SUMANDEEP VIDYAPEETH

An Institution Deemed to be University under Section 3 of UGC Act, 1956
Accredited by NAAC with a CGPA of 3.53 on a Four Point scale at 'A' Grade
Category – I Deemed to be University Under UGC Regulation 2018
At Post Piparia, Taluka-Waghodia, District-Vadodara. Pin-391760

RESEARCH COMPENDIUM

2020-2021

CONTENTS

CHAPTER-1
Introduction to Sumandeep Vidyapeeth

Sumandeep Vidyapeeth (SV), An Institution Deemed to be University was notified through Gazette notification of Ministry of Human Resource Development (MHRD), Department of Higher Education Government of India, through vide notification No.F.9-46/2004-U.3 dated 17th January 2007, as "Deemed to be University" un1der de novo category. The Vidyapeeth was established under section 3 of the University Grants Commission (UGC) Act, 1956 through vide Notification No. F.No.6-106/2004 (CPP-1) dated 9thMarch, 2007 and subsequently, UGC granted permission by vide Notification No. F.6-106(1)/2004 (CPP-I) dated 26th August 2008, to start additional courses allied to Medical stream in the Department of Pharmacy, Department of Management (MBA Health care) and MBA (Hospital Management).

In October 2015, the National Assessment and Accreditation Council (NAAC) carried out an assessment of our Institution. The NAAC Accredited our Institution with CGPA of 3.53 on a four point scale at 'A' Grade as per the prevailing gradation system, which is highest in the state of Gujarat. Based on the UGC Notification No. F.1-1/2018(CPP-I/DU), dated 19th June 2018, the commission has graded Sumandeep Vidyapeeth as Category- I Deemed to be University, as per the provisions of UGC [Categorization of Universities (only) for Grant of Graded Autonomy] Regulations, 2018.

The Ministry of Human Resource Development, Department of Higher Education, Government of India through its notification No. F.9-46/2004-U.3, dated: 16th December 2019, has extended the Deemed to be University status of Sumandeep Vidyapeeth.

Vision

- To be the Centre of Excellence in Health Education, Health Care Services & Innovation.
- To develop Health Care Professionals of Global Competence.
- To be the Center of Excellence in the area of Evidence Based Education and Healthcare

Mission

- To provide state of art Infrastructure and human resource of higher credentials for Research, Hospital services, Teaching - Learning and Administration.
- To contribute towards Nation building by creating intellectually and technically proficient Health Care professionals who are innovative scholars, inspiring leaders and contributing citizens.
- To execute High Quality and Internationally acclaimed academic and research programs in Health Sciences.
- To augment the partnerships between Industries, Community and Institute for collective endeavour towards societal development and establishment of need based program.

CHAPTER-2
Introduction to Department of Central Research and Innovation

The state of art Department of Central Research and Innovation was established since 2006, The Department has been working with the aim of providing thrust to the research activities to be carried out at Sumandeep Vidyapeeth. The Research Cell works with a specific perspective of encouraging the faculty of the Institution in conducting research work, viz; writing basic research protocols, orientation to the regulatory requirements, managing all the research carried out within the ICH-GCP frame and looking after the Ethical requirements. The Research Cell also has a fully functional Institutional Ethics Committee and Animal Ethics Committee as per the requirement of regulatory bodies. There is individual Human Research Review Panel (HRRP) of the individual institute. All the institutes HRRP are following the general guidelines of Research Cell and SOP of SVIEC which is also based on the ICMR, Schedule of new drugs and clinical trial rules March 2019.

Vision

- The vision of Sumandeep Vidyapeeth is to become a leading hub for innovative research that transforms healthcare through knowledge and innovative research practices,
- To execute translational research from bench to bed through hypothesis based, public health oriented, high impact research in clinical and pre-clinical area.

Mission

- To encourage and facilitate faculty, research scholar and students to conduct high- end research.
- To develop various high end research proposals for research funding.

- To provide state of the art research infrastructure for faculty and other researchers for interdisciplinary research.
- To support faculty and students to generate local evidences which helps to develop state or national health policy through translational research.
- To encourage students for conducting research projects by providing the necessary direction and seed funds.
- To support clinical trials which are sponsored from industry or other research organizations.
- To support research via development and implementation of ethical guidelines related to human and animal trials

Objectives

- To develop research skills among the faculty and students
- To promote and to encourage the aspiring students and faculty members to carry out research in the field of Medical and Paramedical sciences, by providing necessary facilities and infrastructures required for them
- To create zeal among the students towards research and innovation
- To work closely with the industrial needs that eventually will result in new or improved products, processes, systems or services that can increase the company's productivity
- Innovative business activity creating added value in the global economy
- To enhance skill development training and self-employment opportunities
- To serve government by taking up sponsored projects
- To conduct research work of the standard that can generate IPR.

Recognitions:

SVDU has obtained recognitions given below:

- DSIR recognition (SIRO certificate) for receiving external research grant from the national funding agencies.
- NABH recognition for Institutional Ethical committee
- NABL recognition for Molecular Laboratory
- CPCSEA recognition for Institutional Animal Ethical Committee
- Gujarat Government recognized Student Startup Innovation Policy (SSIP) Centre

2.1 Department of Central Research and Innovation Organogram

DIRECTOR RESEARCH		
⇩		
DEPUTY DIRECTOR RESEARCH		
⇩	⇩	⇩
RESEACH CELL	HUMAN ETHICS	ANIMAL ETHICS
⇩	⇩	⇩
SENIOR RESEARCH SCIENTIST	CHAIR PERSON	CHAIRMAN
⇩	⇩	⇩
RESEARCH COORDINATOR	MEMBER SECRETARY	MEMBER SECRETARY
⇩	⇩	⇩
JUNIOR RESEARCH FELLOW	PHARMACOLOGIST (2)	SCIENTISTS
⇩	⇩	⇩
RESEARCH ASSISTANTS	CLINICIAN (4)	BIOLOGICAL SCIENTISTS
⇩	⇩	⇩
RESEARCH CLERKS	LAY PERSON	VETERINARIAN
	⇩	⇩
	LEGAL PERSON SOCIAL SCIENTISTS	MEMBER

CHAPTER-3
Research Committees

Research is a multi-facet task to be conducted by researchers and faculty of different levels and require inputs and encouragement from all. Various encouragement policies have been framed and implemented in order to provide impetus to research activities such as interdisciplinary research projects and their ethical approvals, sprouting of new research ideas with improved quality (novelty, impact on society), publications, conference proceedings, awareness of intellectual property, plagiarism check, etc.

To have all the possible ways to foster such activities in all six institutes, Institution has constituted various committees with respective objectives and tasks, as follows:

1. Research Advisory Board (RAB)
2. Constituent Institute Research Committee (CIRC)
3. Research Grant ,Consultancy and Collaboration Committee
4. Sumandeep Vidyapeeth Institution Ethics Committee
5. Sumandeep Vidyapeeth Institution Animal Ethics Committee
6. . Intellectual Property Right Committee (IPR)
7. Academic Integrity Panels (AIPs)
8. Research Awards and Accolades Committee
9. Sumandeep Vidyapeeth Incubation and Innovation committee
10. Institutions Innovation Council
11. Clinical Trail Committee

3.1 Research Advisory Board (RAB):

Objectives:

- The main objective of RAB is development and planning for new research policies through Research Cell, with consideration of existing policies.
- Regular guidance and suggestions for development of suitable mechanism for smooth implementation of research activities.
- Guidance to Research Cell for upgrading new research avenues for high end interdisciplinary research projects.
- Research Advisory board is constituted with 8-10 internal as well as eminent external experts members. Vice chancellor of SVDU shall be the Chairman and Director Research shall be the member secretary of this board.

3.2 Constituent Institute Research Committee (CIRC):

CIRC has been constituted in each institute which is chaired by the head of the respective institute while HoDs / nominated faculty are members of the committee, with the objectives of-

- Receiving all research related feedback from the departments of their institute and communicate them to Research Cell.
- It provides the platform to each faculty to share all his/her views and suggestions (related to research).
- All IRCs are scheduled to conduct their meeting on quarterly basis and shall communicate the minutes to Research Cell.

Composition of Institutional Research Committee (CIRC) of all six institutes:

- Institutional Research Committee consists of One Chairperson, One member Secretary and other selected member(s).

- Head of each institute will be the Chairperson of respective institution's Institutional Research Committee. Member Secretary and other Member(s) will be selected by the Chairperson of IRR.

3.3 Research Grant, Consultancy and Collaboration Committee:

To provide directions and guidelines for SV funded research proposals and their financial support and other financial matters such as budget and research incentives

Table 3.1: Composition of Research Grant & Funding Committee

Sr. No.	Designation	Position
1	Vice Chancellor	Chairperson
2	Director, Research Cell	Member
3	Dy. Director, Research Cell	Member
4	Registrar	Member
5	Chief Finance Officer	Member
6	Member	Member Secretary

3.4 Sumandeep Vidyapeeth Institutional Ethics Committee (SVIEC):

- To evaluate all research proposals received from students and staff of respected institution.
- To discuss about methods and ethical aspects of research proposal under SVIEC guidelines.
- SVIEC classify the research projects under minimal risk and higher risk on ethical aspect of the subjects.

Table 3.2: Composition of SVIEC

Sr. No.	Designation	Position
1	Chairperson	Chairperson Outside the Institute
2	Basic Medical Scientist	Member
3	Clinician	Member
4	Legal Expert	Member
5	Social Scientist	Member
6	Lay Person from Community	Member
7	Member	Member Secretary

3.5 Human Research Review Panel (HRRP) and its objectives:

- To help the researchers to understand the ethical aspects of the research at institutional level
- To receive the research proposal from the researchers of the respective institute and communicate them to SVIEC when needed
- To collect regular ethical reports of ongoing project & a completion report form researcher and submit the same to SVIEC for the update
- HRRP Constitution: HRRP consists of One Chairperson, One Coordinator and other nominated member (s).
- Head of each institute will be the Chairperson of respective institution‘s HRRP. Coordinator and other Member(s) will be selected by the Chairperson of HRRP.

3.6 Sumandeep Vidyapeeth Institutional Animal Ethics Committee (SVIAEC):

IAEC has been constituted under the purview of Department of Pharmacology, SBKSMI & RC, SVDU, with the objectives of-

- To review and approve all type of research proposals involving small animal

experimentation before the initiating the study. In case of research involved higher animals, the IAEC will forward its recommendation to the CPCSEA, New Delhi, for its approval

- To ensure that animal are not subjected to unnecessary pain or suffering before, during and after the performance of experiments on them
- To monitor the research throughout the study and after completion of the study through periodic reports and visit to animal house and laboratory where experiments are conducted.
- IAEC will also participate in –
- Monitor and inspect the housing of animals of breeders/establishments to ensure that it is as per specified standards,
- Regulate experiments on animals as per stipulated conditions and standards,
- Ensure that animals which in course of the experiments are so injured that their recovery would involve serious sufferings are euthanized as per specified norms,
- Ensure the minimum exploration of animals for experiments, wherever possible IAEC also propagate the principles of 3R', i.e. Reduce, Refine & Replace the use of animals in experiments,
- Ensure that experiments on larger animals are avoided when it is possible to achieve the same results by experiments upon small animals like guinea-pigs, rabbits, mice, rats etc.,
- Ensure that required records are maintained with respect to experiments performed on animals,
- Ensure that as far as possible experiments are not performed merely for the purpose of acquiring manual skill,
- Ensure that animals intended for the performance of experiments are properly

looked after both before and after experiments.

Table 3.3: Composition of SVIAEC

Sr. No.	Designation	Position
1	Chairman	Chairman Head of the Institute
2	Main Nominee of CPCSEA	Main Nominee of CPCSEA
3	Link Nominee of CPCSEA	Link Nominee of CPCSEA
4	Scientist from outside the Institute	Member
5	Non-Scientific socially aware member	Member
6	Biological Scientist	Member
7	Scientist	Member
8	Veterinary Doctor	Member
9	Scientist in-charge of animal facility	Member Secretary

3.7 Intellectual Property Rights (IPR) Committee:

Objectives:

- To catalyses awareness about the rights of intellectual property (IP) owners and regulates through by-laws or otherwise by the professional practice, etiquette, conduct and discipline of the Members.
- To govern the handling of inventions, copyright works, and other intellectual property made by individuals involved in educational, research, clinical and other activities of Hospitals and other constituent Institutes.
- To promote development of infrastructural facilities for registration of intellectual property by facilitating the improvement of legal, institutional and administrative framework.

Table 3.4: Composition of IPR Committee

Sr. No.	Designation	Position
1	Director Research	Chairperson
2	Deputy Director Research	Member
3	Professor, SVDU	2-3 Members
4	Senior Faculty, SVDU	Member Secretary

3.8 Academic Integrity Panel (AIP):

3.8.1 Institutional Academic Integrity Panel (IAIP)

Functions:

1) The IAIP shall follow the principles of natural justice while deciding about the allegations of plagiarism against the student, faculty, researcher and staff member.

2) The IAIP shall have the power to assess the level of plagiarism and recommend penalty accordingly.

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

Table 3.5: IAIP of SBKSMI & RC

Sr. No.	Designation	Position
1	Dean, SBKSMI & RC, SVDU	Chairman
2	Professor, SBKSMI & RC, SVDU	Member
3	Professor, KMSDCH, SVDU	Member

Table 3.6: IAIP of KM Shah Dental College and Hospital

Sr. No.	Designation	Position
1	Dean, KMSDCH,SVDU	Chairman
2	Director, Department of Management , SVDU	Member
3	Professor, KMSDCH, SVDU	Member

Table 3.7: IAIP of Department of Pharmacy

Sr. No.	Designation	Position
1	Principal, DoP, SVDU	Chairman
2	Professor, SNG, SVDU	Member
3	Asst. Professor, DoP, SVDU	Member

Table 3.9: IAIP of Department of Management

Sr. No.	Designation	Position
1	Principal, Department of Management, SVDU	Chairman
2	Professor, SBKSMI & RC, SVDU	Member
3	Asst. Professor, DoM, SVDU	Member

Table 3.10: IAIP of Sumandeep Nursing College

Sr. No.	Designation	Position
1	Principal, SNG, SVDU	Chairman
2	Asst. Professor, DoM, SVDU	Member
3	Associate Professor, SNG, SVDU	Member

Table 3.11: IAIP of College of Physiotherapy

Sr. No.	Designation	Position
1	Principal, CoP, SVDU	Chairman
2	Professor, SBKSMI & RC,SVDU	Member
3	Associate Professor, CoP, SVDU	Member

3.8.2 SV Academic Integrity Panel (SVAIP)

Function: To resolve the allegation of plagiarism issue on the report of the Institutional academic Integrity Panel.

