be communicated by the HOD by the same email using 'reply all' option. In case the HOD decides that the said trial is not feasible at our hospital, he/she would communicate to all as mentioned above, stating reasons as to why the trial is not feasible.

Once the probable faculty is identified by the Head of the Department and he/she agrees to undertake clinical trial/study, The UCRS will contact the Principle investigator nominated by the HOD and discuss details of the clinical trial. The Principle investigator will sign non-disclosure agreement and hand it over to the UCRS representative who will forward it to the sponsor.

In case the study site is not approved by the sponsor, UCRS will inform the PI.

On approval of the site feasibility, the sponsor will request for site qualification visit which will also be handled by the UCRS and the PI in the same manner as the site feasibility visit. On successful completion of this visit the sponsor will approve conduct of trial.

UCRS will submit all necessary documents along with the protocol to the Directorate of Research for IEC submission

On receipt of the study protocol, the PI will read it carefully, including the minute details. PI will also identify the Co-PI, if any, and will discuss his/ her role in the study. PI & Co-PI will plan as to where, how and who will do the procedures (lab tests, investigations, storage of samples etc.) PI will prepare PPT for a brief presentation to the institutional Ethics Committee. Once ready for IEC presentation, the PI will communicate to the Research Directorate. The Research Directorate will then decide on the dates for EC meeting and will inform the PI and the UCRS. Senior official of UCRS will ensure their presence in the EC meeting. On review, IEC will issue an approval certificate

IEC review, approval and fees:

IEC will review the clinical trial proposals, forwarded through the Research directorate, on the day of the meeting. The PI will present the proposal to the committee, respond to the querries and questions raised by the members. UCRS representative will supplement PI's response with additional information. Pi will modify the proposals if needed as per

suggestions made by the IEC. On approval, IEC will issue a certificate of approval. The PI will communicate with the IEC periodically, as and when necessary and for annual renewal of the approval

IEC will charge fees for review of clinical trial/study as follows. UCRS will timely facilitate payment of these fees from the sponsor to the university.

Initial Review & approval of study protocol- Rs. 40, 000

Review of amendments	Rs. 15.000 (Per amendment)
Expedited review of protocol	Rs. 15,000 Plus initial approval IEC fees

UCRS and PI will inform by mail to the following officials that the study/ trial (title with study ID number) will be undertaken and with probable date of initiation and duration of recruitment of patients for the trial.

Communicate to- Medical Director, Medical Administrator, Director Research, Hon Vice Chancellor, Co-PI

The PI, Co-PI and the UCRS representative will jointly meet with the nodal person, Dr. Naniwadekar and discuss the details about study implementation.

UCRS will arrange for site initiation and the study will be initiated.

UCRS representative will stamp (identifying clinical trial/ study with ID number) the requisitions for investigations/ hospitalization of the study participants and will get them approved from the Medical administrator and submit to billing section.

On completion of the trial, UCRS will ensure

1. study is appropriately closed
2. Appropriate storage of study documents for required duration at the university campus. UCRS will facilitate agreement for storage of documents and payment from the sponsor for this purpose.
3. Receipt of agreed funds from the sponsor

Income distribution-

As agreed in the MOU, the revenue generated out of clinical trial will be equally shared (50-50%) between UCRS and the University. Fifty percent share of the university will be distributed as follows:

Principle investigator – 40%

University- 40%

Co-PI- 20%

Additionally, UCRS will manage all the bills for investigation and hospitalization and prepare an invoice and forward it to the sponsor for reimbursement. A copy of the invoice will be sent to the Directorate of research

For additional details, refer to –

1. CDSCO website
2. IEC SOPs

ANNEXURES

I. Templates:
   A. Template for New project proposal (For Departmental/Staff proposals)
   B. Template for New project proposal (For PhD student proposals)
   C. Template for New project proposal (For PhD student proposals)

II. Guidelines for Patient information Sheet (English & Marathi translation)

III. Participants Informed Consent Form (English & Marathi translation)

IV. Assent form

V. Template for undertaking from student/author and certificate from supervisor

VI. Protocol to be followed for organization of Academic Endeavour (National/International) such as Conference, Workshop, Seminar, CME, Guest lecture/oration:

Annexure I- A

New project proposal

(For Departmental/Staff proposals)

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==========

SECTION-A (GENERAL INFORMATION)

