SRI DEVARAI URS ACADEMY OF HIGHER EDUCATION AND RESEARCH
Comprising
Sri Devaraj Urs Medical College
And
Departments of Allied Health and Basic Sciences
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A DEEMED TO BE UNIVERSTTY
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RESEARCH POLICY & GUIDELINES FOR RESEARCH PROCEDURES

Department of Research and Innovation

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INTRODUCTION

After the conferment of a Deemed to be University status to Sri Devaraj Urs Academy of Higher Education and Research (SDUAHER) in 2007, with its constituent Medical College Sri Devaraj Urs Medical College (SDUMC) and Departments of Allied Health and Basic Sciences (AH & BS) it was necessary to strengthen the area of research to meet and sustain the concept of the SDUAHER status by way of generating new ideas and knowledge. To achieve this, the Research and Development wing was established in the year 2008 to coordinate all the research related activities of the Academy. In the year R&D was designated as Department of Research and Innovations (R&I). Research and Innovations department identifies and motivates the staff of the Academy to engage in Research and publish the findings in quality national and international indexed journals with a good impact factor. SDUAHER continues to publish its own scientific journal "The Journal of Clinical and Biomedical Sciences" indexed in Index Copernicus.

VISION

To Strive and become an advanced Centre for research in medical and allied fields

MISSION

- To conduct research in medical and allied fields, as a strong complement to Health care professional and training skills and healthcare delivery; so as to equip them as professionals in healthcare, teaching and advanced research.
- To establish collaborative research and consultancy with globally valued premier scientific institutions and other institutions of excellence in higher learning and biomedical industrial research institutions.
- To achieve high levels of originality by utilizing current technology applications to solve the research questions and create new insights into human disease.

PURPOSE

This policy for research supports the development and implementation of research at SDUAHER where the faculty, Post Graduate MD/MS, Ph. D's and Under Graduates of Medical as well as Allied Health and Basic Sciences can carry out research without obligation.

SCOPE OF THE RESEARCH POLICY

SDUAHER expects the highest standards of integrity to be adhered by its researchers and seeks to promote good research practice.

RESEARCH POLICY

SDUAHER Research policy includes discovery and development that leads to new knowledge or insights and use of existing knowledge in experimental development. The policy benefits the researcher to conduct research without any obligation.

RESEARCH PRIORITIES

- The R &I Department of SDUAHER and its members want to raise the research profile of the Academy by focusing on the areas for research excellence and faculty thrust areas.
- R &I Department shall handhold researchers to generate external funding.
- It helps to develop collaborative research with other institutions and industries.
- The focus of R & I Department is in the development of research; identifying societal needs and health problems of the community

SDUAHER POLICIES TO PROMOTE RESEARCH

SDUAHER believes in research as an integral part of teaching-learning-evaluation process. Academy helps the faculty and students to excel in their research thrust area and also societal commitment and patient care.

To achieve this, SDUAHER has a clear policy to promote research in its constituent institution Sri Devaraj Urs Medical College as well as Departments of Faculty of Allied Health and Basic Sciences.

The details include:

- Annual budgetary allocation for research and research related activities
- Faculty are recognised as supervisors to supervise the Ph.D. scholars as per the statutory body and UGC guidelines
- Coordinate faculty with Academy to help sanction seed grants to conduct preliminary research and if required, recommend research proposals for higher funding from the Academy
- Assist faculty and students in submission of research projects to the SDUAHER and external funding agencies
- Strengthening Ph.D. programs in all the Departments

- Active collaboration with other research institutes to carry out research by getting MoU
- Organisation of research conferences, seminars and workshops
- Deputation of faculty to attend conferences/seminars/workshop in India and abroad.
- Encourage research at Undergraduate and Postgraduate levels
- Incentive for publication of research papers published in peer reviewed and high impact factor indexed journals
- Monitor publication of minimum one research paper by post-graduate MD/MS student from the dissertation, and second publication which is optional from additional data collected and which is mandatory as per statutory body regulations.
- Monitor publication of minimum two research papers by Ph.D. scholars before they submit final synopsis.
- Organizing workshops on Research Methodology, Good Clinical Practice, Good laboratory Practice, Intellectual Property Rights, Research grant Writing, Scientific writing by inviting scientists of excellence.
- Intimate all the Departments of SDUAHER as and when there is a call for extramural funding.
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SDUAHER FUNDING POLICIES

"**TO PROMOTE RESEARCH"** the faculty, PG's and Ph. D scholars are encouraged to apply for SDUAHER Funding and needs approval by the Central Ethics Committee (CEC).

Standard Operating Procedures (SOP) for Central Ethics Committee For Human Research at Sri Devaraj Urs Academy of Higher Education and Research, (SDUAHER), Kolar

- **Objective of CEC:**

The objective of SOP is for the effective functioning of the Central Ethics Committee (CEC). It is to perform a qualitative and consistent ethical review of health and biomedical research proposals as prescribed in the Ethical guidelines for biomedical research on human subjects of ICMR.

- **Role of CEC**

CEC will review and approve all research proposals involving human participants with a view to safeguard the dignity, rights, safety and well-being of all actual and potential research participants. The goals of research, however important,

should never be permitted to override the health and well-being of the research subjects.