Table 3.12: Composition of SV Academic Integrity Panel

Sr. No.	Institute	Position
1	Dean/Senior Academician of SVDU	Chairman
2	Senior Academician other than Chairman, to be nominated by the Vice-Chancellor.	Member
3	One member nominated by the Vice-Chancellor form outside the Sumandeep Vidyapeeth	Member
4	A person well versed with anti-plagiarism to be nominated by the Vice-Chancellor.	Member Secretary

CHAPTER 4
Research Conduct (Guidelines and Procedure)

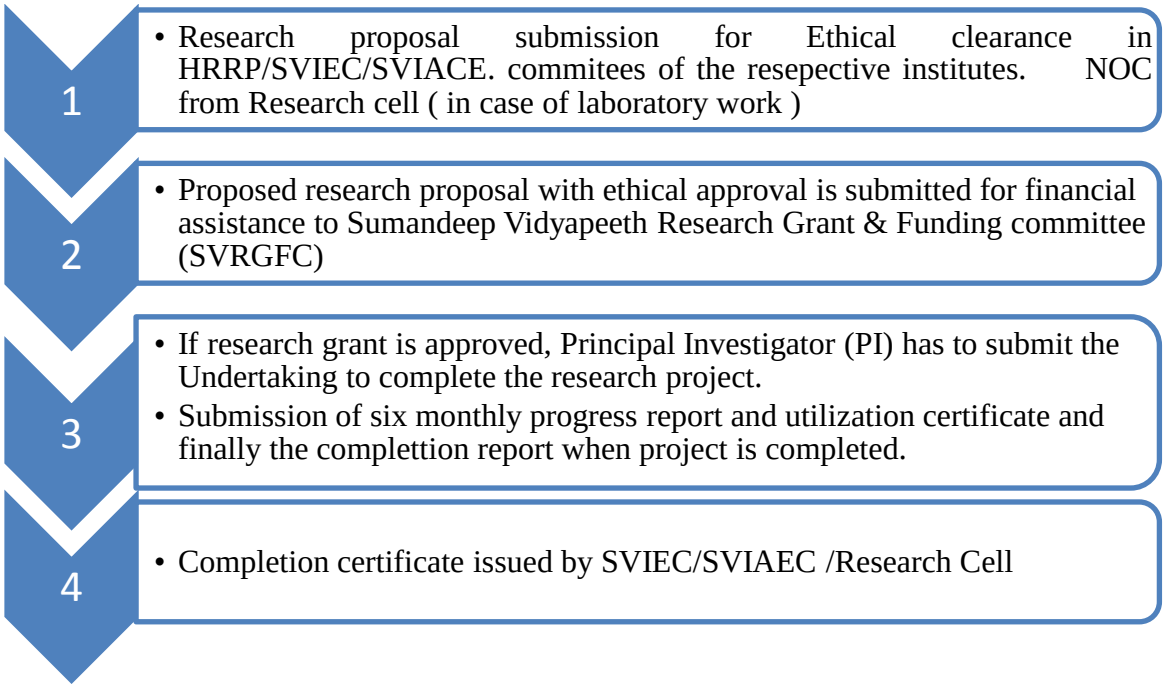
4.1 General Guidelines:

- Research Cell executes all research related activities on behalf of Research Advisory Council of the Institution.
- Research Cell identifies the thrust areas of research in consultation of respective institutions. Research Cell circulates the notification to HoIs regarding annual budgeting to be utilized for various research activities including research projects under Research Grant & Funding Committee (SVRGFC), for all the researchers and faculty of each constituent institute.
- Faculty and researchers shall design their research proposals in the prescribed format and to be submitted it to Research Cell.
- Proposal is forwarded to Research Fund Allocation and Review Committee (RFARC) for review by internal expert of the subject.
- Internal expert of the institute review the proposal and submit its remarks to the RFARC. The improvised/amended proposals will be discussed for further review and the process will continue till it fulfil all the required criteria (Grading sheet), considered for internal funding through SVRGFC.
- The principal investigator has to obtain the SVIEC/IAEC approval/ NOC before commencement of the research work. For ethical clearance, the Principal Investigator (PI) shall submit the application and proposal copy to SVIEC/IAEC through HRRP of his/her institute. After Ethical approval, researcher can precede further to initiate the research as per study design.
- The PI should commence his/her project from the mentioned date of the

proposal and, complete it within stipulated time period.

- ❖ Research Cell officials regularly meet PIs and faculty for motivation and solving operational problem.

4.2 Stepwise procedure for Research Conduct involving Human/Animal subjects/in vitro studies (From Project Submission to completion):



4.2.1 Procedure for obtaining Human Ethics committee:

All proposals shall be submitted via proper channel i.e. forwarded through HOD and HOI in the prescribed application form as per SOP of SVIEC to Institutional Ethical Unit of Research Cell.

- ❖ All relevant documents shall be enclosed with application,
- ❖ The PI will submit fourteen hard copies and one soft copy of the proposal along with the application and documents in prescribed format, duly signed by the PI and Co- Investigators/Collaborators to the HRRP. The HRRP will review the

proposal with details in context to methodology, feasibility, ethical aspect and other. If any weakness will be found, HRRP will ask PI to make correction and resubmit within the time limit. With the correction, PI will re-submit to HRRP. HRRP will forward the proposal with their comments on ethical aspect and send to SVIEC for approval,

- The office of SVIEC will acknowledge the receipt and indicate any modification,
- Based on HRRP, comments the SVIEC will take it as—minimal risk or a—high risk proposal. The minimal risk proposals will be granted permission without waiting for full ethics committee,
- All high risk research, clinical trials and PhD research will be discussed in full ethics committee. The frequency of meeting of SVIEC is once in three months. In this meeting minimal risk research proposal also discussed and granted permission,
- The decision of IEC will be communicated in writing. If the revision is to be made, the revised document in required number of copies shall be submitted within a stipulated period of time as specified in the communication,
- A draft proposal is reviewed by SVIEC followed by evaluation by a team of subject expert. Comments will be given to PI and asked to re-submit with answers of all queries,
- The detailed procedure and format of SVIEC proposal is available in this research compendium.

4.2.2 Procedure for obtaining Animal Ethical Clearance:

- All proposals should be submitted in the prescribed application form, copies of which will be available from the Member Secretary,

- All relevant documents with check list should be enclosed with application form,
- Fifteen copies of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator and Co-investigators/Collaborators should be forwarded by the Head of the Department to the IAEC. Sixteen additional copies for proposals for experiment on large animals will be required for forwarding it to CPCSEA.
- The Member Secretary will acknowledge the receipt and indicate any lacunae. Missing information should be supplied within two weeks.

4.2.3 Procedure for obtaining informed Consent:

- The subjects should be aware about him/her participation in any research study,
- The PI has to explain complete information to participants about research, in the format illustrated in participant information sheet. If participant understands and agrees to sign inform consent voluntarily, the PI will proceed,
- For that, the subject needs to get signed in proposed informed consent form and principal investigator should provide sufficient time to think to get enrol in the study prior to signed informed consent form,
- A copy of informed consent form should be provided to subjects for reference of research study enrolment,
- An informed consent form should be signed by PI, in front of subject and also need to mentioned date.

4.2.4 Procedure for obtaining informed assent:

- The subjects should be aware about him/her participation in any research study,
- The PI has to explain complete information to participants about research, in the format. Illustrated in participant information sheet. If participant understands

and agrees to sign inform assent voluntarily, the PI will proceed,

- For that, the subject needs to get signed in proposed informed assent form and principal investigator should provide sufficient time to think to get enrol in the study prior to signed informed assent form,
- A copy of informed assent form should be provided to subjects for reference of research study enrolment,
- An informed assent form should be signed by PI, in front of subject and also need to mentioned date.

CHAPTER 5
Sumandeep Vidyapeeth Research Grant and Funding Policy

5.1 Introduction:

This policy enables researchers to conduct small-scale research activities of the highest quality, that enable them to bid successfully for larger-scale or small scale funding, and/or to generate publications, and/or to contribute materially in other ways towards the research objectives of their institution.

SVDU has been awarded SIRO Certificate from Department of Science and Industrial Research, New Delhi, in April 2016, which is a prime requirement for getting research funds from any National and International funding agencies by filing extramural research projects.

5.2 Terms, Definition and Synonyms:

Research Fund: Research funding is a term generally covering any funding for scientific research, in the areas of natural science, technology, and social science. The term often connotes funding obtained through a competitive process, in which potential research projects are evaluated and only the most promising receive funding.

Funding agencies: These are Govt. or Non-govt. body providing monitory grants for scientific research Areas-Science and Technology, Social sciences, etc. In India various funding agencies are available which provide grants for a research in a various field For example; All India Council for Technical Education (AICTE) Council of Scientific and Industrial Research (CSIR) Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH) Department of Biotechnology (DBT), Department of Science and Technology (DST) etc.

5.3 Scope:

This policy shall apply to all the researchers of the Institution and for the purpose of this policy 'researchers' are defined to include:

1) All staffs (temporary and permanent) who are active in teaching, research, administration and provision of any form of support to the core function of the Institution.

2) All students registered with the Institution.

3) All mentors, guides, external experts and sponsors associated with any of the research activities of the Institution.

4) All academic and administrative departments of the Institution.

5.4 Purpose:

The primary objective of the proposed Sumandeep Vidyapeeth Research Funding Scheme is to motivate the faculty members of Sumandeep Vidyapeeth to undertake quality research, consultancy and other related activities with the assistance of Govt or non-Govt. funds for the benefit of the society.

5.5 Policy Statement:

Sumandeep Vidyapeeth has categorized two types of research projects as per their research budget.

a) Major Research Projects having budget more than INR 25,000/-

b) Minor Research Projects of which budget is less than INR 25,000/-.

As per above procedure, PI can apply for SVDU-Funded Research Scheme.

The general guidelines for the SVRGFC funding is as mentioned below:

1. Any staff member will be permitted two projects in a year under such scheme.

Funding is subjected to be approved by Internal Review Committee,

2. If proposed project work found under act of plagiarism (as per new plagiarism policy 2018), all benefits of scheme will be withdrawn and amount deducted from salary and further the faculty subjected to disciplinary action as per rules of the institution.
3. The faculty or research scholar is motivated to present work at National and International level,
4. Annual allocated budget to the institution will be utilized under on following heads:

   (a) Revenue account (research staff, chemicals, travel expenses)

   (b) Capital account

   - Equipment, accessories
   - Specific lab development
   - Renovation of existing labs/infrastructure

I. Institution will provide financial support to the research projects up to Rs. 20 lakhs as the upper limit of funds. All high end research projects should be submitted for extramural funding. For those extramural research projects, Institution will provide 10% seed money to PI in the beginning for smooth execution of the project and to avoid unnecessary waiting of the results,

II. If the project is approved by external agency, it will be financed through external agency but if project does not get approval then Institution will provide the financial assistance up to the upper ceiling amount i.e. 20 lakhs. However, SVRGFC may sanction research fund more than 20 lakhs exceptionally to the quality research projects after getting its review from external & internal experts of such research area,

III. All Institutes are required to submit utilization report of their allocated research

budget to the Research Cell on half yearly basis in the standard format. This include the fund disbursed in the current financial year as well as utilization of that budget in the respective heads of Research (i.e. funded projects, salary of staff, RIC, faculty development, others research activities).

5.6 Responsibilities:

The Research Advisory Board of the Institution shall be responsible for implementing this research policy of the Institution by working closely with the Institution's management.

5.7 Reporting:

All the actions pertaining to the research funding policy shall be reported to the Vice Chancellor through the Research Cell.

5.8 Records management:

All the record related to research fund (Govt. & Non-Govt.) shall be maintained by the Research Cell. All the records shall be maintained (soft and hard copy) for the five years from the completion of the research work or project.

5.9 Related Legislation and References:

This policy shall follow the guidelines of the following statutory agencies and implement as and when required.

1. University Grants Commission (UGC)
2. National Assessment and Accreditation Council (NAAC)
3. All statutory Councils of Medical, Dental, Pharmacy and Nursing.

5.10 Policy Administrator:

The policy shall be administered by the chairman of Sumandeep Vidyapeeth Research Funding Scheme (SVRFS). Vice Chancellor of the Sumandeep Vidyapeeth Deemed to be University shall be the final authority.

5.11 Implementation Procedure for SVRGC funding of Research Proposal

The principal investigator is advised to follow the guidelines, regulations and conditions provided for utilization of the grant as under:

1) The PI shall apply the SVDU funded Research Proposal as prescribed format **(Appendix 1A).**

2) The principal investigator has to obtain the SVIEC/SVIAEC permission/NoC from Research Cell before commencement of the research work,

3) To get the first instalment of the project, PI shall submit an application to Director Research along with Declaration form (attached along with this letter),

4) For the release of the fund, PI should submit estimated budget to the Research Cell. In case of equipment purchase, PI has to submit minimum three quotations for the vendor,

5) The PI should commence his/her project at pre-decided date and complete in a stipulated time period. In case of extension or any other subject, PI should inform to Research Cell and the approval committees in prior notice,

6) If project is not initiated within 6 months of sanctioning, PI should submit the reasons to Research Cell and the approval committees through proper channel, for its continuation,

7) All communication related to grant utilization or withdrawal of money shall route

through Research Cell,

8) Kindly submit a hard copy of bills/receipts/FoCs (Invoice letter, including all taxes and freight charges) related to equipments/chemicals/glassware purchased under the project to the Research Cell as a proof of expense after receiving the equipment, within 30 days.

a) FoCs (Free of Cost) should be signed through Medical superintendent, Dhiraj Hospital, SVDU

b) PI shall receive permission letter from MS, Dhiraj Hospital for FoCs before initiating the patient enrolment in the project.