1. A. Title of the Research Project : (IN BLOCK LETTERS)

(b) What is new in this topic that others have not done and not already published in the Journals or textbooks

2. Name and Designation of

   a) Principle investigator : _____

   b) Other investigators :_____

   :_____

   :_____

   :_____

   c) Department : _____

3. Name of the Sponsor :_____

4. Duration of Research/Dissertation Project (_____ Months)

a) Period which may be needed
for collecting the data :_____

b) Period that may be required for : _____
analysing the data

5. Date of submission of the project to the
Department of Research for protocol review committee

6. Date of submission of the modified project
(Modified as per suggestions made by the protocol review committee
to the Department of Research for IEC review

7. Signature (with date) of :

a) Applicant staff : _____

b) Head of the department : _____

c) Dean of the Faculty : _____

8. Signatures of the other departmental heads where part of the research study work is planned (mention, not applicable if so)

d) Head of the department

Biochemistry :_____

Pathology : _____

Microbiology : _____

Any other : _____

_____

9. IEC review

Remarks of the IEC : Approved / Not Approved

10. Signature of the IEC Member Secretary : _____

Date :

11. Signature of IEC Chairman : _____

Date :

SECTION – B

DETAILS OF THE RESEARCH PROJECT

Adequate information must be furnished in a brief but self explanatory manner to enable the Committee to assess the Project:

1. Title of the Research Project:
2. Study rationale including novelty and application of the work in the context of National priorities of Medical Research
3. Objectives:
4. Summary of the proposed research (about 150 to 200 wards) indicating overall aim of the research, Methodology, expected outcome etc.
5. Present knowledge and relevant bibliography relating to the problem (about 250 to 300 words)
6. Detail research plan :
   (Give here the design of study, indicating the total number of cases/samples to be studied, the mode of selection of subjects , equipment and other material to be used, Questionnaire, the techniques to be employed for evaluating the results including statistical methods etc.
7. Facilities & equipment, etc. available in the department concerned and/or in the institution for the proposed investigation.
8. Budget of the project:

Details of the investigations/procedures planned in house

Sr. No.	Name of investigation/Procedure	Number to be performed	Unit cost	Total cost
1				
2				
3				
4				

Details of the investigations/procedures planned to be outsourced

Sr. No.	Name of investigation/Procedure	Number to be performed	Unit cost	Total cost
1				
2				

9. Applicant's signatures with date-

Annexure I- B

New project proposal

(For PhD student proposals)

==========

==========

SECTION-A (GENERAL INFORMATION)

1. (a) Title of the Research/Dissertation Project : (IN BLOCK LETTERS)

_____

_____

_____

(b) What is new in this topic that others have not done and not already published in the Journals or textbooks.

2. Name and Designation of

a) PhD guide : _____

b) PhD student :_____

c) Department :_____

d) Month and Date of Registration: _____

3. Duration of Research/Dissertation Project : _____ Months

From: _____ to _____

a) Period which may be needed : _____

For collecting the data

b) Deadline for collecting the data : _____

c) Period that may be required for : _____
Analysing the data

d) Deadline for analyzing the data : _____

e) Deadline for presentation of data: _____
to the experts in the subject

4. Deadline for submission of Dissertation: _____
To the University

5. Date of submission of the project to the
Department of Research for protocol review committee

6. Date of submission of the modified project
(Modified as per suggestions made by the protocol review committee
to the Department of Research for IEC review)

7. Signature (with date of :

a) PhD. student : _____

b) PhD Guide : _____

c) Head of the department : _____

d) Signatures of the other departmental heads where part of the research study work is planned (mention, not applicable if so)

Biochemistry : _____

Pathology : _____

Microbiology : _____

_____

8. IEC review

Remarks of the IEC : Approved/ Not Approved

9. Signature of the IEC Member Secretary: _____

Date

10. Signature of IEC Chairman : _____

Date:

SECTION – B

DETAILS OF THE RESEARCH PROJECT

Adequate information must be furnished in a brief but self-explanatory manner to enable the Committee to assess the Project:

1. Title of the Research Project:
2. Study rationale including novelty and application of the work in the context of National priorities of Medical Research
3. Objectives:
4. Summary of the proposed research (about 150 to 200 wards) indicating overall aim of the research, Methodology, expected outcome etc.
5. Present knowledge and relevant bibliography relating to the problem (about 250 to 300 words)
6. Detail research plan :