The CEC will ensure that all the cardinal principles of research ethics viz. Autonomy, Beneficence, Non - maleficence and Justice are taken care of in planning, conduct and reporting of the proposed research. It will look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensations wherever required. It will review the proposals before start of the study as well as monitor the research throughout the study until and after completion of the study through appropriate well documented procedures for example annual reports, final reports and site visits etc. The committee will also examine compliance with all regulatory requirements, applicable guidelines and laws. The mandate of the CEC will be to review all research projects involving human subjects to be conducted at the Institute, irrespective of the funding agency.

- **Composition of CEC**

CEC shall be multidisciplinary and multisectorial in composition. Independence and competence are the two hallmarks of the CEC.

The number of persons in CEC shall be kept fairly small (9 members) as large Committee makes it difficult in reaching to a consensus opinion. The Chairperson of the Committee shall be from outside the Institution and not head of the same Institution to maintain the independence of the Committee. The Member Secretary is from SDUAHER and he/she shall conduct the business of the Committee. Other members will be a mix of medical / non-medical, scientific and non-scientific persons including lay public to reflect the differed viewpoints.

The composition may be as follows:-

1. Chairperson
2. 1-2 basic medical scientists
3. 1-2 clinicians from Institutes
4. One legal expert or retired judge
5. One social scientist / representative of non-governmental voluntary agency
6. One philosopher / ethicist / theologian
7. One educated lay person from the community
8. Member-Secretary

The CEC will have as its members, individuals from other institutions or communities as per the ICMR guidelines. There shall be adequate representation of age, gender, community, etc. in the Committee to safeguard the interests and welfare of all sections of the community / society. Members in the CEC shall be aware of local, social and cultural norms, as this is the most important social control

mechanism. If need arises, subject experts will be invited to offer their views, for example for drug trials a pharmacologist, preferably a clinical pharmacologist, will be included. Similarly, based on the requirement of research area, for example HIV, genetic disorders etc. specific patient groups will be represented in the Committee. The membership of CEC will include Epidemiologist(s), Sociologist(s), Lawyer(s), Theologian, Statistician(s), Clinician(s), and Basic scientists, Pharmacist /Clinical Pharmacologist(s) etc. They will be appointed by the Head of the Institute based on their competencies and integrity, and could be drawn from any public or private Institute from anywhere in the country.

- **Constitution of CEC**

CEC shall be constituted by the Vice Chancellor of SDUAHER and notified by the Registrar, SDUAHER in the following pattern:

i) A Chairperson
ii) A Deputy Chairman (Optional)
iii) A Member Secretary from the institute
iv) 5-9 members from different Departments / Specialties / disciplines or areas etc.

CEC members will be reconstituted every 3 years.

- **Membership duration and responsibilities**

1. The duration of the membership will be for 3 years.
2. At the end of 3 years, the committee is reconstituted, and 50% of the members will be replaced by a defined procedure.
3. A member can be replaced in the event of death or long-term non-availability (3 meetings) or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member. Institutional Head will have the authority to replace the member.
4. A member can tender resignation from the committee with proper reasons to do so.
5. All members should maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form at the start of their term. Each member of the committee will submit a declaration to maintain the confidentiality of the documents submitted to them during their membership period.
6. Conflict of interest should be declared by members of the CEC at the beginning of every meeting.

- **Quorum requirements:**

The minimum of 5 members including at least three outside members which includes the lawyer as well as the lay person is required for quorum. All decisions should be taken in meetings and not by circulation of project proposals.

- **Offices/Conduct of the Meeting**

The Chairperson will conduct all meetings of the CEC. If for reasons beyond control, the Chairperson is not available, the Deputy Chairperson or an alternate Chairperson will be elected from the members by the members present, who will conduct the meeting. The Member Secretary will be responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get it approved by the Chairman before communicating to the Principal Investigator.

- **Independent consultants**

CEC may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities; patient groups or special interest groups e.g. Cancer patients, HIV/AIDS positive persons or ethnic minorities. They are required to give their specialized views but will not take part in the decision making process.

- **Application Procedures:**

1. All proposals should be submitted in the prescribed application form, the details of which are available with the department of R&I.
2. All relevant documents should be enclosed with application form
3. Required number of copies of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators or Collaborators should be forwarded by the Head of the Departments.
4. The date of meeting will be intimated to the PI to be present, if necessary to offer clarifications.
5. The decision CEC will be communicated in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting.

- **Documentation:**

For a thorough and complete review, all research proposals should be submitted with the following documents:

1. Title of the project

2. Name of the PI and Co-Investigator with designation
3. Name of the Institute/ Hospital / Field area where research will be conducted.
4. Approval of the Head of the Department and Institution
5. Protocol of the proposed research
6. Ethical issues in the study and plans to address these issues.
7. Proposal should be submitted with all relevant enclosures like proforma, case report forms, questionnaires, follow - up cards, etc.
8. Informed consent process, including patient information sheet and informed consent form in English, Hindi, Kannada and Telugu should be enclosed. The patient information sheet should provide adequate and complete information in understandable language. It should also assure that any new information that becomes relevant during the trial and is related to their participation will be given to them.
9. Drug / device trial, all relevant pre-clinical animal data and clinical trial data from other centres within the country / countries, if available.
10. Curriculum vitae of all the investigators with relevant publications in last five years
11. Any regulatory clearances required
12. Source of funding and financial requirements for the project
13. Other financial issues including those related to insurance
14. An agreement to immediately report Serious Adverse Events (SAE) to CEC. Statement of conflicts of interest, if any.
15. Agreement to comply with the relevant national and applicable international guidelines.
16. A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants; a description of the arrangements for indemnity, if applicable (in study-related injuries); a description of the arrangements for insurance coverage for research participants, if applicable; all significant previous decisions(e.g., those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided.
17. Plans for publication of results – positive or negative- while maintaining the privacy and confidentiality of the study participants.
18. Any other information relevant to the study
19. Agreement to submit annual progress report and final report at the end of study.