9) Any intellectual property generated by research work under this scheme will be shared by Sumandeep Vidyapeeth Deemed to be University as applicant.

10) In all research communications (publication, conference proceedings), it is mandatory to mention Sumandeep Vidyapeeth Deemed to be University as the affiliating institute of the presenter.

11) PI shall submit the declaration form in prescribed format (Appendix 1B)

12) PI shall submit six monthly progress reports in the prescribed format to the Research Cell in every six month (Appendix 1C).

13) Report should include all updates and budgetary details (Utilization report and certificate) with proofs (Appendix 1D).

14) PI shall submit final completion report in a timely manner in the prescribed format (Appendix 1E).

CHAPTER 6
Collaboration Policy

6.1 Introduction:

Collaboration in various research institute / organizations/ laboratory offers better solution as well as opportunity of Upgradation of ideas and infrastructure requisites for the researchers to pursue high-end research work in their fields.

This policy has been formulated for our faculty and researchers to acquire global knowledge by collaborative research involving national, international, private and government universities, industries/agencies as well research labs of councils, ICMR, CSIR, DBT, DST, AYUSH, DHR and DRDO etc.

6.2 Terms, Definition and Synonyms:

Collaboration: The term "collaboration" in academic research is usually thought to mean an equal partnership between two academic faculty members who are pursuing mutually interesting and beneficial research.

6.3 Purpose:

The purpose of Collaboration is essentially the practice of sharing knowledge and ideas to achieve a common goal. Partnership among researchers ensures that their knowledge, skills and techniques are made available to everyone interested and mutually benefit the participants. The more researchers collaborate, the greater are the chances for success and problem solving.

6.4 Scope:

Collaborative research work shall-

a) Produce higher impact of publications: there is a direct correlation between the number of authors and impact factor.

b) Encourage greater creativity.

c) Produce high end research work due to collaborative funds and facilities.

d) Result in quality work done without compromising on results.

e) Have scope of efficient learning as team of experts solves the problem.

f) Have good scope to impress investors and the funding agencies.

6.5 Policy Statement:

a) Collaborative policies for Inter-institutional/ Inter-departmental Research:

b) Research Cell encourages all sort of research collaboration within institutes as well as within departments for making the research feasible with quality improvement. Faculty of participating department / institute must have mutual understanding for execution of the project since all six institutes belong to SVDU as a parent organization.

c) All concerned lab–in–charge / faculty of department must support the collaborative research project in all means. He/she should develop certain SOP/time schedule/timing specified for instrument/research facility specific for research. Preferably the schedules can be set-up on weekly basis so that researcher can plan his/her experiments accordingly.

d) Principle investigator should include the name(s)of the participating faculty / lab-in-charge in any publication as one of the author in case where his/her contribution in the project found indispensable or otherwise at least his / her name must be acknowledged with relevant support.

Collaborative policies for Research with External Institutes/ Universities/ Organizations:

a) Research Cell encourages and appreciates collaboration with external

participants (i.e. other scientists or local/state/ national/international level government/ non-governmental institution/ universities/ industries/ NGOs/ agencies) for multi-disciplinary, trans-disciplinary and inter–disciplinary research projects to promote high end research by utilizing sophisticated research facilities and expertise of collaborative partner. This can be initiated by signing MoU between the partners mentioning all terms and conditions. The MoU should be duly signed by the officials of both the parties.

b) For small scale research work, linkages and collaboration should establish between two department/Institute or minimum between two representative faculty.

6.6 Responsibilities:

Any collaborative research work is initiated by signing MoU between the partners mentioning all the terms and conditions. The signing authorities of collaborative institutes shall be responsible for the collaborative research work till it completion. Research Cell shall monitor and review the collaborative work and it is mandatory to submit the six monthly report of the work to the research Cell. The collaborators shall strictly follow conditions and scope of work mentioned in the MoU.

6.7 Records management:

All relevant documents related to the collaborative research work shall be maintained by the Research Cell. The record pertaining to collaborative research work shall be maintained in soft and hard copies for five years after the completion of the project.

6.8 Related Legislation and References: NIL

6.9 Policy Administrator:

The policy shall be administered by the Director Research of Sumandeep Vidyapeeth Deemed to be University. Vice Chancellor of the Sumandeep Vidyapeeth Deemed to be University shall be the final authority in case of any dispute arises and his/her decision shall be final.

6.10 Implementation Procedure:

[A] Preparation of MoU:

a) In case of any collaborative work or research project, a Memorandum of Understanding is signed between the collaborative parties,
b) MoU should specify the name & other details of the parties between whom memorandum of understanding is being signed,
c) It should clearly specify the purpose and the goals for which the memorandum is being signed,
d) The memorandum should specify the amount of capital contribution to be made by the parties (if any),
e) It should also mention the person authorized to make the major financial decisions.
f) The financial record keeping of the assignment/program being undertaken should also be maintained,
g) Once the MOU is prepared and agreed upon by parties involved, it should be signed and dated by the authorized individuals representing each party or organization,
h) The memorandum should specify the duration of such an agreement between the parties i.e. the beginning and the ending dates of the memorandum. Also,

it should provide for the circumstances in which such memorandum will be terminated.

Following are the content of MoU:

1) Objective or purpose of entering into MoU
2) Responsibilities of the each party
3) Meetings and Manner of Reporting
4) Technical and Financial Support, if any
5) Financial Consideration, if any, involved in the transaction
6) Person responsible for the Management
7) Duration of MoU
8) Confidentiality Clause
9) Conditions driving towards Termination of MoU
10) Possibility of Extension
11) Ways of Communication
12) Arbitration Clause
13) Indemnity Clause, etc

Depending upon the nature of transaction covered under MOU, the clauses can be added or removed and agreed upon with mutual consent.

[B] Execution of collaborative work:

Once the MoU is signed and exchanged, the work shall be initiated as per the terms and conditioned mentioned in the MoU.

[C] Periodical discussion:

Meeting of the both the collaborative parties shall be conducted in order to review the work and future guidelines for the quality work.

[D] Submission of Reports:

It is mandatory to submit the six monthly progress report to the Research Cell. At the completion of the work, a final report shall be submitted with details of the outcome and publication.

CHAPTER 7
Publication Policy

7.1 Introduction:

Sumandeep Vidyapeeth Deemed to be University (SVDU) is a Healthcare Institution. Continuous research projects have been going on in order to generate new products, drug mechanism, new therapy, clinical, and epidemiological research by the students, faculty and the research scholars with the financial assistance provided by the Institution or the Govt. and non-Govt. funding agencies. SVDU is required to report annually on its research publications and income. This information is also reported to the Govt. Accreditation agencies as part of its institutional assessment of the quality of research being undertaken at Institution. Information on research activity is collected and maintained by the Institution's Research Cell and information about SVDU research publications is available in various indexed online /offline Journals. Academic staff members report their research activity information to the SVDU and these data are verified, maintained and monitored for compliance with SVDU specifications.

The Institution recognizes that all academic staff as well as faculties and discipline areas have a responsibility to ensure that the research publication and other outputs meet appropriate quality standards and support the Institution's strategic directions. It is also necessary to comply with recent policy changes announced by the SVDU from time to time. All the researchers must submit research paper to the institutional Research Cell as soon as possible after the paper is accepted for publication in order to record it at Institution level and to assess the Institution on the ground of research activities annually.

7.2 Terms, Definition and Synonyms:

a) **Accepted Manuscript** - is the version of an article that has been accepted for publication and which may include any author-incorporated changes suggested through peer review.

b) **Scholarly peer review -** is the process of subjecting an author's scholarly work, research, or ideas to the scrutiny of others who are experts in the same field, before a paper describing this work is published in a journal, conference proceedings or as a book.

c) **First Author-**is usually the person who has made the most significant intellectual contribution to the work, in terms designing the study, acquiring and analyzing data from experiments, and writing the manuscript.

d) **Corresponding Author-**is the individual who, when working on a paper with multiple authors, takes primary responsibility for communicating with the journal.

e) **H-index-** It was invented by Jorge Hirsch in 2005, which denotes numerical indicator to how productive and influential a researcher is. It reflects an author-level metric that attempts to measure both the productivity and citation impact of the publications of a scientist or research scholar.

The h-index is calculated by counting the number of publications for which an author has been cited by other authors at least that same number of times.

For instance- h-index of 12 means that the scientist has published at least 12 papers that have each been cited at least 12 times.

f) **i 10- index-** number of publications with at least 10 citations.

g) **The impact factor (IF) of Journal**- is a measure of the frequency with which the average article in a journal has been cited in a particular year. It is used to measure the importance or rank of a journal by calculating the times its articles are cited.

7.3 Purpose:

This policy forms part of the Institution's governance framework for the management of research outputs. It outlines responsibilities with respect to approvals and roles, and informs procedures and guidelines related to the recording and management of the Institution's research outputs. The policy is to ensure that the Institution meets its requirement of research activity according to the various accreditation and statutory councils of Medical, Dental, Pharmacy, Physiotherapy and Nursing etc.

7.4 Scope:

- The publication policy provides scope to the Institution in improving the profile of Institution across the globe with high-impact research,
- Encourage researchers to publish their research outputs in reputed, high impact factor journals,
- Increases research profile, citation, H-index and impact factor of the Institution at National and International level,
- Provides the scope of maintaining the research data of all the researcher in the Institution in a systematic format which makes the Institution to evaluate it position every year in terms of research activity and innovation.

7.5 Policy Statement:

The SVDU is responsible for ensuring the integrity and accuracy of the Institution's research data for the purposes of providing internal and external jurisdictional reports. Faculties, Students and research Scholars of SVDU have a responsibility to ensure that the research publication outputs meet appropriate definitional and quality standards. The SVDU is responsible for compiling the norms of UGC, NAAC and other Funding agencies in order to put itself in the list of high rank Institution.

Research Cell rewards specified incentives to the researchers as per the research incentive policy for motivation and inspiration for more intensive research and development.

Research Cell shall maintain all the data, records and documentation regarding publication and projects of the constituent institutes.

7.6 Responsibilities:

All Institution staff members are required to report the final version of their research publication outputs as outlined in this policy. Faculties are responsible for ensuring that the research outputs shall be submitted to the Research Cell for record soon after acceptance and/or publication.

7.7 Reporting:

In case of any dispute and misinterpretation or misunderstanding pertaining to the publication policy, matter can be reported to the Research Cell for the resolution.

7.8 Records Management:

All records and documents pertaining to the research papers shall be maintained by the Research Cell in the soft and hard copies. All the records shall be maintained and managed by the Cell for the period of five years.

7.9 Related Legislation and References:

The publication policy shall consider any updates as received by the UGC, and NAAC.

7.10 Policy Administrator:

This policy shall be administered and by the Director Research Cell. In case of any dispute and lawful matter, the decision of the Vice chancellor shall be the final.

7.11 Implementation Procedure:

Any student/faculty presents/publish the review/original research work/chapter in the book/books should follow the *"SVDU Guidelines on the Publication"* (Appendix 2) and should report to Department of Research and Innovation through HoD and HoI to in the prescribed format along with its proof.

The aim of this policy is to put all possible forms of research outcome, on record. This policy requires each researcher to provide accepted version of a research output (books/book chapter/research article/review article, any communication to publishing houses) to be deposited to the Research Cell in order to maintain the records of the published research articles of the Institution.

In case of any research publication (paper, poster, etc.), corresponding author should be either guide or faculty involved in the research work. Student/Interns/PGs/Scholars should not be advocated as corresponding author in order to deal with any query which may arise in future.

CHAPTER 8
Plagiarism Policy

8.1 Introduction:

Plagiarism is a serious and widespread educational issue which represents another author's language, thoughts, ideas, or expressions as one's own original work. It is considered as a breach of journalistic ethic or academic dishonesty. The persons involved in this unethical practice may be subjected to sanctions such as penalties, suspensions, expulsion from the institute, substantial fines and even incarceration.

The Sumandeep Vidyapeeth has been adopting the existing plagiarism policy in order to maintain the Zero Tolerance'. Presently, UGC has issued a Regulation vide it notification No. F-1-18/2010(CPP-II), dated July 23, 2018, for the Promotion of academic integrity and prevention of plagiarism in higher educational institutions.

8.2 Terms, Definition and Synonyms:

- **Self-Plagiarism:** It is to copy one's own work done previously. Self-Plagiarism is not allowed as the credit for the work has already been taken and credit can't be taken again for the same work.

  Dual Submission: Submitting the same work in two different journals or conferences is also liable to be punished.
- **Fake Authorship:** Including friend's name as a co-author without his contribution or paying some person for doing own work is fake authorship. Giving a person's credit as an author without his contribution is an offense.
- **Material Theft:** Stealing other's work physically is material theft. Sometimes, people copy work from someone's computer or some other source. It is a rigorous act of

plagiarism. Unauthorized Copy of Source Code: Code required for specific purposes should be cited. If the source is not in the public domain, then prior permission must be taken.

- **Academic Integrity:** is the intellectual honesty in proposing, performing and reporting any activity, which leads to the creation of intellectual property.
- **Author:** includes a student or a faculty or a researcher or staff of Higher Educational Institution (HEI) who claims to be the creator of the work under consideration.

Institutional Academic Integrity Panel: shall mean the body constitutes date at the Institute level to investigate allegations of plagiarism.