   (Give here the design of study, indicating the total number of cases/samples to be studied, the mode of selection of subjects , equipment and other material to be used, Questionnaire, the techniques to be employed for evaluating the results including statistical methods etc.
7. Facilities & equipment, etc. available in the department concerned and/or in the institution for the proposed investigation.
8. Budget of the project:

Details of the investigations/procedures planned in house

Sr. No.	Name of investigation/Procedure	Number to be performed	Unit cost	Total cost
1				
2				
3				
4				

Details of the investigations/procedures planned to be outsourced

Sr. No.	Name of investigation/Procedure	Number to be performed	Unit cost	Total cost
1				
2				

9. signatures with date-

Signature of PhD. Guide Signature of PhD Student Signature of Head of Dept.

Annexure I- C

New project proposal

(For PG student proposals)

==========

==========

SECTION-A (GENERAL INFORMATION)

1. (a) Title of the Research/Dissertation Project : (IN BLOCK LETTERS)

_____

_____

_____

(b) What is new in this topic that others have not done and not already published in the Journals or textbooks?

2. Name and Designation of

   a) PG guide : _____

   b) PG student :_____

   c) Department :_____

   d) Month and Date of Registration: _____

3. Duration of Research/Dissertation Project :_____ Months

   From: _____ To _____

   b) Period which may be needed : _____

   for collecting the data

   b) Deadline for collecting the data : _____

c) Period that may be required for : _____
analysing the data

d) Deadline for analyzing the data : _____

e) Deadline for presentation of data: _____
to the experts in the subject

4. Deadline for submission of Dissertation : _____
To the University

5. Date of submission of the project to the
Department of Research for protocol review committee

6. Date of submission of the modified project
(Modified as per suggestions made by the protocol review committee
to the Department of Research for IEC review)

7. Signature (with date of :

a) PG student : _____

b) PG Guide : _____

c) Head of the department : _____

d) Signatures of the other departmental heads where part of the research study work is planned (mention, not applicable if so)

Biochemistry : _____

Pathology : _____

Microbiology : _____

8. IEC review

Remarks of the IEC : Approved/ Not Approved

9. Signature of the IEC Member Secretary: _____

Date

10. Signature of IEC Chairman : _____

Date

SECTION – B

DETAILS OF THE RESEARCH PROJECT

Adequate information must be furnished in a brief but self-explanatory manner to enable the Committee to assess the Project:

1. Title of the Research Project:
2. Study rationale including novelty and application of the work in the context of National priorities of Medical Research
3. Objectives:
4. Summary of the proposed research (about 150 to 200 wards) indicating overall aim of the research, Methodology, expected outcome etc.
5. Present knowledge and relevant bibliography relating to the problem (about 250 to 300 words)
6. Detail research plan :

   (Give here the design of study, indicating the total number of cases/samples to be studied, the mode of selection of subjects , equipment and other material to be used, Questionnaire, the techniques to be employed for evaluating the results including statistical methods etc.
7. Facilities & equipment, etc. available in the department concerned and/or in the institution for the proposed investigation.
8. Budget of the project:

Details of the investigations/procedures planned in house

Sr. No.	Name of investigation/Procedure	Number to be performed	Unit cost	Total cost
1				
2				
3				
4				

Details of the investigations/procedures planned to be outsourced

Sr. No.	Name of investigation/Procedure	Number to be performed	Unit cost	Total cost
1				
2				

9. signatures with date-

Signature of P. G. Guide Signature of P. G. Student Signature of Head of Dept.

Annexure II

Guidelines for Patient information Sheet (English & Marathi translation)

Protocol No:

Name of Institute:

Name of Principal Investigator:

Name of co-Investigator (at least 1)

Title of study: ----------

You are invited to take part in the above mentioned research study. You are invited because you fulfill the eligibility (inclusion) criteria-

i) ----------

ii) ----------

iii) ----------

You will be one of the -------participants to be enrolled in this study. You will be assigned to either of two/three groups of participants in this study. One group of participant will be treated with ---------- (Investigational drug/procedure). The other group will be treated with ---------- (standard drug/procedure)

The purpose of study- We want to compare the efficacy and safety of this--------- (drug/intervention/surgery) in ----------disease with the standard treatment

The safety of this (drug/intervention is tested in (animal/humans)

The study procedure- Once you are voluntarily enrolled in this study you are expected to follow all instructions given by investigator about your diet, taking drugs, visits for follow up and any other precaution to be taken by you. [write here specific instructions about diet, drug, avoidance of smoking/ alcohol/driving etc) follow up visits, investigations etc in detail in nontechnical words)]

The total duration of study is ----------In between the two follow up visits if you want to tell any treatment related problems/adverse effects, you are free to call or visit investigators

Possible benefits to you- You are not expected to get any benefit other than free treatment and free investigations. You will not be paying any charges for this treatment. (Add information which suits your study)

Compensation- (Write here about conveyance allowance if applicable) In case of any study related injury of adverse effect you will be treated free of charge in this hospital.