- **Review procedures:**
  1. The meeting of the CEC shall be held on scheduled intervals (once in 3 months / 8 Proposals or whichever is earlier for which the dates will be decided at the end of previous meeting). Additional meetings may be held as and when the proposals are received for review.
  2. The proposals will be sent to members at least 2 weeks in advance.
  3. Decisions will be taken by consensus after discussions, and whenever needed voting will be done.
  4. PI should be available during the meeting and may be invited to offer the clarifications.
  5. Independent consultants/Experts will be invited to offer their opinion on specific research proposals if needed.
  6. The decisions of the meeting shall be recorded in the minute's book and shall be confirmed during the next meeting with signature of Chairperson at each page.

- **Element of review**
  1. Scientific design and conduct of the study.
  2. Approval of appropriate scientific review committees.
  3. Examination of predictable risks/harms.
  4. Examination of potential benefits.
  5. Procedure for selection of subjects in methodology including inclusion/ exclusion,
  6. Withdrawal criteria and other issues like sample size and advertisement details.
  7. Management of research related injuries, adverse events.
  8. Compensation provisions.
  9. Justification for placebo in control arm, if any.
  10. Availability of products to the trial subjects after the study, if applicable.
  11. Patient information sheet and informed consent form in English, Hindi, Kannada and Telugu.
  12. Protection of privacy and confidentiality.
  13. Involvement of the community, wherever necessary.
  14. Plans for data analysis and reporting
  15. Adherence to all regulatory requirements and applicable guidelines
  16. Competence of investigators, research and supporting staff
  17. Facilities and infrastructure of study sites
  18. Criteria for withdrawal of patients, suspending or terminating the study
  19. Protocol and Proforma of the study including the consent form.

- **Expedited review**

All revised proposals will be examined in a meeting of identified members convened by the Chairman to expedite decision making. Proposals which are recommended for minor revisions will be reviewed by a sub committee appointed by the CEC for clearance and approved by the Chairperson. The approvals will be reported in the next CEC meeting by Member Secretary. The revised form of proposals requiring major changes will be reviewed at the next ethics committee meeting. Rejected proposals may be reconsidered only if a very strong background is there.

- **Decision-making**

1. Members will discuss the various issues before arriving at a consensus decision.
2. A member shall withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and this shall be indicated to the chairperson prior to the review of the application and recorded in the minutes.
3. Decisions will be made only in meetings where quorum is complete.
4. Only members will make the decision. The decisions shall be taken in the absence of investigators, representatives of sponsors, consultants.
5. Decision may be to approve, reject or revise the proposals. Specific suggestions for Modifications and reasons for rejection should be given.
6. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified.
7. Modified proposals may be reviewed by an expedited review through identified members.
8. Procedures for appeal by the PI should be clearly defined.
9. All approved proposals will be subject to the following standard conditions. Additional conditions may be added by the CEC.

i. PI should submit annual report of the on-going+ project to the CEC on format prescribed by the Institute

ii. The final report of the completed study should be submitted by PI.

iii. The PI should highlight the changes in the protocols/brochures/informed consent form etc. being amended from the previous documents while submitting amended documents to CEC.

- **Communicating the decision**

1. Decision will be communicated to the PI by the Member Secretary in writing.

2. Suggestions for modifications, if any, shall be sent by the CEC to the PI.
3. Reasons for rejection should be informed to the PI.

- **Memorandum of Understanding and Indemnity Agreement for Sponsored Drug/Device/Collaborative Trials**

After the approval from CEC, the sponsor/CRO will submit the clinical trial agreement/Memorandum of Understanding and Indemnity Agreement document on Rs. 100 stamp paper separately (two copies) to the Institute which will be signed by sponsor and the Registrar, SDUAHER with the counter signature of PI. As per existing policy of the Institute, there will be 25% overhead charges to the total cost of the trial/per patient cost. The drug trial shall be started by the PI after the agreement is signed by both the parties as well as DCGI and required regulatory approvals are available for the concerned trial.

- **Follow up procedures**

Annual reports should be submitted by the PI on prescribed format along with comments for review.

1. Final report should be submitted at the end of study on prescribed format including a copy of the report which has been sent to sponsoring agency.
2. All SAEs and the interventions undertaken should be intimated. The PI should submit the SAEs reported by other centres from time to time to the Member Secretary for information to CEC along with comments if any action is required in the current study.
3. Protocol deviation, if any, should be informed with adequate justifications.
4. Any amendment to the protocol should be submitted for approval.
5. Any new information related to the study should be communicated to CEC.
6. Premature termination of study should be notified with reasons along with
7. Summary of the data obtained so far.
8. Change of investigators / sites should be done with the approval of the CEC.