- **Faculty:** refers to a person who is teaching and/or guiding students enrolled in Sumandeep Vidyapeeth in any capacity whatsoever i.e. regular, ad-hoc, guest, temporary, visiting etc.
- **Information:** includes data, message, text, and images, sound, voice, codes, computer programs, software and databases or microfilm or computer generated microfiche.
- **Programme:** means a programme of study leading to the award of a masters and research level degree.
- **Researcher:** refers to a person conducting academic/scientific research.
- **Script:** includes research paper, thesis, dissertation, chapters in books, full- fledged books and any other similar work, submitted for assessment/ opinion leading to the award of master and research level degrees or publication in print or electronic media by students or faculty or researcher or staff members. However, this shall exclude assignments/ term papers/ project reports/ course work/ essays and answer scripts etc.

- **Source:** means the published primary and secondary material from any source whatsoever and includes written information and opinions gained directly from other people, including eminent scholars, public audio, video, image or text.

8.3 Purpose:

The purpose plagiarism policy is prevent the unethical practice which is done for the financial benefit, for fame, to increase the number of publication or to get promoted.

8.4 Scope:

- To create awareness about responsible conduct of research, thesis, dissertation, promotion of academic integrity and prevention of misconduct including plagiarism in academic writing among student, faculty, researcher and staff.
- To establish institutional mechanism through education and training to facilitate responsible conduct of research thesis, dissertation, promotion of academic integrity and deterrence from plagiarism.
- To develop systems to detect plagiarism and to set up mechanisms to prevent plagiarism and punish a student, faculty, researcher or staff of Sumandeep Vidyapeeth committing the act of plagiarism.
- To establish the mechanism as prescribed in this Policy to enhance awareness about responsible conduct of research and academic activities to promote academic integrity and to prevent plagiarism.
- To train students, faculty, researchers and staff members about proper attribution, seeking permission of the author wherever necessary, acknowledgement of source compatible with the needs and specificities of disciplines and in accordance with rules, international conventions and regulations governing the source by conducting sensitization/awareness

programmes.

8.5 Policy Statement:

The constituent Institutions shall:

1. Include the cardinal principles of academic integrity in the curricula of Undergraduate (UG/Postgraduate (PG) Master‘s degree etc. as a compulsory coursework/module,
2. Include elements of responsible conduct of research and publication ethics as a compulsory course work/module for Masters and Research Scholars,
3. Include elements of responsible conduct of research and publication ethics in Orientation and Refresher Courses organized for faculty and staff members,
4. Train students, faculty, researcher and staff for using plagiarism detection tools and reference management tools,
5. Encourage students, faculty, researcher and staff members to register on international researcher‘s Registry systems,
6. Declare and implement the technology based mechanism using appropriate software so as to ensure that documents such as thesis, dissertation, publications or any other such documents are free of plagiarism at the time of their submission. This mechanism shall be made accessible to all engaged in research work including student, faculty, researcher and staff members,
7. Submit a thesis, dissertation, or any other such documents of students, research scholars with undertaking indicating that the document has been prepared by him or her and that the document is his/her original work and free of any plagiarism,
8. Include the fact in the Undertaking that the document has been duly checked through a Plagiarism detection tool approved by the Sumandeep Vidyapeeth.

a) Submit a certificate of each research supervisor/guide indicating that the work done by the researcher under him/her is plagiarism free.

b) Place the approved plagiarism policy on the homepage of the Institution website.

8.5.1 Similarity Checks for Exclusion from Plagiarism:

The similarity checks for plagiarism shall exclude the following:

I. All quoted work reproduced with all necessary permission and/or attribution.

II. All references, bibliography, table of content, preface and acknowledgements.

III. All generic terms, laws, standard symbols and standards equations.

Note: The research work carried out by the student, faculty, researcher and staff members 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 fourteen (14) consecutive words.

8.5.2 Levels of Plagiarism:

Plagiarism would be quantified into following levels in ascending order of severity for the purpose of its definition:

i. Level 0 : Similarities up to 10%- Minor similarities, no penalty

ii. Level 1 : Similarities above 10% to40%

iii. Level 2: Similarities above 40% to60%

iv. Level 3 : Similarities above60%

8.5.3 Detection/Reporting/Handling of Plagiarism:

In case any member of academic community suspects with appropriate proof that a case of plagiarism has happened in any document, he or she shall report it to the Institutional Academic Integrity Panel (IAIP). Upon receipt of such a complaint or

allegation, the IAIP shall investigate the matter and submit its recommendations to the Sumandeep Vidyapeeth Academic Integrity Panel (SVAIP) of the Sumandeep Vidyapeeth.

The authorities of the Sumandeep Vidyapeeth can take action on the act of plagiarism and initiate proceedings under this Policy.

8.5.4 Institutional Academic Integrity Panel (IAIP):

1. All Institutes of Sumandeep Vidyapeeth shall notify a IAIP whose composition shall be as given below:
    a. Chairman- Head of the Institute
    b. Member- Senior academician from outside the constituent Institute, to be nominated by the Vice-Chancellor.
    c. Member- A person well versed with anti-plagiarism tools, to be nominated by the Head of the constituent Institute.
2. The IAIP shall follow the principles of natural justice while deciding about the allegations of plagiarism against the student, faculty, researcher and staff member**,**
3. The IAIP shall have the power to assess the level of plagiarism and recommend penalty (ies) accordingly,
4. The IAIP 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.

8.5.5 Sumandeep Vidyapeeth Academic Integrity Panel (SVAIP):

1. The Sumandeep Vidyapeeth shall notify a SVAIP whose composition shall be as given below:
    a. Chairman- Dean/Senior Academician of the Sumandeep Vidyapeeth

b. Member- Senior Academician other than Chairman, to be nominated by the Vice-Chancellor.
c. Member- one member nominated by the Vice-Chancellor form outside the Sumandeep Vidyapeeth
d. Member- A person well versed with anti-plagiarism to be nominated by the Vice-Chancellor.

Note: The Chairman of IAIP and SVAIP shall not be same. The tenure of the committee members including chairman shall be three years. The quorum for the meetings shall be 3 out of 4 members (including Chairman)

2. The SVAIP shall consider the recommendation of IAIP,

3. The SVAIP shall also investigate cases of plagiarism as per the provisions mentioned in this policy,

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

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

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

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

8.5.6 Penalties:

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 Sumandeep Vidyapeeth 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.

- **Penalties in case of plagiarism in submission of thesis and dissertations (PhD and Masters Programme):**

The Sumandeep Vidyapeeth Academic Integrity Panel (SVAIP) shall impose penalty considering the severity of the Plagiarism**.**

i. **Level 0:** Similarities up to 10%- Minor Similarities, no penalty.
ii. **Level 1:** Similarities above 10% to 40%- Such student shall be asked to submit a revised script within a stipulated time period not exceeding 6months.
iii. **Level 2:** Similarities above 40% to 60%- Such student shall be debarred from submitting a revised script for a period of one year.
iv. **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 SVAIP and approved by the Vice-Chancellor.

- **Penalties in case of plagiarism in academic and research publications:**

i. **Level 0**: Similarities up to 10% -Minor similarities, no penalty

ii. **Level 1:** Similarities above 10% to 40% - Shall be asked to withdraw manuscript

iii. **Level 2** : Similarities above 40% to60%

iv. Shall be denied a right to one annual increment

v. Shall not be allowed to be a supervisor to any new Master's, PhD student/scholar for a period of two years.

vi. **Level 3:** Similarities above60%

(a) Shall be asked to withdraw manuscript

(b) Shall be denied a right to two successive annual increments.

(c) Shall not be allowed to be a supervisor to any new Master's, PhD students/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 serve rules shall be taken by the Sumandeep Vidyapeeth.

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 SVAIP and approved by the Vice-Chancellor.

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

Note 4: If there is any complaint of plagiarism against the Head of the Institute, a suitable action, in line with this policy shall be taken by the higher authority, preferably Vice- Chancellor.

Note 5: If there is any complaint of plagiarism against the Head of the Department at the constituent Institution level, a suitable action, in line with this policy shall be recommended by the SVAIP and approved by the competent authority.

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

8.6 Responsibilities:

The responsibilities for the conduct of plagiarism in on the shoulders of the following persons those are directly involved in the research work and its publication:

a) Research Scholar
b) Supervisor
c) Head of the Institute

8.7 Reporting:

In case of any report of plagiarism by student, research scholar or faculty, matter should be reported to the Institutional Academic Integrity Panel (IAIP) of the constituent institution. IAIP shall investigate the matter at its level and prepare the report of penalty and forward the report to the Sumandeep Vidyapeeth Academic Integrity Panel (SVAIP) to take the final decision.

8.8 Records management:

All the records and the documents shall be maintained and managed in soft and hard

copy by the Department of central Research and Innovation.

8.9 Related Legislation and References:

a) Indian Penal Code

b) UGC Regulations on Curbing Plagiarism

8.10 Policy Administrator:

The policy is administered by the Director Research, Sumandeep Vidyapeeth Deemed to be University.

8.11 Implementation Procedure:

The tool of anti-plagiarism "URKUND" is provided by the Sumandeep Vidyapeeth to check the plagiarism of all documents (thesis, dissertation, Publication of research paper, case report, chapter in book, full-fledged book etc.) of students, faculty, researcher and any staff All researchers/faculty /students can avail the free access of anti-plagiarism software "URKUND" for the academic year 2020-21.

The applicant shall submit the application through proper channel to the Librarian at Learning Resource Centre, SVDU. The report generated is required to be submitted to ethical committee for getting the completion certificate and follow the necessary requirements according to this policy.

CHAPTER 9
Research Promotion Policy

9.1 Introduction:

Research Promotion Scheme is aimed to create research ambience in the institutes by promoting research in healthcare sciences and innovations in established and newer technologies; and to generate Master's and Doctoral degree candidates to augment the supply of research experience faculty and research personnel in the country.

Research and development activities are considered as an essential component of higher education because of their role in creating new knowledge and insight and imparting excitement and dynamism to the educational process, as well as make them need based in view of the national requirements.

9.2 Terms, Definition and Synonyms:

Research Incentive: It includes anything offered to participants, monetary or otherwise, to encourage participation in research.

9.3 Purpose:

The purpose of this Policy is-

- To motivate the faculty members of our institution to undertake quality research, consultancy and other research related activities.
- To create and update the general research capabilities of the faculty members of the various healthcare and technical institutes.
- To encourage greater effort and success in securing external research funding.
- To make the Institution's research environment more attractive to current and prospective staff.

9.4 Scope:

The scope of the scheme envisages, in particular:

- To motivate our faculty members to concentrate on research related activities, in addition to the teaching, so as to publish research articles in reputed refereed international and national journals with impact factor.
- To pursue efforts to write books monographs for publication by International and National publishers of repute.
- To show interest among the members of faculty so that they take efforts to establish collaborative research projects with their counterparts in reputed national and foreign universities.
- To encourage our faculty members to submit proposals and secure funded research projects from various funding agencies in India and Abroad.
- To undertake consultancy projects sponsored by Government & Private, Industrial and other organizations.
- To encourage creativity in the minds of faculty members, so that they make original contributions by way of products, concepts etc. and obtain patents.

9.5 Policy Statement:

1) To promote Research and publications by the faculty members and students of the Institution, the guidelines for research promotion are categorized as:-
2) Incentives for Research publications
3) Incentives for Research projects for extramural funding
4) Incentives to the Principal and co-Investigator in Clinical Trials
5) Financial assistance for pursuing Ph.D
6) Financial assistance for attending National and International Conferences and

Faculty Development programmes

7) Deputation without financial support abroad and India

9.5.1 Incentives for Research publications and other research related work:

The Research incentive scheme shall be offered for research activities subject to the following conditions:

a) Publication of original research paper, review article, systematic review, meta-analysis and case study should be published in indexed journals i.e. PubMed, Scopus, Web of Science and UGC Care list.

b) Book/Book chapter in reputed National/International publishers. Only first author of the book/book chapter from Sumandeep Vidyapeeth will be eligible.

c) One chapter per book will be the eligible for incentive claim.

d) Book/book chapter should have ISBN number and Sumandeep Vidyapeeth as an affiliation.

e) Presentation of scientific research work (performed in SVDU) via oral/poster paper in scientific event such as conference, workshop, CME, etc. (Claims to be submitted at FDC office)

f) Research work conducted in Sumandeep Vidyapeeth or in association/collaboration with other institute/industry/research lab is eligible; provided a due permission letter is to be obtained from the collaborative institute and submit to the Research Cell.

g) The publications of the research work should belong either to PI/Guide/Faculty of Sumandeep Vidyapeeth constituent Institutes.

h) The research work being presented or published should have been carried out in SVDU; however the part of work may be conducted in collaborative

Institute/Research labs in case such facilities are not available in SVDU. In addition, the name of SVDU should be depicted in the publication as a first affiliation.

i) All research studies should be conducted only after obtaining due written permission (clearance/approval) from SVIEC/ IAEC. In case of *in-vitro* studies, NOC from Research Cell is required.

j) Applicant shall apply for the research incentives in prescribed format with proof **(Appendix 3).**

k) Incentives will be given as mentioned in Table 9.1.