Possible benefits to society-The results of this research may provide benefit to the society in terms of advancement of medical knowledge and therapeutic benefit to future patients

Possible risks/adverse effects to participant

Common adverse effects

Very rare adverse effects

Reports of earlier studies have proven safety of this drug/intervention. Your safety is the prime concern of this research. If you notice any other side effect you should bring it to the notice of investigator at the earliest.

If the investigator notices any side effect or any untoward effect in you he will be withdrawing you from study and inform you.

In case of any study related injury/medical problem you will be entitled to get medical treatment free of charge from this institute.

Benefit to participant- You will not be required to pay for study related investigations/drug /treatment

[Mention if you are going to pay travelling or daily allowance to the participants] You will not be paid any amount for your participation in this study.

Confidentiality of information obtained- You have the right to confidentiality regarding the privacy of medical information (your personal details results of physical examination, investigations and medical history). Your identity will not be disclosed to unrelated persons.

By signing the informed consent document you will be allowing the research team investigators, institutional ethics committee, sponsors and any higher authority like drug controller General of India, to view your data if required.

The results of this research may be published in scientific journal or presented at scientific meetings without disclosing your identity.

Treatment alternatives available- If you do not wish to participate you have alternatives of getting other standard treatments for your medical condition e.g. ----------

---

Effect of your decision-Your decision not to participate in this research will not affect your medical care or you relationship with the investigator or the institute in future.

The participation in this study is purely voluntary and you have the right to withdraw from this study at any point of time with or without giving any reason through not mandatory it will be advisable to consult your investigator before you withdraw.

Contact persons-For further information/questions you can contact any of the following

Principal Investigator: Dr. ----------

Dept. of ----------

Name of Institution----------

Phone ----------

Co-Investigator: Dr. ----------

Dept. ----------

Institute----------

Phone----------

Annexure III

Participants Informed Consent Form (English & Marathi translation)

Protocol No:

Title of study:

Name of Participant:

Name of Principal Investigator:

Name of Department:

I, ------- have read the information or the information has been read to me. The nature of study, possible risk and benefits to me, precautions to be taken by me, my rights and responsibilities related to this study are explained to me by the investigator to my satisfaction. I have understood that the information/data obtained from this study may be used for scientific purpose (Publication/presentation in scientific meetings) by the investigators, without revealing my identity. I have no objection for this.

I have understood that I can withdraw from this study at any point of time without giving any reason and this will not affect my future treatment in this hospital. I have understood whom to contact in case of any adverse effect/doubt

I am also aware that the investigator can terminate my participation in this study at any time due to any reason, without taking my consent

I hereby give my consent to participate in the study titled "----------

1) Signature/left thumb impression of participant

2) Name & Signature/left thumb impression of legal guardian/parent (if participant is incompetent/child below 18 years

3) Signature & Name of impartial witness (In case of participant/legal guardian is illiterate person)

   contact No

   - If child participant-
   - Child Assent taken-Yes/No

4) Name & signature of Investigator/Co-investigator

Annexure IV

ASSENT FORM

I_____, exercising my free power of choice, hereby give my consent for participation in the research study entitled: "……". I have been informed, to my satisfaction, by the Principle Investigator of the study about the purpose of the study and the nature of the procedure to be done. I am aware that my parents/guardians do not have to bear the expenses of the treatment if I suffer from any study related injury, which has causal relationship with the said study drug/investigation/procedure.

I am also aware of my right to opt out of the research study, at any time during the course of the trial, without having to give reasons for doing so and my withdrawal from the study will not impact the treatment and I shall continue to receive it.

Name and Signature of the study participant ……Date:

Name and Signature of the parent/legally acceptable guardian of study participant ……Date:……

Name and Signature of the attending Physician …… Date: ……..