- **Record keeping and Archiving**

1. Curriculum Vitae (CV) of all members of CEC.

2. Copy of all study protocols with enclosed documents, progress reports, and SAEs. All documents should be archived for minimum of ten years after the

completion of study. A copy of filled CRF shall remain with the PI for minimum of fifteen years.

3. Minutes of all meetings duly signed by the Chairperson

4. Copy of all existing relevant national and international guidelines on research ethics and laws along with amendments.

5. Copy of all correspondence with members, researchers and other regulatory bodies.

6. Final report of the approved projects.

- **Updating CEC members**

  1. All relevant new guidelines on ethics will be brought to the attention of the members of the CEC by the Member Secretary.

  2. Members will be encouraged to attend national and international training programs/conferences/seminars in research ethics to help in improving and maintaining the quality of research protocols/ethics committee submissions and review, and be aware of the latest developments in this area.

- **Standard operating procedures to be followed by the committee for vulnerable population.**

Academy follows the National ICMR ethical guidelines 2017 on selection of Vulnerable and special groups individuals. The vulnerable populations are addressed as per the ICMR 2017 ethical guidelines by the Academy while conducting the study. The CEC monitors the protection of the vulnerable populations and they have equal right to be included in research so that benefits accruing from the research which apply to them as well. The EC determines vulnerability and ensures that additional safeguards and monitoring mechanisms are established. The committee advises the researcher in this regard and also special care to be taken by the researchers to ensure participant's privacy and confidentiality.

Principles of research among vulnerable populations are followed as per the ICMR 2017 ethical guidelines and clause 6.1.

Central Ethics Committee of our Academy have set the Obligations/duties of stakeholders as per the ICMR 2017 ethical guidelines which has been kept as a record and a copy will be issued to the researcher while carrying out research on vulnerable population.

Stakeholders	Duties
Researchers	• Recognize the vulnerability of the participant and ensure additional safeguards, which is a policy of our Academy as per ICMR 2017 ethical guidelines and are in place for their protection. • Justify inclusion/exclusion of vulnerable populations in the study • COI issues are addressed at the institutional level • Have well defined procedures (SOPs) to ensure a balanced benefit-risk ratio • Ensure that prospective participants are competent to give informed consent • Take consent of the LAR when a prospective participant lacks the capacity to consent • Respect dissent from the participant • Seek permission of the appropriate authorities where relevant, such as for institutionalized individuals, tribal communities, etc. • Research should be conducted within the purview of existing relevant guidelines/regulations
Ethics Committees	• CEC reviews whether the prospective participants for a particular research are vulnerable • Inclusion/exclusion of the vulnerable population should be justified by the investigators • CEC ensures that COI does not increase harm or lessen benefits to the participants. • CEC ensures determination of benefits and risks to the participants and advise is given to the investigators on minimization strategies wherever possible • CEC suggests additional safeguards, such as more frequent review and monitoring • CEC ensures initial and continuing review of all such proposals and if desirable, involves representatives from the specific populations during deliberations • CEC has special responsibilities when research is conducted on participants who are suffering from mental illness and/or cognitive impairment exercise caution and expects researchers to justify cases for exceptions to the usual requirements of participation or essentiality of departure from the guidelines governing research. CEC ensures that these exceptions are as minimal as possible and are clearly spelt out in the ICD

	• CEC has SOPs for handling proposals involving vulnerable populations
Sponsors	• Institution also justifies the inclusion of vulnerable groups in the protocol and has made provisions for protecting the safety of vulnerable population • Academy has enabled monitoring and ensures that procedures are in place for quality assurance (QA) and quality control (QC) • Academy ensures protection of the participants and research team if the research is on sensitive topics

The inclusion of certain groups of participants who may be vulnerable to undue influence or coercion may require additional protections. When the CEC reviews research involving vulnerable populations, the CEC applies state and local laws, as applicable. The CEC evaluates whether additional safeguards have been included in the study to protect the rights and welfare of participants who may be vulnerable to undue influence. The CEC requires at least one or more individuals who are knowledgeable about or have experience in working with these participants are part of the review process.

New study submissions including prisoners as potential research participants are reviewed by the convened CEC and cannot be reviewed under expedited procedures. Subsequent review of amendment and continuing review applications involving prisoners may also be reviewed by a convened board. Expedited review procedures may be allowed, where the expedited reviewer is an CEC member who is a designated prisoner representative. New study submissions, amendment and continuing review applications involving other vulnerable populations may be reviewed by the convened board or by expedited review.

The board will evaluate the research proposal to ensure that precautions are taken to protect the participant's i.e., Prisoners, Children, Wards of State, Pregnant Women, Foetuses and Neonates, and Individuals with Decisional Impairment.

- **Policy regarding training for new and existing committee members along with standard operating procedures.**

    - Training of CEC members is critical if the CEC is to fulfil its mandate to protect the rights and welfare of research subjects consistently throughout the University research community.
    - Regular CEC members are expected to complete currently required training on ethics and regulations. They are also expected to attend on-going training meetings. When appropriate, education pertaining to existing or new policies and procedures will be presented at a convened meeting. The members will receive initial and on-going training regarding

the responsible review and oversight of research and all policies and accompanying procedures.