I. Table 9.1: Incentive of Various Research Activities

Particulars	Indexing Data Bases	Incentive amount per publication
Research Publication:	**I. Indexed Journal with Impact Factor of Clarivate Analytics**	
	1) Upto 3 Impact factor - Indexed in PubMed Central / Medline, Scopus, and Web of Science (Science Citation Index Expanded, and Emerging Sources Citation Index).	Rs. 10,000/-
	2) From >3 to 5 Impact factor - Indexed in PubMed Central / Medline, Scopus, and Web of Science (Science Citation Index Expanded, and Emerging Sources Citation	Rs. 15,000/-

Original Research Paper / Review article / Case Report / Case Series / Narrative (Only for First Author who is a Teaching Faculty of SVDU)	Index).	
	3) From >5 to 10 Impact factor - Indexed in PubMed Central / Medline, Scopus, and Web of Science (Science Citation Index Expanded, and Emerging Sources Citation Index).	Rs. 20,000/-
	4) From >10 to 20 Impact factor - Indexed in PubMed Central / Medline, Scopus, and Web of Science (Science Citation Index Expanded, and Emerging Sources Citation Index).	Rs. 25,000/-
	5) From >20 Impact factor - Indexed in PubMed Central / Medline, Scopus, and Web of Science (Science Citation Index Expanded, and Emerging Sources Citation Index).	Rs. 30,000/-
	II. **Indexed Journal with <u>NO</u> Impact Factor with Clarivate Analytics**	
	1) Indexed in PubMed Central / Medline, Scopus, and Web of Science (Science Citation Index Expanded, and Emerging Sources Citation Index).	Rs. 6,000/-
	2) Indexed in UGC Care Journal list.	Rs. 1,500/-

Publication: **Books / Chapters** (First author).	Health Profession related Book, with ISBN number.	Rs. 25,000/-
	Chapter in Health Profession related Book, having ISBN number.	Rs. 7,000/-
	Non-Health Profession related Book, with ISBN number.	Rs. 12,000/-
	Chapter in Non-Health Profession related Book, having ISBN number.	Rs. 4,000/-
	Creative writing in Registered Magazines, News Paper, etc.	Rs. 1,000/-

II. Intellectual Property Rights (IPR):

Particular	Type	Status	Incentive amount
Intellectual Property Rights (IPR) Only for Teaching Faculty who is the First applicant.	**1.** Indian Patent	Awarded / Granted	Rs. 25,000/-
	2. International Patent	Awarded / Granted	Rs. 50,000/-
	3. Patent Design	Awarded / Granted	Rs. 15,000/-
	4. Copy Right	Awarded / Granted	Rs. 2,000/-
Patent / Patent Design Royalty on		**80:20** (80% of profit is to	

commercialization of innovation where Sumandeep Vidyapeeth Deemed to be University is the First applicant and the Teaching Faculties are other applicants.	Indian / International Patent / Patent Design	Sumandeep Vidyapeeth Deemed to be University and 20% of the profit distributed equally to the related Teaching Faculty of SVDU).

Note:

I. The Teaching Faculty of SVDU is eligible for incentive claim as under:

1. For Research Publication:

- Shall be as First author of the Research Paper.
- Shall be as Principal Investigator / Postgraduate Guide of the Research Project, as approved by Ethics Committee.
- In case of Dissertation / Thesis of the Student or Research Scholar is published by the Postgraduate Guide / Research Supervisor, then he/she is eligible for incentive claim. In this context, if the Postgraduate Guide / Research Supervisor has left the Institution, then any other Teaching Faculty of the same Dept. at SVDU, can publish the Dissertation / Thesis, with the approval of Academic Integrity Panel of SVDU.
- In case of publication of Dissertation / Thesis during the tenure of the Student, no Postgraduate Guide / Research Supervisor, who shall be second author, shall claim for incentive.
- In case of mandatory Publication for PG student / Research Scholar during the

course of study, the PG Guide / Research Supervisor is not entitled for incentive claim, irrespective of authorship.

- The Research Paper must have Designation and affiliation mentioned as 'Sumandeep Vidyapeeth Deemed to be University' for incentive claim. The Designation as Teaching Faculty will be considered for Incentive claim. The Teaching Faculty who is mentioning Ph.D. Scholar as affiliation will not be eligible for Incentive Claim.
- If the Research Paper is outcome of collaborative project between Institutes, than the Teaching Faculty of SVDU who is the First author in the said paper, shall have obtained prior permission from Research Director and / or Ethics Committee of SVDU, for the conduction of study.
- Papers published in SVDU Journal/s, shall not be considered for incentive.

2. Books / Chapters:

- Shall be the First author of Book / Chapter.
- No incentives shall be given to the First author of Book, who has written Chapter/s in the same Book.
- The Second / Third / Fourth author of the Book shall claim for incentives for Chapter/s written in the same Book, as First author.
- It will be the sole prerogative of the First author of the Book or Chapter, whether to distribute the received incentive, to the other authors.
- The published book shall have ISBN number. The published chapter shall be in ISBN registered book. The book / chapter published with publishing agencies / houses which are blacklisted / debarred by UGC, NAAC, NIRF or any other statutory body or Accreditation body shall not be considered for Incentive. (e.g.

Lambert etc.)

3. Intellectual Property Rights:

- Teaching Faculty who is the First applicant.
- Patent / Patent Design Royalty on commercialization of innovation where Sumandeep Vidyapeeth Deemed to be University is the First applicant and the Teaching Faculties are other applicants.
- **80:20** (80% of profit is to Sumandeep Vidyapeeth Deemed to be University and 20% of the profit distributed equally to the related Teaching Faculty of SVDU).

4. Miscellaneous:

- Papers / Columns written in SVDU related magazines etc. will not be considered for incentive.

9.5.2 Incentives for Research projects for extramural funding:

The SVDU offers additional reward to the Researchers receiving grants from External Agencies:

a) The faculty and research scholar getting research grant from national funding agencies viz., ICMR, CSIR, DST, DBT, GUJCOST, Pharmaceutical companies or International funding agencies like; WHO, UNICEF, UNESCO or other private funding organization including registered NGOs etc. shall be eligible for benefits under scheme.

b) Researchers will be offered additional reward as per rules given in Table 9.2.

Table 9.2: Additional Monetary Reward for Extramural Research Project

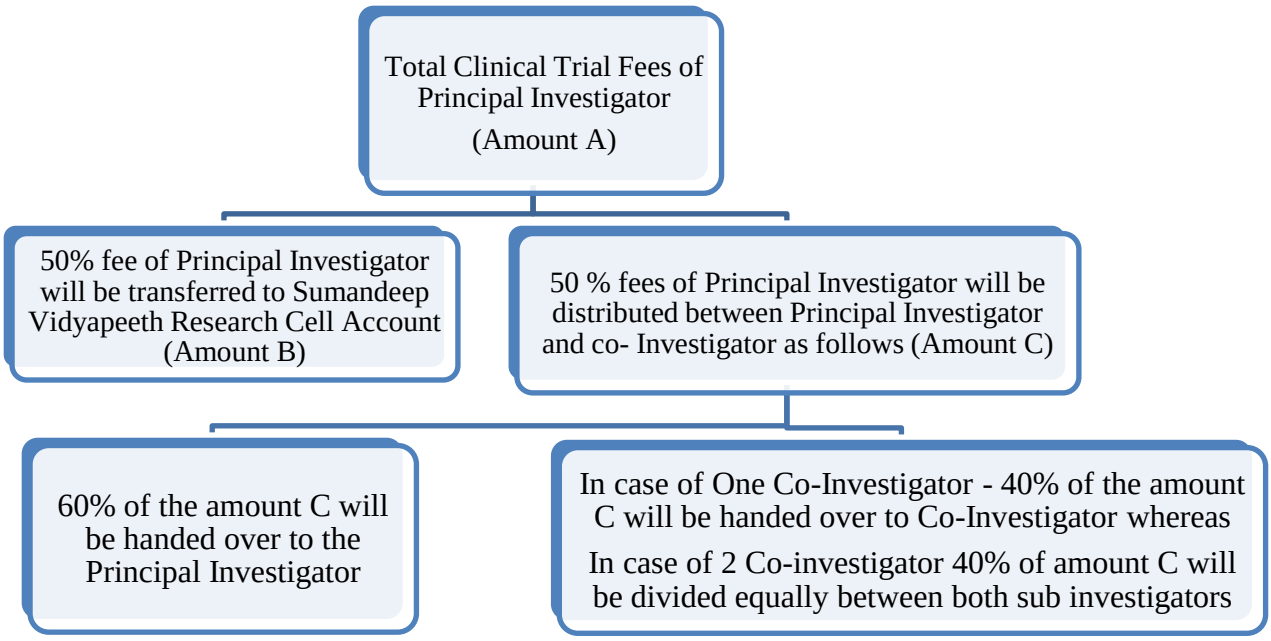
S. No.	Extramural fund received (INR)	% to be paid as total one time performance incentive* to all PIs(Co-PIs and supportive staff)

1	Fund received up to 10 L	3% of fund received
2	Fund received above 10 L	5% of fund received

* Disbursement of the incentives shall be executed after the completion of the project

9.5.3 Incentives to the Principal and co-Investigator in Clinical Trials:

Clinical Trial consultancy among Principal Investigator and co-Investigator shall be distributed as described in the following scheme:



9.5.4 Financial assistance to Faculty for pursuing Ph.D:

The Objective of this promotion scheme is to encourage the faculty member to improve their qualifications by pursuing Ph.D. programme available in the Institution. Any teacher of the Institution can enrol for the Ph.D. programme as per the procedure laid down by the Institution.

a) A faculty who is admitted to the Ph.D. course shall be provided fee concession to the tune of 40% of the fee charged for the course.

b) The fee of the faculty pursuing PhD will be deducted in instalments monthly from his/her salary.

c) The faculty will have to give an undertaking that he/she shall continue to be in the employment of the Institution for minimum two year after completing Ph.D. course.

9.5.5 Financial assistance for attending National and International Conferences/Seminar/Workshop and Faculty Development programmes:

a) Faculty is given incentives in the form of actual registration fee, and TA/DA to attend the conference or seminar as per the FDP policy of the Institution provided their research paper either oral/poster is accepted.

b) The prescribed application form for conference/symposia/seminar etc. in India and abroad is to be used.

c) Application duly forwarded by the Head of the Department and Dean of Faculty with their specific recommendation (regarding eligibility and amount to be given), to the Office of the FDC Coordinator, preferably 30 days before the date of the programme along with the brochure of the programme, acceptance letter from the organizer of the Conference or Seminar and other details of the registration fee and expense of TA/DA as per FDC policy of the Institution.

d) The incentive will be reimbursed to the faculty after submitting the detailed report of the event and all the relevant bills of registration fee and TA/DA.

e) For International Conference/Seminar, a consolidated amount of Rs. 50,000/- is given as a financial assistance with academic leaves to the faculty who is presenting the either oral or poster paper.

9.5.6 Deputation without financial support abroad and India:

Faculty seeking permission to attend conferences/seminars/symposia/ workshop / training programme in India or abroad without financial support from the Sumandeep Vidyapeeth but (academic) leave only, should also follow the same procedure as mentioned in procedure of applying for financial assistance for attending conferences/seminars/symposia etc abroad and India as per the guidelines of the FDP of Institution.

9.6 Responsibilities:

The responsibility pertaining to the disbursement of the research incentive according to the Research Incentive Scheme/Research Promotional policy is on the Research Coordinator of the Research Cell involved in verification of the data submitted by the researcher with the requirement of the Research Incentive policy.

9.7 Reporting:

In case of any dispute arising related to the research incentive shall be reported to the Vice Chancellor of the Institution.

9.8 Records management:

The records pertaining to the Research incentive scheme/Research Promotional policy is maintained and managed by the Department of central Research and Innovation of the Institution in soft and hard copies for at least five years.

9.9 Related Legislation and References: NIL

9.10 Policy Administrator:

This policy is administered by the Vice Chancellor of the Sumandeep Vidyapeeth Deemed to be University with the inputs of the Research Advisory Board.

9.11 Implementation Procedure:

1. An eligible applicant may apply in a prescribed application form as mentioned in compendium.
2. The applicant should submit the duly filled application along with a copy of publication and SVIEC/SVIAEC approval letter and NOC (if applicable) through the concern HoI to the Research Cell.
3. The application must be submitted within six month of publication or else it will not be considered.
4. The Research Cell will scrutinize the applications for their eligibility as per policy and forward to SV review committee for its approval.
5. After approval from SV review committee, Research Cell disperses the letter to the respective applicants for acceptance/rejection of the incentive claims.
6. Incomplete applications at any sense shall be rejected.

Note:

- In case of failure to submit the above relevant documents and fulfil the requirement shall debar the applicant from the benefit of this scheme.
- In case the proposed project work is found under act of plagiarism, all benefits of scheme will be withdrawn and incentive amount will be deducted from the salary and further the faculty will be subjected to disciplinary action as per Institution rule.

7. Disbursement of incentive
   i. All incentive claims are reviewed and sanctioned from the Research Cell as per the policy.
   ii. The incentive amount shall be remitted to the applicant who shall be

responsible for disbursal to all authors according to their mutual understanding.

iii. Incentives are disbursed on quarterly basis.

iv. Incentives other than publication shall be disbursed only after submission of the necessary documents through the HoI/Dean Faculty to Research Cell. Research Cell will verify the application and the relevant documents and will forward the application to the Registrar for the disbursement

v. The Vice Chancellor, SVDU reserves the rights in case of any dispute of any incentive claim.

CHAPTER 10
Research Award Policy

10.1 Introduction:

The research Award is instituted by the Sumandeep Vidyapeeth Deemed to be University in order to inculcate the scientific temper and Research Culture among the Students, Research scholars and faculty members of Medical, Dental, Pharmacy, Physiotherapy and Nursing.

10.2 Terms, Definition and Synonyms:

Research Award: The research award recognizes the efforts of those for their research excellence and outstanding academic achievements. The award may carry a cash prize and/or a citation.

10.3 Purpose:

The purpose of Research Award policy is-

a) To recognize the efforts of students and faculty, who are sincerely involved into academic and research activities, especially with innovative ideas.

b) To motivate the students and teaching faculty of the Institution to conduct high end research activities.

c) To create and inculcate research environment among the students and teaching faculties.

10.4 Scope:

The scope of this policy is –

a) To promote excellence, all round growth and development of students, research scholars and faculty of the Institution.

b) To foster the Human Resource Development initiatives for high end research and innovation for the future population needs in order to improve the healthcare system in the urban as well as the rural areas.

c) To recognize the outstanding contribution made by academic members of the Institution for promoting Organizational Growth.

10.5 Policy Statement:

10.5.1 Eligibility for the Sumandeep Vidyapeeth Research Award:

a) The applicant shall be a registered student of Sumandeep Vidyapeeth.

b) The faculty should be a permanent faculty of Sumandeep Vidyapeeth.