Annexure V

Policy for Prevention of Plagiarism

A) Composition of Institutional Academic integrity Panel (IAIP)

a. Chairperson- Hon'ble Vice Chancellor

b. Member – Senior Academician-

c. Member- Outside member-

d. Member- A person well versed with anti-plagiarism tools-

Tenure of the committee members- Three years

Quorum for the meetings shall be 3 out of 4 members (including chairperson)

B) Composition of the Departmental Academic Integrity Panels (DAIP) for Faculties of Medicine, Dental, Nursing, Physiotherapy, Pharmacy, Allied Sciences

a. Chairperson- Head of the Institution

b. Member- Senior academician from outside of the Institution

c. Member- A person well versed with anti-plagiarism tools

d. Ex Officio – HOD of concerned department

Tenure of the members in respect of points 'b' and 'c' – Two years

Quorum for the meetings shall be 2 out of 3 members (including chairperson

UNDERTAKING FROM STUDENT/AUTHOR

KRISHNA INSTITUTE OF MEDICAL SCIENCES

DEEMED UNIVERSITY, KARAD

UNDERTAKING FROM STUDENT

1. Name of Student:

2. Name of degree:

3. Registration Number:

4. Title of the thesis:

5. Department:

6. Name of Guide and Designation:

7. Name of Co-guide and Designation:

This is to state that the above mentioned document has been prepared by me and that the document is my original work and free of any plagiarism.

Place: Signature:

Date: Name:

KRISHNA INSTITUTE OF MEDICAL SCIENCES

DEEMED UNIVERSITY,, KARAD

UNDERTAKING FROM AUTHOR

1. Name of Author:

2. Designation:

3. Department:

4. Title of the manuscript:

5. Name of Journal:

This is to state that the above mentioned manuscript has been prepared by me and that the document is my original work and free of any plagiarism.

Place: Signature:

Date: Name:

CERTIFICATE FROM SUPERVISOR

KRISHNA INSTITUTE OF MEDICAL SCIENCES

DEEMED UNIVERSITY,, KARAD

CERTIFICATE FROM SUPERVISOR

1. Name of Student:

2. Name of degree:

3. Registration Number:

4. Title of the thesis:

5. Department:

6. Name of Guide and Designation:

7. Name of Co-guide and Designation:

This is to certify that my student Mr..... has prepared the above mentioned document under my supervision and that the document is free of any plagiarism.

Place: Signature:

Date: Name:

Annexure VI

Protocol to be followed for organization of Academic Endeavour (National/International) such as conference, workshop, Seminar, CME, guest lecture/oration:

- For any activity to be conducted by the department, get the permission from the HOD, and the Head of Institution.
- The plan for undertaking the above-mentioned activity should be communicated, through a proper channel, to the Hon'ble Chairman Sir, Hon'ble Vice-Chancellor, Registrar KIMSDU, Director Research and Finance Officer well ahead of time. If a scientific activity needs financial assistance from the university, it should be applied to the Director of Research well in advance along with an item-wise estimated budget.
- If is the activity is planned by the staff of KIMS, a copy of the approved programme along with other details should be submitted to the Assistant Registrar Academics, at least one month in advance, for MMC accreditation.
- Local organizing committee should be formed which will deal with all issues related to the planned activity.
- Organizing chairman/secretary will nominate one treasurer for handling the account. Treasurer along with the organizing secretary will be responsible for proper maintenance of accounts
- The deposits and withdrawals for the planned academic activity will be managed through a separate university account (Conclave account) The

Conclave account is operated by the following signatories- Mr. John/ Mr. Kale (Finance, Dr. Risbud/Dr. Arun Patil, Dr. S. R. Patil/ Ms Archana Kaulgekar

- The registration fees will be deposited in the said account by cash/NEFT/net banking or RTGS.
- **Withdrawal of money from the account**: As far as possible, the account transactions (deposits/withdrawals) will be made cashless (internet banking/Account payee cheques). For withdrawal of money, the organizer should communicate, in advance in writing, to Dr. S.R. Patil, Prof. Microbiology, and Secretary SSS.
- The academic report and financial report of the said activity should be prepared and submitted to Dr. S.R. Patil (within three working days) and to the Finance Office (within one month)

SOP FOR VARIOUS EVENTS LIKE CONFERENCES, CME'S & WORKSHOPS

All academic activities like Conferences / Workshops / CME's should be planned well in advance and these should be included in the Comprehensive Calendar.