- CEC members will complete training in the protection of human research subjects. CEC members may complete any of the training options offered for researchers that are approved by the University. CEC members will participate in initial and ongoing training in areas germane to their responsibilities.
- CEC members will be encouraged to attend workshops and other educational opportunities focused on CEC functions and human subject research. The University will support such activities to the extent possible and as appropriate for member responsibilities.

- **Policy to monitor or prevent the conflict of interest along with standard operating procedures.**

Conflict of interest (COI) is a set of conditions where professional judgment concerning a primary interest such as participants welfare or the validity of research tends to be unduly influenced by a secondary interest, financial or non-financial (personal, academic or political). COI can be at the level of researchers, EC members, institutions or sponsors.

- The University follows and adheres to the Conflict of Interest policy as per the National ICMR ethical guidelines 2017. All investigators engaged in research are required to comply with the policy.
- The protection of human subjects requires objectivity in communicating risks, selecting subjects, promoting informed consent, and gathering, analysing and reporting data. Therefore, the CEC considers conflict of interest issues. All principal investigators must complete a Conflict of Interest declaring whether they have any significant financial interests related to the research. Conflict of Interest Disclosure Forms must be completed for each new proposal.
- If COI is inherent in the research, CEC ensures declaration and establishes appropriate mechanisms to manage it
- All principal investigators must complete a Conflict of Interest declaring whether they have any significant financial interests related to the research. Conflict of Interest Disclosure Forms must be completed for each new proposal.
- Academy has developed and implemented policies and procedures to identify, mitigate conflicts of interest and also educates the staff about such conflicts.
- Researchers must ensure that the documents submitted to the CEC includes a disclosure of interests that may affect the research

- CEC evaluates each study in light of any disclosed interests and ensure that appropriate means of mitigation are taken
- The CEC requires financial interests of principal investigators to be managed so that they do not adversely affect participant protections or the credibility of the human research protection program. The CEC has the final authority to decide whether the conflicting interests and management plans adequately protect participants and allow research to be approved.
- COI within the CEC is declared if required and managed in accordance with standard operating procedures (SOPs)

CODE OF ETHICS is complying and is in accordance with the National ICMR ethical guidelines 2017.The Institution has a stated Code of Ethics for research, the implementation of which is ensured by the following by conducting regular workshops on Research methodology and research ethics. All the members of Ethics committee and publication board are trained in GCP and also workshop on GCP is conducted annually by R & I.

INCENTIVES FOR PUBLICATIONS

- The Academy insists that the publications should be in the Scopus / PubMed /Web of Science indexed journals/ or high impact factor journals.
- The publication charges / incentives to publishers are also awarded and as per the notification vide No. SDUAHER/KLR/ADMN/2320/2018-19 dated 29-10-2018.
- The incentives are given to publishers who contribute a chapter in a text book or reference book published by a national or international or publishers or in a SDUAHER Press and the amount incentives would be Rs.5000/- (Rupees Five Thousand Only).
- The incentives for a text book or a reference book solely authored by our faculty and published by a national or international publisher or a SDUAHER publication the incentive would be Rs.20, 000/- (Rupees Twenty Thousand Only).
- However, in case, publication charges are paid by our Academy, the proportionate amount would be deducted from the incentives and the remaining amount will be credited to the author.
- The publication charges shall be paid directly to the publisher and not to the author. However the author needs to take prior approval from Registrar SDUAHER through a representation forwarded through proper channel and R & D Section SDUAHER.
- The text books / chapters written and accepted for publication need payment for publication; it will be scrutinized by an internal expert and / or an

external expert who has expertise in the area the author has submitted for publication.

- The Institution also provides incentives and recognizes teachers who receive state, national or international recognitions/awards through Career Advancement, Salary increment, recognition by SDUAHER website notification and commendation or letter of appreciation.
- Best teacher Award is also awarded to the faculty annually in the form of cash prize during the Teacher's day Celebration.

THRUST AREAS

- Molecular studies in congenital malformation
- Oral cancer research
- Community health research- cervical cancer, fluorosis, Health status of gold miners
- Proteomics
- Treatment protocol development in cardiac arrest

RESEARCH GUIDELINES

- To perform research and publish the findings are the right and requirement of all Academic staff. The requirement to undertake research is a career prospect and over time will be balanced as appropriate and may include administrative responsibilities depending on the research record of academic staff

PROCEDURE TO CONDUCT RESEARCH

- Researchers should be honest with respect to their actions in research and in their responses to the actions of other researchers. This applies to the entire process of research including designing, data collection, analysing data, applying for funding, publishing results, acknowledging the direct and indirect contribution of colleagues, UG's, PG's, Ph.D. scholars, research fellows, statistician, collaborators and others.
- All researchers must refrain from plagiarism, deception or the fabrication or falsification of results or any other action that could be interpreted as research misconduct
- Researchers are encouraged to report cases of suspected misconduct to the R &D section for further investigation of allegations of research misconduct.
- Researchers should identify, declare and manage any real or potential conflict of interest whether ethical, financial or of any other nature.

RESEARCH PLANNING AND EXECUTION

- The researcher should identify the area of research and prepare the research proposal as per the research proposal plan format of R & I.
- The research proposals have to submit to R & I section followed by presentation and approval by the CEC Chairman.