10.5.2 General Guidelines

a) Duly filled application form along with score sheet should be submitted to the Research Cell on or before the date declared by the Institution,

b) The academic and research performance for applicants shall be considered for the academic year of the Institution,

c) The publications which clearly possess Sumandeep Vidyapeeth shall be considered for grading,

d) The research study must have an approval of SVIEC & IAEC or else NOC from Research Cell should be attached,

e) The applicant shall submit substantial proofs (Soft Copy Only) for every activity mentioned in the scoring form,

f) A special award shall be conferred upon to a researcher/research team who published their research article in a journal of highest impact factor (Clarivate Analytics/Thomson Reuter).

g) All awardees of the constituent institutions of Sumandeep Vidyapeeth will be

given a token of Appreciation and a Certificate.

10.6 Responsibilities:

The research cell shall be responsible for collecting the applications for the research award within the stipulated time, collection of the proofs of the researchers for the claim, scrutiny of the document and declaring the winner in all category of UG, PG and Faculty research award by constituting a Research Award committee for verification of the documents and proofs of the applicants**.**

10.7 Reporting:

The names of the winner of all categories shall be sent to the Registrar, Sumandeep Vidyapeeth Deemed to be University, for official declaration of the Research awards.

10.8 Records management:

All the records pertaining to the Sumandeep Vidyapeeth Research Award in soft and hard copies shall be maintained and managed by the Research Cell, SVDU for minimum five years

10.9 Related Legislation and References: NIL

10.10 Policy Administrator:

Director Research of Sumandeep Vidyapeeth Deemed to be University shall be the administrator of this policy.

10.11 Implementation Procedure:

A. For submission of application:

a) The applicant shall have to submit hard copy of duly filled application with the scoring sheet to Research Cell and soft copy of all the necessary proofs as supporting documents on email :

<.researchcell@sumandeepvidyapeethdu.edu.in>

b) Applications received after last date of submission will not be considered.

B. For selection of awardees:

a) After receiving all the applications, SV fund allocation and review committee screened the application for their eligibility and finalize the awardees as per the score sheet **(Appendix 4).**

b) The committee shall also check the authenticity of the proofs if found irrelevant; grades will be deducted.

c) The committee shall scrutinize the application form and check the grading of the applicants mentioned in the scoring format.

d) The applicants scoring highest grading shall be considered for the Research award for the respective institutes.

CHAPTER 11
Intellectual Property Rights (IPR) Policy

11.1 Introduction:

Intellectual Property (IP) refers to creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce.

IP is protected in law by, for example; patents, copyrights and trademarks, which enable people to earn recognition or financial benefit from what they invent or create. By striking the right balance between the interests of innovators and the wider public interest, the IP system aims to foster an environment in which creativity and innovation can flourish**.**

11.2 Terms, Definition and Synonyms:

Copy right: Copyright is a legal term used to describe the rights that creators have over their literary and artistic works. Works covered by copyright range from books, music, paintings, sculpture and films, to computer programs, databases, advertisements, maps and technical drawings.

Patents: A patent is an exclusive right granted for an invention. Generally speaking, a patent provides the patent owner with the right to decide how or whether the invention can be used by others. In exchange for this right, the patent owner makes technical information about the invention publicly available in the published patent document.

Trademarks: A trademark is a sign capable of distinguishing the goods or services of one enterprise from those of other enterprises. Trademarks date back to ancient times when artisans used to put their signature or "mark" on their products.

11.3 Purpose:

The purpose of this policy is to promote these missions by making inventions, copyrightable works and other intellectual property that may be created by Clinician, researcher, trainee and others who are at or associated with the Institution for the benefit of the public while also providing for a fair allocation of the financial costs and rewards associated with them.

11.4 Scope:

The scope of intellectual property rights (IPR) is quite broad, consisting of many aspects. Defining intellectual property rights is difficult because globalization, technology, and IP law are constantly changing. In general, intellectual property is a concept that consists of a grouping of rights designed to protect the ownership of patents, trademarks, inventions, and works of art and literature.

11.5 Policy Statement:

Intellectual Property Cell on behalf of Research Cell looking after overall activities concerning with intellectual property of the Institution**.**

a) IPR cell is responsible for arranging social activities for members of the organization and promotes knowledge of intellectual property law by lectures, discussions, books, correspondences, pamphlets, dissemination of information or otherwise.

b) IPR cell shall assist and facilitate owner of intellectual property.

c) IPR cell also fosters ties, mutual cooperation and understanding among those who are practicing in the field of intellectual property law and through such ties promotes the protection and development of intellectual property in Institution.

d) IPR cell shall provide customized corporate services such as legal consultancy in Intellectual Property Rights and in related areas such as anti-dumping, anti-competition, IP audits, anti-trust laws and respond to questions affecting intellectual property law and/or the interest of the Institution faculty/students.

e) IPR cell shall encourage innovation of IPR‘s by interacting and keeping pace with development outside the Institution and engage in activities in conjunction with other bodies or associations within the limits of the Institution's objects.

f) IPR cell shall arrange reciprocal concessions and co-operation with other such bodies and associations and assists in implementing the rules and enforcement of laws pertaining to IPR.

g) IPR cell shall conduct training and capacity building activities for students and faculty and seeks affiliation with National or International bodies keeping in view of the fact that personal empowerment and convergence plays a crucial role in IPR issues.

h) IPR cell shall monitor all the IPR concerned on-going activities in the Institution, maintains the data, records and documentations at IPR cell.

i) If faculty is applying for any patent, the Institution has special incentive for the same.

11.6 Responsibilities:

It is the responsibility of the Research Cell, Sumandeep Vidyapeeth Deemed to be University for implementation, monitoring and review the IPR of the researcher of the Institution.

11.7 Reporting:

The reporting authority is the Director Research of Sumandeep Vidyapeeth Deemed to

be University.

11.8 Records management:

The documents pertaining to the IPR of the researchers of the Institution shall be maintained and managed in soft and hard copies for minimum five year after granting the patents, copyrights and trademarks**.**

11.9 Policy Administrator:

Director Research shall be the administrator of this policy.

11.10 Implementation Procedure:

a) In practice, upon submission of IP documents to Research Cell or verbal intimation by innovator to Research officials, Research Cell forward the innovator‘s idea to Sumandeep Patent Attorney, for further screening and identification of IP in the innovator claims.

b) Upon finding the content, Patent Attorney files the application for eligible claims.

c) All the expense for filing the application will be borne by Sumandeep Vidyapeeth Deemed to be University and will consider as “The Applicant”.

d) Innovator has all the authority for commercialization of the IP with prior MoU. For any commercial benefits, Innovator and Sumandeep Vidyapeeth will engaged in 80:20 ratios.

CHAPTER 12
Consultancy Policy

12.1 Introduction:

Consultancy is essentially a knowledge based profession and consultants play an important role in technological, industrial and economic development and are effective agents of change in the society. Over the years, consultancy capabilities have grown in several sectors, public and private and more recently a number of foreign consultants have also started operations in India. However, the domestic consultancy capabilities need to be strengthened and skills be upgraded continually in several sectors, since the consultancy profession growth in India has not kept pace with the industrial and economic developments over the years. Consultancy plays an important role in providing a competitive edge to an organization. The intangible assets of an organization such as technical know-how and expertise of the staff, are often more valuable than its physical assets. Over the last few decades, legitimate appreciation of the commercial value of technical know-how has grown both within the academic / non-academic community and in the society at large. The pace of development of the human mind, resulting in new and useful inventions, initiated a need for a central policy in determining the course of the creation, protection and commercialization of technical know-how in the Institution in the form of consultancy services which are now not only being used as a tool to share the knowledge, generate revenue but also to build strategic alliances for the socioeconomic and technological growth.

Keeping in mind the intellectual strength of Sumandeep Vidyapeeth growing awareness about the innovative research of commercial value and the need for collaboration with other organizations for mutual benefits, the Consultancy rules have been formulated to

provide guidance to the Full time faculty and Core Research Scientists, and any other Professionally Technically well qualified employees of Sumandeep Vidyapeeth, interested in the consultancy work. This document specifies the rules and norms of Sumandeep Vidyapeeth regarding consultancy and obligations depending upon the nature of consultancy. The rules laid down in this document are expected to fulfill the commitment of the Institution to promote academic freedom and provide a conductive environment for research and development of commercial importance.

12.2 Terms, Definition and Synonyms:

A consultancy project/task/work: is one where faculty and research staff provide knowledge and intellectual inputs to industry or other organizations (within India and abroad), primarily for their purposes.

Sponsored Projects: Projects wholly funded by the client having specified R & D objectives and well defined expected project outputs/ results, generally culminating in generation of intellectual property. Sponsored projects could be multi-client also, with sharing the project funding and research results.

Collaborative Projects: Projects partially funded by the client and supplemented by provision of inputs from the Institute such as extra manpower, production/ fabrication of product in bulk for testing infrastructural facilities, etc. Collaborative projects could be for up scaling/ proving of laboratory level knowhow, technology development or generation of intellectual property etc. The expected project output/ results are well defined.

Advisory Consultancy: Wherein the services would involve scientific, technical, engineering or other professional advice, provided to a client purely on the basis of available expert knowledge and experience of individual.

General Consultancy: Wherein the services shall comprise scientific, technical, engineering or other professional advice/ assistance based on the available knowledge base/ expertise of Sumandeep Vidyapeeth and envisaging only minimum use of laboratory facilities for essential experimentation needed to meet the objectives of the consultancy assignment.

12.3 Purpose:

The purpose of consultancy policy is to establish a framework to support consultancy activities and services at the Sumandeep Vidyapeeth Deemed to be University (SVDU).

12.4 Scope:

This policy applies to:

- All staff, of the SVDU, who are involved in the conduct of a consultancy service,
- All funds provided to the Institution for the purpose of conducting or supporting a consultancy service.

12.5 Policy Statement:

(I) Scope of Consultancy Services offered:

a) Consultancy Services may be offered to Industries, Service Sector, Govt. Departments and other National and International agencies in niche areas of expertise available in the Institution.

b) The services offered shall be along the lines of 'Professional Services' and will hence carry with them obligations and ethical requirements associated with such services as indicated in the Standard Terms and Conditions **(Appendix 5).**

c) Consultancy services offered may cover a variety of activities related to Technology, Medical and paramedical areas.

d) Testing & Evaluation services are to be normally offered in selected specialized areas. In order to meet the needs of clients, routine testing services may also be offered.

e) Technical infrastructure / Computational facilities of the Institution may be offered to undertake the outside work of the clients. The use of physical infrastructure of the Institution purely for Rent Purpose will not be covered under consultancy work.

f) All Consultancy and related Jobs need to be structured and executed in order to augmenting current levels of excellence in teaching and research, and in the process, generating funds.

(II) Consultancy Project Categories:

a) Each project shall be undertaken under-

I. Standard Term and Conditions **(Appendix 5)** and other specified General Consultancy rules

II. Specific research agreement or Memorandum of Understanding describing the details of contract (if any)

In the former case, the work is taken up in good faith between the consultant and the client, the obligations and responsibilities of both parties.

The latter case refers to consultancy projects that usually involve non- disclosure agreements, detailed negotiations of contract terms and signing of contracts in the form of agreement or MOU covering various aspects such as deliverables, milestones, payment schedules, role and responsibilities of the parties, non-disclosure of

confidential information, disputes resolution, liability, IPR matters, arbitration, and applicable law. These projects involve significant amount of effort and time associated with the negotiation and implementation of the research contracts.

The consultant (as defined in item III) may undertake the consultancy project under any of the categories below**:**

b) The consultant (as defined in item III) may undertake the consultancy project under any of the categories below:

Category I: Expert Advice and R&D Consultancy: - This type of consultancy will be Expertise intensive and based on the expertise of the Consultant.

Category II: Testing Consultancy: -This type of Consultancy will involve testing of sample/component/product against a standard. The Institution will undertake testing jobs provided testing facilities and expertise are available in the Institution.

Category III: Minor& Major Research Consultancy:- This type of Consultancy will involve use of Institution's Physical, instrumental and other infrastructure by the client in order to proceed with a minor or major research projects involving all sophisticated instruments for product development, stability studies, work on molecular biology, and cell culture studies.

(III) Who can be a Consultant(s)?

There shall be a Principal Consultant in every category of consultancy project who will act as a team leader. The office of Research Cell will communicate with Principal Consultant only regarding the consultancy project. A consultant must fulfill the following eligibility criteria for undertaking consultancy project in the respective category.

For Category I:

Full time regular faculty, Core Research Scientists and any other Professionally & Technically well qualified employee of the Sumandeep Vidyapeeth may take up the consultancy work in this category. However, the Principal Consultant in this category shall be a regular Faculty member of the Sumandeep Vidyapeeth. Merely possessing academic qualification and designation at SV level will not entitle a consultant(s) for the consultancy project in this category. In addition to the academic qualifications in the relevant field, the consultant(s) must possess expertise and proved credentials (in terms of published research work / R&D experience / practical experience in relevant field, etc.) in the area of the consultancy work.

For Category II:

Full time regular faculty, Core Research Scientists and any other technically well qualified employee of the SV are eligible to take up this category of consultancy work. However, the Principal Consultant in this category also shall be a regular Faculty member of the SV. The consultant(s) must possess the practical experience of handling and operating the testing equipment. The Principal Consultant must have the capability to interpret the results obtained through testing.

For Category III:

Full time regular faculty, Core Research Scientists, and any other Professionally / Technically well qualified employee of the SV are eligible to take up this category of consultancy work either as a Principal Consultant / Consultant(s). The consultant(s) must be well versed with the use of all sophisticated equipments and other technical infrastructure required for the consultancy work. Further, merely possessing any designation at SV level will not entitle a consultant for this category of consultancy

projects.