Sr. No.	Particulars	Action	Responsibility
1.	Planning of academic activity (e.g. conference, CMEs, workshop,	To decide planning an academic activity and to constitute a core committee (1 or 2	concerned department

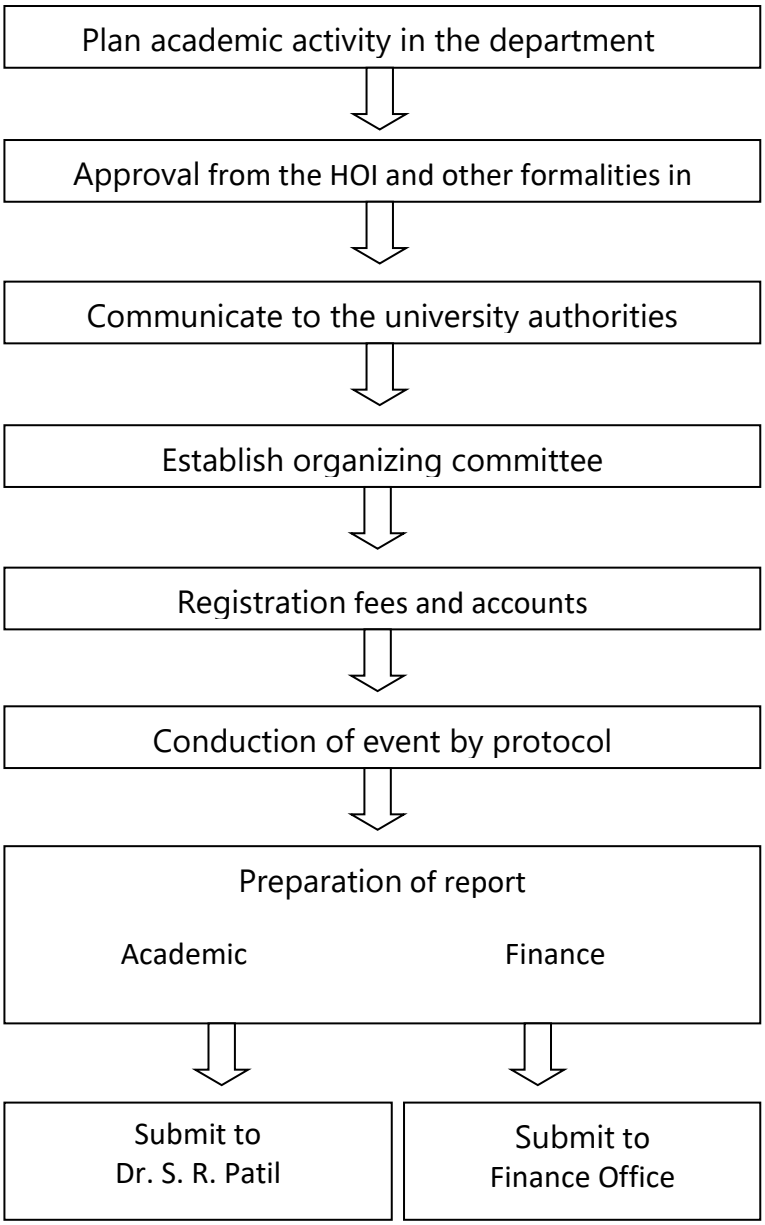
	symposiums, Think-tanks, master course etc)	members)	
2.	The primary work- up of the activity	To decide type and title of the activity, proposed dates, delegate fees, expenses, availability of collaborators / sponsors etc.	Core Committee
3.	Approval of the activity	To get approval (verbal) from respective Head of Institute and to inform Dean (Academics).	Core Committee
4.	Communication with University	To inform Asst. Registrar (Academics) about the event	Core Committee
5.	Approval of Higher Authorities of University	To update Higher Authorities of the University about the proposed event	Asst. Registrar (Academics)
6.	Proposal to the Directorate of Research	To prepare detailed proposal of the activity including probable budget and submit it to Directorate of Research for budgetary approvals.	Core Committee
7.	Approval from	To issue letter of approval	Directorate of