IPR POLICY

The contemporary and stated Intellectual Property Policy of Sri Devaraj Urs Academy of Higher Education and Research (SDUAHER) endeavours to facilitate the protection and upliftment of intellectual properties generated during the scientific pursuit (of knowledge/resource) in the Academy and offer scope for ingenuity and commercialization. It targets the provision of unbiased intercession between the various interests involved.

In order to lessen the possibility of adopting a specification or other technology which might infringe on a patent or other IPR, SDUAHER will, in the course of carrying out its program of work, and in accordance with such Policies and Procedures of the Academy as may be in place from time to time, issue calls to its staff and faculty to disclose patents or other IPR ("patent calls") which are owned by them, or of which they might be aware, which might be infringed by the implementation of a specification proposed for adoption. Such a patent call shall be made at such times as the SDUAHER's policies and procedures shall provide.

1) Applicability:

The Policy on Intellectual Property (IP) is applicable to following personnel:

1.1 Employees, faculty members, staff (permanent and temporary), visiting scholars, fellows, research scholars and students associated with SDUAHER and include, but is not limited to, those who are directly under the Academy payroll and/or receive assistance in the form of fellowships, scholarships, honorarium, either from SDUAHER or from outside government and private institutions/agencies.

1.2 Employees, faculty, staff, research scholars, visiting scholars, fellows or students who are making use of SDUAHER facility and resources, and include financial support to generate, file and prosecute any form of intellectual property and invention related issues.

1.3 Various forms of intellectual property under this policy include, but does not limit to, Patent, Copyright, Trademark / Service Mark, Design Registration, Trade Secret, Confidential Information, Integrated Circuit Layout and Plant Varieties.

2) Ownership of IP:

An invention for which an intellectual property application is filed where in the Academy resources like space, equipment, facilities, are utilized and when the applicant(s) receive financial support towards professional and statutory fees for acquiring such intellectual property, the assignee of such intellectual property will be SDUAHER.

Individual(s), who obtains a patent or any other form of intellectual property or introduces an invention into public domain without use of resources from the Academy or outside their regular assigned duties during official hours under terms of their appointment with the Academy, and without substantial involvement by Academy personnel, shall retain full IP rights.

3) Copyrights:

Any original work of intellectual nature can be protected under copyright law. Ideas per se are not copyrightable but only in their expressed form.

When the copyrightable pedagogical, scholarly, computer software, integrated circuit layouts, designs, films, cassettes and other such literary and artistic works, specified as copyrightable works under relevant Copyrights Act as amended form time to time by the government, which are created for Academy, the author shall retain ownership of their original work, while at the same time granting Academy and all implementers of its specifications full rights to revise, modify, and create derivative works based on that original work, under the Academy's own copyright.

If the Academy foresees a gainful return from copyrights, it may initiate steps to file and protect such copyrights and share the financial rewards with the inventor on terms and conditions of the Academy as specified from time to time.

When the copyrightable work is generated for an external sponsor/Academy/company of foreign country/ lndia then ownership will be jointly shared according to the agreement between external sponsor and the Academy.

In case of copyrightable work created by non-Academy personnel without absolute intellectual contribution of Academy personnel and Academy resources the respective author shall retain his/her ownership.

Copyrights on books and publications authored by Academy personnel shall be in the name of the respective authors.

4) Inventions and Patents:

An idea when manifested in tangible form is patentable provided it fulfills the below criteria for patentability:

- Non-obviousness (the invention should be non-obvious to the person skilled in the art)

- Utility (it should be commercially applicable) and
- Novelty (invention may relate to a new product or an improvement of an existing one or a new process of manufacturing an existing or a new product)

If such a patentable invention is developed at SDUAHER, and qualifies for protection under the relevant Acts of government related to patents, then patent belongs to SDUAHER. It can be in the form of knowhow, solutions, processes, genetically engineered microorganisms, scientific or technological developments, business models and other forms as the need arises. The filing of a patent application shall be with the researcher as named inventor.

In such instance or instances where the patent is owned by the Academy, the inventor or inventors have the right on such form of intellectual property till the time protection of such intellectual property is agreed upon by the Academy and inventor(s) or the life of such intellectual property according to relevant Acts has expired. The Academy also reserves the right to initiate discussions on sale/license or technology transfer of patents or other forms of intellectual property, as the case may be, and which are deemed suitable for such activity. In an event of successful outcome through sale/license or technology transfer, the revenue sharing from either sale/license or transfer of technology shall be as specified in the royalty sharing clause mentioned below.

Whenever there is any patentable invention obtained under research or a related activity between an external sponsor and the Academy, then it is subject to agreement between the involved parties.

Party shall grant to each of the other parties and their respective affiliates, a nonexclusive, worldwide, perpetual, irrevocable, non-sub licensable license under any (if any) of such party's claims in its contributions, solely to make, have made, use, import, offer to sell, sell and otherwise distribute and dispose of compliant portions as agreed upon; provided that such license need not extend to any part or function of a product in which a compliant portion is incorporated that is not itself part of the compliant portion. Such license shall be granted on a royalty-free basis or will be subject to otherwise reasonable and non- discriminatory terms.