(IV) General Consultancy Rules:

a) The services of permanent employees of the SV will be utilized for the execution of the consultancy projects provided it does not affect at any cost their primary functions and responsibilities to the SV.

b) Consultancy assignments must not have any adverse impact on the ongoing academic, research, official and administrative activities. Further, such assignments need to be carefully scheduled in the light of ongoing commitments.

c) The consultancy assignments under Category-I are of highly specialized nature and must be handled with utmost sincerity. The assignments under this category may have far reaching impact on academia as well as society. Thus, any compromise in the execution of these assignments may tarnish the image of SV. Keeping this in view, it is mandatory to ensure that the concerned consultant possess proper academic qualifications and well established credentials in the area of consultancy.

d) The consultant must undertake any consultancy assignment under Category – II only after ensuring that the machine/equipment used for testing is duly calibrated and provide accurate results against a reference / standard. It is understood that the testing equipment will be used only by the consultant(s) and not by the client.

e) The consultant must undertake any consultancy assignment under Category – III only after ensuring that all sophisticated instruments for product development, stability studies, work on molecular biology and cell culture studies in proper working conditions.

f) Merely possessing any position / designation / supervisory role at SV level will not entitle a consultant for the consultancy project.

g) The total annual income of an individual Consultant from the Consultancy work shall not exceed his / her Gross Salary for 6 months in a financial year.

h) The time spent on consultancy and related assignments shall be limited to the non-working days /holidays. However, an individual Consultant / staff member shall not undertake consultancy work more than 60 days in a calendar year.

i) Outstation travel on Consultancy Assignments will be undertaken with the prior approval of the Vice-Chancellor under intimation to the Head of the Department / Office concerned. TA-DA, expenses towards boarding and lodging, etc. as per entitlement of the consultant shall be admissible as per SV rules. However, depending on the urgency of the consultancy work and the consent of client, the consultant(s) may claim TA-DA irrespective of his / her entitlement as per actual on the production of original tickets / bills. All these expenses will be met out of the concerned consultancy project funds.

j) No ceiling limit has been prescribed for undertaking consultancy projects provided consultancy work does not interfere with the normal teaching / research / official work in the Institution and other duties of the consultant(s) and the associated staff.

k) No retiring employee of the Institution will be allowed to submit a fresh consultancy project proposal as a consultant, if the duration of the project is beyond his/her date of retirement. However, in exceptional circumstances, a retired employee may continue to work as consultant with the approval of the Vice Chancellor, if he/she continues to serve the SV in some other capacity.

l) If the Principal Consultant leaves the SV or proceeds on leave or not available for

some reason (emergency / critical illness), the Director Research Cell on the recommendation of the Principal Consultant (if he/she is available) will appoint a new Principal Consultant in consultation with the client subject to the eligibility criteria of the consultancy rules and the written consent of new Principal Consultant. The new Principal Consultant will also give an undertaking to complete the project in the remaining funds and time period to the Director Research Cell through Head of the department / office concerned. However, in case of death of Principal Consultant, a mutually agreeable solution with the client will be worked out by the office of Research Cell.

m) Normally the agreed charges of the consultancy project are to be deposited by the client, in full, before the consultancy work commences. However, this stipulation is negotiable. In cases where the consultancy work is started with only partial charges deposited in advance, the arrangements of subsequent receipt of funds from the client have to be clearly spelled out in advance while submitting the proposal before screening committee. However, the project will commence only after depositing 50% of total contracted amount of the consultancy project by the client. The final report of the consultancy work shall be released subject to the full payment of the total contracted amount.

n) All purchases / procurement under consultancy projects shall be made as per norms prevailing in the SV.

o) If any of the Consultant(s) or supporting staff wishes to donate part or whole of his/her own remuneration, the same will be permissible and transferred to Research Cell SV Fund only.

p) Items like Book royalty and honorarium for Expert Committee meetings, invited lectures, PhD viva/evaluation, invited training programmers, organization of

conferences/workshops are not covered under consultancy.

q) A consultancy project is normally expected to be closed soon after the date of completion as stipulated in the original project proposal, unless an extension has been sought and granted. The completion certificate should be taken from the client on his letterhead by the Principal Consultant.

r) Consultant(s) shall disclose in writing at the time of submission of consultancy project proposal, the existence of (i) any relationship between him / her and the client funding the consultancy project or any vendor to whom payments are made from the consultancy project funds, in the form of involvement of any immediate relatives or (ii) any scope for potential disproportionate self- gain. The Director Research Cell will review such cases and decide appropriately, with the advice of the committee formed by Research Cell SV, to ensure that no actual conflict of interest exists and that such an involvement by the consultant does not adversely affect the consultant's objectivity, integrity, or commitment to the SV and to the profession.

s) In case any legal dispute arises between the consultant(s) and the client such that the consultant(s) are in any way, held responsible to make good the losses incurred by the client, such liability will be restricted to a maximum limit which will be calculated as follows:

Maximum Liability = the total contracted amount (excluding Service Tax) charged for the consultancy project – the expenditure / liabilities on the project. It is in the interest of the consultant(s) to bring this fact to the notice of the clients well in advance. The expenditure / liabilities as determined by the Institution will be calculated as the expenditure / liability till such date on which the client inform the consultant(s) in writing to stop work on the project for on-

going projects, or till the end of the project for completed projects. The expenditure will also include the remuneration paid to the supporting staff of the SV. Submission of the requisite report itself in such cases shall constitute the Utilization Certificate / final bill.

t) If a prima-facie case of malpractice and/or misconduct is established by a fact finding committee (duly approved by Vice-Chancellor through Director Research Cell) against the consultant(s) or the associated staff in connection with consultancy project(s), the Vice Chancellor, on the recommendation of Director Research Cell may prohibit the concerned person to take part in any new project either as consultant or the associated staff, till such time that a final decision is taken by the appropriate authority in the matter. However, in such cases the concerned person will be expected to complete his/her obligations in the ongoing consultancy project(s) with which he/she is connected, in order that the ongoing projects and obligations to the client do not suffer.

u) Any disagreement within the SV arising at any stage of a Consultancy project will be resolved in consultation with Director Research Cell and the Vice Chancellor to ensure an expeditious removal of bottlenecks and smooth functioning of the project. In case of any dispute arising at any stage of Consultancy project between Consultant(s) and the client(s), the Consultant(s) will be responsible for settlement of the dispute. The arbitration power shall lie with Registrar, SV, Vadodara, in case of any dispute and the decision taken by the Vice-Chancellor shall be final.

12.6 Responsibilities:

In case of any consultancy project, it is necessary to review the project every three months. It is the responsibility of Director Research to look after such projects.

12.7 Reporting:

In case of any dispute arising, the Director Research shall immediately report to the Registrar of SVDU in order to resolve the matter.

12.8 Records management:

All the records pertaining to the consultancy projects shall be maintained in soft and hard copies minimum for five year after the completion of the project.

12.9 Related Legislation and References: NIL

12.10 Policy Administrator:

The Director research shall be the administrator of this consultancy policy.

12.11 Implementation Procedure:

[A] CONSULTANCY PROPOSAL INITIATION AND MANAGEMENT

a) Consultancy projects are normally initiated by requests / enquiries from the Client directly to the SV or by discussion between the Client and the Consultant(s). When the enquiry is directly received by the SV, the Principal Consultant and other consultants (if required) will be identified depending on their expertise, and existing commitments, by the Director Research Cell on the recommendations of the Head of the constituent Institutes and on the recommendations of the Registrar in case of non-teaching staff.

b) In the event of a client preferring the services of a specific consultant, the consultant must fulfil the specified eligibility criteria and proper justification by the client for preferring a specific consultant must be given. The Director Research Cell after satisfying himself / herself shall ask the identified Principal Consultant to submit the detailed proposal as per the specified procedure.

c) The Principal Consultant identified by the office of Director Research Cell shall read the standard terms and conditions **(Appendix 5)** and submit a detailed project proposal **(**as per the Performa at **Appendix 6)** for the consultancy work through the respective Head of the Institute to the office of Director Research Cell.

d) An employee of the SV, who finds himself / herself eligible for the consultancy work, can also submit a detailed project proposal (as per the Performa at Appendix **6** through respective Head of the Institute to the office of Director Research Cell with Consultant(s) certificates (**Appendix 7).**

e) The proposal so submitted shall be placed for screening before a Committee constituted by the Research Cell considering expert members of relevant field in case the total cost of Consultancy project is more than Rs. 10,000/-. The said committee may accept / reject the proposal depending on its merit. The recommendations of the committee will be approved by the Vice-Chancellor through Director Research Cell in case the total cost of Consultancy project is more than Rs. 1,00,000/-. If the total cost of Consultancy project is less than or equal to Rs. 1,00,000/-, the Director Research Cell will approve the proposal.

Table 12.1: Committee constituted by Research Cell

Designation	Position
Director Research	Chairman
Dean of Faculty Concerned (in case of Teaching Staff) OR Registrar (in case of Non-Teaching Staff)	Member
Head of the Institute concerned	Member
One member from the Research Advisory Committee (to be nominated by Director Research Cell)	Member
Chief Finance Officer	Member
One Outside Expert**(to be nominated by Vice-Chancellor)	Member

** In case the total cost of Consultancy project is more than Rs. 2 Lakhs. The consultant(s) shall not be a part of the said committee.

f) The office of Director Research Cell will intimate the Principal Consultant through respective Head of Institute about the decision of screening by the committee after getting approval from the Vice-Chancellor.

g) For large projects (>Rs. 10 Lakhs), the said Committee shall review and assess the progress periodically (at least once in a year or twice in the total duration of the project) for timely completion of the projects. The Principal Consultant shall submit his progress report every six months to the office of Director Research Cell, SV. Also, consultant(s) shall submit his/her annual progress regularly to the office of Director Research Cell.

[B] DOCUMENTS TO BE MAINTAINED

Following documents will be maintained by the Principal Consultant through his team members and produced as and when required.

a) Attendance Records: Attendance record of the Consultant(s), supporting staff etc.

with man-hours spent during the consultancy work.

b) Inspection / Site Visit Register: A register to record any site visit by the Consultant(s) be maintained by the Principal Consultant. The suggestions rendered by the Consultant(s) during site visit along with remarks of the clients must be recorded. Further, if any expert advice by external expert is required during the Consultancy project, the same may also be recorded along with the remarks of the Consultant(s).

c) Salary/Payment Record: To record all payments made to Consultant(s), supporting staff etc.

d) Consumable and Non-Consumable Register: Register for recording hire/purchase of all equipments, materials, all consumables, non- consumables items etc. and its utilization.

e) Travel Record Register: To record details of all expenditure incurred on travel.

f) Log books and Warranty/Guarantee Record: Log books are used to record number of hours, laboratory equipment or hired or purchased equipments have been used. Besides, maintain warranty/guarantee certificates and also breakdown details of equipments.

g) Correspondence File: For all correspondence since initiation.

h) Agreement/Contract File: To maintain complete record of all agreements, contracts, drawings and such document which may constitute legal requirement.

i) Work Progress Report: Record of monthly progress report will be maintained by the Consultant(s). Every three months, the consultant(s) is supposed to submit a copy of progress report to the client.

j) Any Other Document: Any other document as per the requirement of the client / nature of consultancy project, etc. shall also be maintained by the Consultant(s).

At the time of completion of a consultancy project, the Principal Consultant shall submit a copy of final report along with duly audited expenditure statement, utilization certificate and completion certificate from the client in the office of Director Research Cell, SV.

[C] BUDGETARY NORMS AND DISTRIBUTION OF CONSULTANCY FUNDS

a) All payments related to Consultancy work will be received by the SV under separate budget head "Consultancy Services". The funds for Consultancy work will be operated by Director Research Cell/Registrar and Accounts officer of the SVDU.

b) The norms for calculation of various percentages for distribution of the total money received from client will be as follows:

Item	Amount
Total money received from client	X
Service Tax	Y
Total Contracted Amount	Z= X-Y
SV Share (U)	U=0.4Z
Remaining Amount (RA)	RA=Z-U
Total Expenditure* (E)	E
Balance Amount for Distribution (D)	D=RA-E
To Consultant	0.9D
To Institute Development Fund	0.1D

*Expenditure Details:

The actual expenditure in the consultancy work should cover the following costs related to the project. The taxes will be applicable as per government rules.

c) All expenditure under consultancy projects shall be made as per norms prevailing in the SV, unless otherwise mentioned in the MoU or Agreement of the Consultancy project.

CHAPTER 13
Standard Operating Procedures for Clinical Trials

13.1 Assessing Protocol Feasibility:

Purpose

To describe the procedures for assessing the feasibility of conducting a study at Sumandeep Vidyapeeth & Dhiraj Hospital (referred as Site) in compliance with standard protocol.

Site is committed to maintain the highest scientific, clinical and ethical standards while conducting research at Site. Further, Site is committed to comply with all applicable regulations and guidelines in this regard. In view of the same, before agreeing to participate in a clinical research study, the Principal Investigator (PI) and Institution must agree to the scientific, clinical, and ethical merits of the study; the financial impact to the hospital; compliance with regulations; and the operational feasibility of conducting the study at Site. This standard operating procedure (SOP) describes the steps for assessing the feasibility of conducting a research study at Site.

This standard operating procedure (SOP) describes the steps for fulfilling the regulatory, medical, and ethical requirements for assessing the appropriateness and feasibility of implementing a protocol within the SITE research network.

Scope

This SOP applies to the activities involved in assessing protocol feasibility for all research studies conducted at Site involving human subjects.

Procedure

Protocol Assessment

When a Sponsor/CRO contacts the study Site about a potential study, the Principal Investigator (PI) will assess whether or not it would be feasible to conduct the protocol with the existing staff and facilities.

Clinical/Scientific/Ethical Feasibility

- Clinical importance to Site patients/subjects.
- Scientific merit.
- Benefits and risks associated with the protocol.
- Consistency with the priorities of the hospital and the clinical department.