	Directorate of Research	to the core committee	Research
8.	Information to concerned officials for necessary arrangements	Registrar : for overall support *Dr. S. R. Patil, Professor, Dept. of Microbiology : for financial arrangements *Ms. Archana Kaulagekar, Asst. Reg. (Academics): • For credit points from respective councils. • For printing material and website ** details conveyed in a separate circular, attached herewith for ready reference.*	Core Committee
9.	Information to Hon'ble Vice-Chancellor	A written communication along with the approval letter from Directorate of Research should be submitted to Hon'ble Vice-Chancellor for her kind information.	Core Committee
10.	Formation of Organizing Committee	To constitute the Organizing Committee and distribute the job	Core Committee

		responsibility	
11.	Conduction of the activity	To conduct the event considering necessary aspects	Organizing Committee
12.	report of the activity	After the event is over a detailed report should be prepared and submitted to Directorate of Research within 3 working days	Organizing Committee
13.	Financial report	Financial report should be submitted to Dr. S. R. Patil within 3 working days	Organizing Committee
14.	Financial Audit	Financial Audit should be carried out within one month after the event	Dr. S. R. Patil

FLOWCHART

For implementation of Academic Activity:



Calendar for Research studies to be undertaken by the UG and PG students and interns of all faculties of KIMSDU

Name of the Faculty		Mandatory/ Voluntary	Number per yeaar	Duration availablle	Month of Joining	Month Protocol to be ready	Month Protocol Review	Month IEC Review	Study Initiation	MS to be sent for publication
KIMS	UGs (2 Yr)-STS	V	25	1 yr	July/ Aug	Nov	Jan	January	Feb	Next_ Apr
	UGs (2 Yr)-STF	V	25	1 Yr	July/ Aug	Nov	Jan	January	Feb	Next_ Apr
	PGs	M	80	3 Yrs	May	Sept	Oct	Oct	November	After 1.5 yrs
	Interns	V	20	6 months	Jan/ July	Feb/ Aug	Feb /Aug	Feb/ Aug	Mar/ Sept	In 6 Monts
SDS	UGs (3 Yr)-STS	V	10	1 yr	July/ Aug	Sept	Oct	Nov	Dec	Next_ Apr
	UGs (3 Yr)-STF	V	15	1 Yr	July/ Aug	Sept	Oct	Nov	Dec	Next_ Apr
	PGs	M	25	3 Yrs	May	Sept	Oct	October	Nov	After1 .5 Yrs
	Interns	V	05	1 yr	July/ Aug	Sept	Oct	October	Nov	Next March
KCP										
	UGs (Regular)-	M	70	1 Yr	Aug	Nov	Dec	Dec	Jan	Next April

	STF									
	UGs (Odd)-STF	M	10	1 Yr	Jan	April	May	May	June	Next Aug
	PGs	M	20	2 Yrs	July	Oct	Nov	Nov	Dec	After 1.5 Yrs
	Interns (Regular)	M	70	6 Months	July	Aug	Aug	Aug	Sept	In 6 Months
	Interns (Odd)	M	10	6 Months	Jan	Feb	Feb	Feb	March	In 6 Months
KINS										
	UGs (3 Yr B.Sc)- STF	M	15	1 Yr	July	Sept	Oct	Oct	Nov	Next Apr
	UGs (3 Yr B.Sc) Group projects	M	15	1Yr	July	Sept	Oct	Oct	Nov	Next Apr
	PGs (1 Yr. MSc)	M	10	2 Yrs	Aug	Nov	Dec	Dec	Jan	After 1.5 yrs
	PGs (1 Yr. NPCC)	M	10	2 Yrs	Aug	Nov	Dec	Dec	Jan	After 1.5 yrs

Month-wise protocol review meetings at each faculty and ethics committee review meetings

Month	**Faculty Protocol Review committee**	**KIMS protocol review Committee**	**Institutional Ethics committee review**

	Number	students	Number	Students ' Details	Number	Students ' Details
January			50 20	UG, KIMS Interns, KIMS	50 20	UGs, KIMS Interns, KIMS
February	10	Interns (Odd), KCP	20	Interns, KIMS	20 10	Interns, KIMS Interns (Odd), KCP
March						
April						
May	10	UGs, Odd, KCP			10	UGs, Odd, KCP
June						
July						
August	70	Interns, Regular, KCP	20	Interns, KIMS	20 70	Interns, KIMS Interns, Regular, KCP
September						
October	25 25 05 15 15	UGs, SDS (10 STS+15 STF) PGs, SDS Interns,	80	PGs, KIMS	80 25 05 15 15	PGs, KIMS PGs, SDS Interns, SDS UGs, STF,