5) Royalty Sharing:

Net revenue received by the Academy through sale/license or technology transfer of intellectual property of such inventions or creative works, royalty shall be distributed as follows, unless otherwise specified in arrangements for commissioned works. The share shall be 60 % for the inventor and 40 % for the Academy. In an event when more than one inventor contributes for the generation of the intellectual property then the percentage of royalty shall be

equally shared as 60 % principal investigator/research guide/supervisor and 40% for co-investigators contingent upon such invention being sold, licensed or transferred under technology transfer agreement with third party(ies). No royalty shall be claimed by the inventor(s) for patents which fail to generate interest for sale, licensing or technology transfer.

6) Technology Transfer:

SDUAHER reserves the right to initiate and commercially leverage intellectual property of the Academy or jointly owned with other institute/Academy/industry under the agreements dealing with technology transfer, licensing and revenue sharing models in consultation with the named inventors.

In the case of sponsored activity, the sponsored industry/organization will have the first right to commercially leverage the intellectual property or products originating from the collaboration activity, whether or not the same have been formally protected by patent(s).

In the case of sponsored activity, if the sponsored industry/organization fails to commercially leverage the intellectual property or products within one year from the first date of development of the technology, then SDUAHER shall reserve the right to transfer the said know-how to a third party for its commercial advantage. However, Academy shall share the net revenues derived henceforth with the sponsored organization/industry as per the agreement regarding technology transfer.

7) Conflict of Commitment and Interests:

To manage and minimize conflict over intellectual property rights, all potentially patentable inventions created or discovered by faculty in the course of their Academy activities, or with use of Academy resources, SDUAHER be disclosed to the Academy on a timely basis ("Patent calls").

The inventor(s), to the respective Heads of Institutions, should disclose any conflict of interest or any potential conflict of interest.

SDUAHER discourages its employees, faculty members, staff (permanent and temporary), visiting scholars, fellows, research scholars and students against any legal recourse. In case of any disputes regarding the implementation of intellectual property policy, efforts shall be made to address to the concerns of the inventor(s) by developing and incorporating an arbitration mechanism and arrangement, or any other suitable mechanism as agreed upon by the parties and arrive at an amicable solution. The decision taken in this regard by the competent authority of SDUAHER or through arbitration shall be final and binding to all the parties under dispute.

8) Infringement:

SDUAHER shall retain the right to engage in or abstain from any lawsuit concerning patent and license infringements.

SDUAHER shall ensure that Academy personnel have an insurance clause built into the agreement with the licensee(s) while transferring technology or copyrighted material to licensees.

9) Incentive Awards for Granted Patents:

- INR 18,000 shall be awarded for each granted patent.
- All the members listed as inventors in granted patent shall receive INR 18,000 each.
- The incentive is awarded to the inventor(s) affiliated to Academy only for the granted patents, filed through the Academy.
- The certificate of grant of patent SDUAHER has to be submitted along with the evaluation form to claim incentive award.
- No incentive shall be awarded for filed patent applications.

ETHICS INVOLVING HUMAN SUBJECTS

The researchers are expected to follow the ICMR guidelines and ethics involving human subjects.

All research projects that involve human subjects must secure prior approval of CEC.

RESEARCH INVOLVING ANIMALS

Research involving animals must seek approval from IAEC. Stringent safeguards on animal pain and suffering to ensure care and welfare of animals must be put in place and observed.

ROLES AND RESPONSIBILITIES OF RESEARCHERS

- A research environment is encouraged in line with SDUAHER's policies. The HOD's and faculty should ensure that a research climate of mutual cooperation is created in which all members of research team are encouraged to develop their research ideas. Research concordat, good practice includes mentoring of junior faculty or colleagues, UG's, PG's and Ph.D. scholars as a mechanism for the development of research activity.

RESEARCH MANAGEMENT

- Researchers should follow SDUAHER research policies in carrying and managing projects.

DEVELOPMENT OF RESEARCH SKILLS

- Responsibility for good research practice lies with the research team. It is expected that the Principal investigator will have the overall responsibility of the conduct of the research project.

DISSEMINATION OF RESEARCH RESULTS

- Researchers must keep clear and accurate records of the procedures followed and the approvals granted during the research process including records of results obtained as well as the final research outcomes.
- Consent forms and data generated in the course of research should be kept securely in paper or electronic format as appropriate.
- Data should be stored in such a way as to allow a complete retrospective audit and records should be monitored regularly to ensure completeness and accuracy.
- Storage of human samples and data should be clearly marked with a "do not dispose of before" date. Storage of human samples must comply with the SDUAHER's licence under the Human Tissue Act.

PROMOTION POLICIES

- The faculty is called for promotion interviews bi-annually and CAS scheme is also available for deserving faculty.

STUDY TOUR/TRAINING POLICIES

- The deputations to outstation for the purpose of research are considered as OOD and support will be provided.

LANGUAGE TRANSLATION RESEARCH POLICIES

A professional Kannada translator or local members are available to facilitate translation of Patient information sheet and consent form, however, autonomy is given to Principal investigator.

INCREMENT POLICIES

- To enhance the quality publication numbers, SDUAHER has a policy that each faculty has to publish minimum one quality article annually in indexed journal such as Scopus/PubMed/Web of Science/approved by UGC and / or MCI to release increment

RESEARCH GRANT TO PG'S/Ph.D. STUDENTS

- All admissions of PG's, MD/MS are based on SDUAHER entrance examination qualification, minimum 55% in Post-graduation (Non-Medical

degrees) and for MBBS and MD/MS as per the MCI guidelines. The student – supervisor ratio adheres by the UGC guidelines.

- A synopsis or thesis topic has to be selected by the candidate and approval needs to be taken for the start of the study.
- A six months progress report of the thesis needs to be presented in the department by the PG's/MD/MS/Ph. D's and also before the committee to assess the progress made.
- The maximum period that can be extended to fulltime scholars or part time scholars shall not be beyond twice the stipulated time period i.e. six years for full timers and ten years for part timers. Further, with respect to early completion a candidate can be given six months advance submission of synopsis for final presentation with due permission from Hon'ble Vice-Chancellor, if the student has fulfilled all the requirements.
- The PG's/Ph. D's are also encouraged to take up funded projects.
- Approved Ph. D projects are supported with Rs.2 lakhs under the SDUAHER research grant program.
- The research supervisor shall serve as the Principal Investigator and the Guarantor for the grant.
- Further support of up to Rs.1 lakh may be provided after the scholar publishes at least 1 thesis related original article in Scopus/PubMed/Web of Science indexed journals

STUDENT RESEARCH POLICIES

- Financial support is also provided for ICMR non approved projects to both UG's and PG'S

COLLOBORATIVE POLICIES

- R & D has implemented policies to accept collaborative research only if the collaborator accepts to give Co-Principal Investigator to SDUAHER faculty.
- Collaborative studies should take into account the values/benefits expected from the research as compared to the risks involving the persons/population being studied.
- The participating centres should function as partners withthe collaborator(s) and sponsor(s) in terms of ownership of samples and data, analysis, dissemination, publication and IPR as appropriate. There must be free flow of knowledge and capacity at bilateral/multilateral levels.
- Careful consideration should be given to protecting the dignity, rights, safety and well-being of the participants in

cases where the social contexts of the proposed research can create foreseeable conditions for their exploitation or increase their vulnerability to harm.

- The nature, magnitude and probability of all foreseeable harm resulting from participation in a collaborative research programme should be specified in the research protocol and well explained to the participants.
- The benefits and burdens should be equally distributed amongstparticipants recruited by all collaborating institutions.
- All participants in collaborative research should have access to the best nationally available standard of care.
- If there is exchange of biological material involved between collaborating sites, the EC may require appropriate MoU and/or MTA to safeguard the interests of participants and ensure compliance while addressing issues related to confidentiality, sharing of data, joint publications, benefit sharing, etc.

EXTRAMURAL FUNDING POLICIES

- R & I hand holds faculty and PG's / beginners for publication to get extramural funding (all working Saturdays 2.30 PM to 4.30 PM at R & I)
- Research concept topics which can be carried out with minimum infrastructure / manpower / investment involving data collection / interpretation / presentation / publication are encouraged.
- R & I encourages STS ICMR / PG ICMR and also encourages add on publication in addition to dissertation work.
- R & I encourages qualitative research in addition to quantitative research
- R &I encourages health survey and community oriented research

JRF/SRF POLICIES

- JRF/SRF policies in the institute are as per the Guidelines Junior research fellowship in sciences, humanities and social sciences given in UGC. The Junior Research Fellowship (JRF) scheme of the UGC is open to candidates who qualify in the NET-JRF of the UGC and the UGC-Council of Scientific and Industrial Research (UGC-CSIR) joint test.
- The objective of the JRF scheme is to provide opportunities to NET-JRF qualified candidates to undertake advanced studies and research leading to M.Phil. / Ph.D. Degrees in Humanities and Social Sciences including Languages and Sciences.
- The tenure of fellowship is initially for two years under the JRF scheme. Upon expiry of this period, the work of the Fellow will be evaluated by experts. If the research work is found satisfactory, his/her tenure will be extended for a

further period of three years under the enhanced emoluments of the Senior Research Fellowship (SRF).

- In case the work is not satisfactory, an additional year will be given to him/her for improvement. However, during this period he/she will be designated as a Junior Research Fellow. In such cases work will be evaluated again after three years, and if improvement is found, the Fellow will get two more years under the SRF. Thus, the total period of fellowship (JRF and SRF) is five years and there is no further provision of extension.

INDEXATION CALCULATION POLICIES

- **The h-index** is calculated based on a list of the publications ranked in descending order by the Times Cited count. The "value of h" is equal to the number of papers (N) in the list that have N or more citations.

OUTREACH HEALTH POLICIES

Pradhan Mantri Jan Arogya Yojana (PMJAY), Ayushman Bharat-National Health Protection Mission contributed by both central and state govt. are utilised by the patients in RLJH, Kolar and aims at covering poor and vulnerable families for the secondary and tertiary care hospitalization.

Mission Indradhanush is also used aiming at maximum immunization coverage for less than 2 years children and to sustain the same yearly.

COPYRIGHTS

- **Copyright** is the right to copy and publish a work.
- Under **copyright** law, the investigator doing the original work owns the **copyright** of that work. In **research**, the researcher can use the **copyrighted** work as long as the work or source is cited in the reference or publication.