		SDS UGs, STF, KINS UGs , Group projects, KINS				KINS UGs , Group projects, KINS
November	20	PGs, KCP			25 20	UGs, SDS PGs, KCP
December	70 10 10	UGs (Regular) STF. KCP PGs, Msc, KINS PGs , NPCC, KINS			70 10 10	UGs (Regular) STF. KCP PGs, Msc, KINS PGs , NPCC, KINS

Annexure VI

Invention Disclosure Form Information
(IDF)

Purpose and Format of Invention Disclosure Form

This form is used to disclose an invention. An invention disclosure should be made when something new and useful has been conceived or developed, or when unusual, unexpected, or unobvious research results have been achieved and can be utilized.

IPR & Claims Division needs the information requested in this form to permit evaluation of your invention to determine whether the invention is patentable and whether commercial development is feasible. The invention should be clearly described so that someone having knowledge in the field of the invention can understand the technical merits of the invention, its usefulness, and possible practical applications. Information that helps evaluators appreciate the invention will increase its ultimate chances for successful patenting, if that is appropriate, and later market development.

All questions are important, so please respond to each of them even if the answer is "none" or "not applicable". Be careful to describe what, specifically, makes your invention *different from what has gone before*. **Avoid general statements that your invention is "better" - why is it better, or what makes it better?** If more space is needed, feel free to use additional sheets.

Invention Disclosure Form (IDF) No._____

INVENTION DISCLOSURE

Disclosure of Invention

1. Your invention is complete or not? If not, how many days you need to finish this invention? If a fear arising in your mind that the invention on which you working is incomplete and you somehow aware that similar type of work is conducting by your competitor and patent application could be filed by them.
   Therefore don't wait for work completion, file a provisional specification including description only. Accordingly you get one year to file the complete specification in order to meet section 9(1). Please be informed that complete specification if is not filed within 12 months from date of filling provisional specification, said application would be deemed abandon under section 9(1).

2. I) is claimed invention previously being published in any journal, book, newspaper, magazine or any disclosure? If so, provide the details including date of publication, authors name etc.
   II) Is claimed invention commercially used so far?

   III) Is claimed invention publically known so far?

If so, please let us know with such details. Then the proceeding is different.

3. **What is the problem to be solved? What are the solutions available in the art to solve the problem? What are drawbacks associated with these arts.**

3.1 How does your invention solve the said problem?

4**. Please mention the prospective title of your invention.**

(Brief, but comprehensive, technically accurate, and descriptive)

5. **What is novel in your invention? Also specify the essential features of your invention.**

6. **What is the surprising feature or effect of your invention? What makes your invention surprising?**

6. **Please mention the use/ applications (obvious and non-obvious) of your invention?**

7. **Please enumerate "Is there anything in art (including patent and non-patent literature) wherefrom the person skilled in art would motivate and arrive to instant invention what you are claiming" (Please be informed that this is one of assessment of inventive step, we have to establish that there is no motivation).**

8. **Drawings of your invention, if any.**

9. **Detailed description of your invention including principal embodiment and other embodiments of the drawing, data or**

demonstration that can <u>ESTABLISH ADVANTAGEOUS TECHNICAL EFFECT WITH REGARD TO THE EXISTING TECHNOLOGY</u>, If your invention is an improvement of existing technology please provide the comparative data in view of closest prior art to demonstrate the advantageous feature of your invention.

9. Who will be benefited by your invention and how?

10. Format of the specification<u>?</u>

Field of the invention
Background of the invention (Existing technology and their drawbacks)
Objective of the invention
Summary of the invention (our part)
Brief description of the accompanying drawings
Detailed description of the invention followed by the example/description
Of the drawings
Claims (Our part)
Abstract
Drawing sheet

Name of inventor or inventors and his/their complete address along with email id and mob no. (s):

Name of the applicant or applicants and his/their complete address along with email id and mob no (s):

Please be informed that if the Applicant is Mr. X and the inventor is Mr. X and Y, Proof of Right either in separate assignment or Original Form 1has

to be submitted within 6 months from date of filling the application u/s 7(2) of the Act. If this requirement is not being met, the Applicant can file a petition u/r 137 along with prescribed fee for condoning such irregularity.

The above is applicable for the case wherein the Applicant is a company or the inventors are Mr. X, Y and Z.

Signature:

Date and Time:

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