Operational Feasibility

- Availability of personnel and other resources required to conduct the study.
- Availability of patients meeting the inclusion / exclusion criteria of the study.
- The level of interest expected from the physicians needed to recruit patients into the study.
- The operational complexity of the protocol.
- Whether there are any conflicting studies in progress.

Regulatory Feasibility

- The PI reviews the protocol to determine whether there is anything required that may be problematic when submitting the project to the Sumandeep Vidyapeeth Institutional Ethics Committee (referred as SVIEC). As part of the review the Clinical Trial Coordinator (refereed as CTC) can consult with SVIEC representatives.

- The PI must check the following points before submitting the protocol to the SVIEC for approval, as SVIEC determines:
    - Research studies have the resources necessary to protect participants.
    - Adequate time for the researchers to conduct and complete the research.
    - Adequate number of qualified staff
    - Adequate facilities
    - Access to a population that will allow recruitment of the necessary number of participants.
    - Availability of medical or psychosocial resources that participants might need as a consequence of the research.

Financial/ Legal Feasibility

- A detailed review of the costs, including staff time needed to complete protocol activities and patient care visits are determined by the PI.
- The PI and CTC prepare the budget worksheet.
- The budget worksheet is compared with the sponsor's budget.
- The PI and CTC will negotiate with the sponsor to establish a feasible budget. Once an agreement is made, the budget will be signed by the PI and sent to the sponsor.
- If an agreement cannot be reached with the study sponsor to cover all costs of the study, the PI and CTC will work together to determine whether the study will be conducted at SITE.
- The Legal expert will facilitate legal review of the contract.

Decision

The PI will notify the sponsor (in case of sponsored study) of the Site's decision. In the event that the protocol not meet the above mentioned criteria the convener may, at his/her discretion, provide rationale for the decision to the PI and PI will inform the same to the sponsor, allowing the Sponsor the opportunity to make changes in the suggested part of the protocol and have it reassessed.

Applicable Staff

This SOP applies to all the personnel's of the clinical research team and the PI and others who may be responsible for making decisions regarding conduct of the research studies at Site.

13.2 Communication with Sponsor or Contract Research Organization (CRO):

Purpose

This standard operating procedure (SOP) describes the communication between key research personnel at site and the sponsor/Contract Research Organization (CRO), including telephone and written interactions, during the entire course of a research study conducted at Site and to ensure proper documentation of communications with the Sponsor/CRO concerning study activities.

Scope

This SOP applies to communications between the site and sponsors/CROs involved in the conduct of research study.

These communications serve to protect the safety and well-being of subjects by assuring that studies are conducted compliantly, sponsors/CROs are fully appraised of

study site activities, and key research personnel are informed of new information about the study provided by the sponsor/CRO.

Any new study which initiated during active period of the SOP will be covered under the SOPs, unless otherwise indicated. If necessary a study specific SOP may be prepared.

Procedure

General communications

- Provide the sponsor/CRO a contact list of site personnel involved in study start up, along with each individual's role and responsibilities.
- Communicate regularly, courteously and in accordance with Site standards, with the sponsor/CRO about all study related issues.
- Be familiar with the sponsor's SOPs pertaining to communications, including reporting timelines and preferred communication mode.
- Keep originals or photocopies of all study-related communications, including faxes with corresponding confirmations, e-mails, and written summaries of phone conversations.
- File all communication documents in the appropriate section of the SITE MASTER FILE.
- Retain all sponsor-generated communications regarding conduct of the study (e.g., tele conference announcement) in the correspondence section of the SITE MASTER FILE. Budget, payment and other contractual or financial communications should be filed separately from the regulatory binder. Ensure information is communicated to the Principal Investigator (PI) and other key research personnel as applicable.

Pre-Study communication

- The Clinical Trial Coordinator is responsible for sending the Confidentiality Agreement to the sponsor/CRO once reviewed and signed by PI.
- Notify the sponsor/CRO of the PI's decision to conduct the research study at Site.
- Review the protocol and submit if any questions concerning interpretation of the protocol or conduct of the study to the sponsor/CRO in writing and file the copy in the Site Master File.
- Fill the questionnaires provided by the sponsor/CRO regarding the study related requirements.
- Prepare questions to clarify protocol procedures, subject eligibility criteria, and other study-related issues in writing and file the reply in the Site Master File.
- The PI/Co I will discuss how the site is equipped to perform the study. This discussion will include a description of the potential subjects available for the study and methods being considered for recruitment.

Communications while the study is ongoing

- Investigator/Clinical Trial Coordinator will submit the updated screening and/or enrolment logs to the sponsor/CRO by the preferred mode of communication.
- Notify Sponsor/CRO about unanticipated issues, including adverse events (AEs) and Serious Adverse Events (SAEs), per the sponsor's definitions and timelines, as defined in the protocol or SOP.
- Communicate protocol deviations, as they occur, according to the sponsor requirements.
- Submit completed CRFs (paper-based or e-CRF) to the sponsor/CRO in accordance with the Clinical Trial Agreement (CTA).

- Respond promptly to data queries as requested via fax, e-mail, and/or direct electronic data capture resolution, per the sponsor's requirements and document the same in the specified Site Master File.
- Communicate significant regulatory changes as per the sponsor's requirements (e.g., SEC acknowledgement of an unanticipated issues or protocol deviation, SVIEC approval of a revised consent document, etc.). Typically these documents are reviewed during interim monitoring visits; however specific sponsors/CROs may require prompt notification in specific circumstances.
- Submit sponsor-generated protocol amendments to the SVIEC. Once approval is obtained, PI will train the study team regarding the changes prior to implementation and same will be documented and informed to Sponsor/CRO
- Forward safety reports received from the sponsor (e.g., off-site SAE/SUSAR) to the PI who will review the event and report to the SVIEC as per SVIEC SOP. Notification of other key research personnel and/or enrolled subjects may be necessary (e.g., new risk identified related to investigational treatment).

Communication after study is completed

- Inform SVIEC regarding scheduled site close out visit.
- Communicate with sponsor and confirm the close out date.
- Provide the sponsor/CRO with any SVIEC required correspondence (e.g. information requires in the SVIEC study closure letter) related to the study close out.
- Ensure that all close out activities are performed and all sponsors requirements are met.
- After receiving the final close out letter and study result from the sponsor, submit the same to the SVIEC in the required SVIEC format.

- File all the communication in the appropriate section of the site master file.

Sponsor Contact

1. Telephone Contacts – All study personnel will document critical conversations with the Sponsor/CRO in the source notes, especially those pertaining to eligibility criteria, protocol deviations, and serious adverse experiences. If requires the CLINICAL TRIAL COORDINATOR or delegate will file the Telephone Contact copy in the SITE MASTER FILE.
2. Letters and Faxes – All study personnel will make copies of all correspondence written to the Sponsor/CRO. The CLINICAL TRIAL COORDINATOR or delegate will file this correspondence in the SITE MASTER FILE.
3. e-mails – All study personnel will print out copies of critical e-mails with the Sponsor/CRO. The Clinical Trial coordinator or delegate will file this correspondence in the Site Master File and if required in the source notes.

At a minimum, the Sponsor/CRO should be notified:

- When the first subject is enrolled in the study.
- When there is a question concerning a potential subject's eligibility.
- When recruitment issues occur.
- When a protocol violation occurs.
- When an SAE occurs.

Applicable Staff

This SOP applies to all the personals of the clinical research team involved in communication with the Sponsor/CRO and responsible for the management of the data.

These include the following:

- Principal Investigator
- Sub Investigator
- CLINICAL TRIAL COORDINATOR
- Pharmacist
- Support Staff

13.3 Interaction with Institutional Ethics Committee:

Purpose

To describe the procedures related to communication with the Sumandeep Vidyapeeth Institutional Ethics Committee (SVIEC) during the entire study duration right from study initiation to completion, and to describe what documents should be retained to reflect interaction with the SVIEC.

Scope

This SOP will apply to all studies being conducted at Site.

Procedure

Interactions with the Sumandeep Vidyapeeth Institutional Ethics Committee (SVIEC) continue throughout the duration of a research study. Establishing effective ongoing SVIEC communication and reporting procedures are essential to the successful management of research studies. An effective working relationship with the SVIEC strengthens the team approach to the protection of participant safety in addition to enhancing compliance with applicable SOPs, guidelines and regulations governing research studies.

Interaction with SVIEC required during the entire course of the research study, the phases could be:

Initial Submission of project to SVIEC

i. **Detailed description of project submission**

- The PI/ Co-I/CTC should submit all study related documents to the SVIEC, no fewer than fourteen (14) days before the scheduled meeting.
- The PI/Co-I/CTC should complete the SVIEC submission form (Refer SVIEC SOP) and PI must sign and date in the form wherever required.
- PI/Co-I/CTC must check the submissions as per the SVIEC checklist (Refer SVIEC SOP) to ensure that all mandatory forms and documents are enclosed.
- The CTC will submit the signed forms and documents to the SVIEC. These include, but are not limited to:
    - Covering letter with brief description regarding the list of documents enclosed for SVIEC approval, including the no. of copies submitted, document enclosed relevant version number and date of all the documents.
    - Project submission Form as mentioned above
    - Study protocol
    - Other related documents necessary for initial review as mentioned in the SVIEC
    - Curriculum Vitae and updated GCP certificate of the investigator and study team.
    - SVIEC fees cheque in the favour of “Soniya Khanna”, in case of sponsored studies.
    - Number of copies required for SVIEC submission will be as per SVIEC SOP

Note: One additional copy for PI Acknowledgement

The PI/CTC should keep a copy of the acknowledged (SVIEC stamp with sign and date) submission letter of the above mentioned documents in the Site Master File (SMF) and send scan or copy to the sponsor (via mail or courier as required by the sponsor).

PI/CTC must document the unique "Project no." given by the SVIEC after project submission for future communication and collect updated SVIEC membership roster and SVIEC registration number and should place in the Site Master File (SMF).

ii. EC Response

The PI and CTC should ensure that the letter of response from the SVIEC includes the following information:

- Clinical study identification, protocol number and title;
- Name and version date of all documents reviewed by the SVIEC.
- Date of review by the SVIEC
- Approval for the number of participants to be recruited in the study.
- Decision/opinion/approval of the clinical study, including required modifications, ifany; (Note: Reply to the SVIEC in case of any suggested modifications)
- If conditional approval given, it is not valid for more than 6 months (Refer SVIEC SOP)
- Procedures for appealing the decision/opinion of the committee;
- Any other information, if applicable, as described in the SVIEC SOP
- Date of renewal of approval;
- Signature of the SVIEC member secretary and date of the response.

- Following Schedule Y and GCP (ICH 3.2.1 et 3.2.2) a list of the members of the Ethics Committee and their qualifications, as well as the procedures of the said committee should be available.
- The PI/CTC should keep an original copy of the SECs approval letter in the SMF and provide one copy to the sponsor/CRO (via email/fax).
- Immediately after receiving SVIEC approval, register the study on CTRI and if applicable on ClinicalTrials.gov
- Notify SVIEC after receiving registration number.

Study Progress

PI can start project at site after receiving approval letter from SVIEC and as study progress at site PI must communicate with SVIEC for all required notification and reporting such as:

Protocol Amendments

a. Major Amendments

- Notify the SVIEC of any changes to the protocol and/or informed consent and/or of new information on the investigational product no fewer than fourteen (14) days before the next scheduled meeting.
- All amendments should bear amendment number and version number with date(s).
- CTC must make sure that all changes or modifications in the amended version are underlined or highlighted along with detailed summary of changes.
- The amendment /documents along with the covering letter should be accompanied by Amendment Reporting Form (Refer SVIEC SOP)

- Number of copies required for SVIEC submission will be as per SVIEC SOP
- Note: One additional copy for PI Acknowledgement
- The PI/CO-I/CTC should obtain a copy of the acknowledged (SVIEC stamp with sign and date) amendment submission letter of the above mentioned documents, and file the same in relevant section of SMF and send Scan or a copy to sponsor/ CRO(via email/fax).
- The amendments in the protocol and/or informed consent and of new information on the IP will be valid only after SVIEC approval, and should immediately implement the documents at the site after approval.
- Document the approval letter in the relevant section of the SMF and send a copy to sponsor/CRO(via email/fax)

b. Minor amendments and notifications

Minor amendments are those that do not increase the risk or decrease the potential benefit to subjects and may be approved by the SVIEC (Refer SVIEC SOP).

This may include but may not restrict to:

- Renewed insurance policy
- DCGI and DGFT approvals
- Administrative notes
- Documents of administrative nature

Deviations/Violation and Waivers

- Submit protocol deviations/violations and waivers to the SVIEC for review and approval according to SVIEC and regulatory requirements

- Deviation/ non-compliance/ violation/waiver happens at site, when investigators/trial sites, fail to follow the procedures written in the approved protocol
- comply with national / international guidelines for the conduct of human research
- fail to respond to the SVIEC requests
- PI/CO-I//CTC must submit the deviations /violations/waiver reports as per the SECSOP.
- Protocol deviation/ non-compliance/ violation/waiver can be detected during monitoring visit for the investigator initiated study by SVIEC and for sponsored studies by the monitor/ CRA also. Sometimes it can be detected by PI /study team member.
- The SVIEC members and/or monitor/ CRA performing monitoring of the project at study site can detect protocol deviation/non-compliance / violation, if the project is –
  - not conducted as per protocol / national / international regulations
  - when scrutinizing annual / periodic reports / SAE reports
  - fail to respond to requests from SVIEC within reasonable time limit
  - fail to adhere to protocol required procedures
- Protocol Waiver is analogous to a Protocol Deviation, except that prior SVIEC approval must be obtained before implementing the necessary departures from the protocol. Therefore, Protocol Waivers are anticipatory, while Protocol Deviations are not. E.g. Protocol Waiver means a prospective decision by a sponsor or investigator to permit accrual of a subject who does not satisfy the approved inclusion /exclusion criteria for enrolment.

- SVIEC action could include one or more of the following:
  - SVIEC will inform the PI that SVIEC has noted the violation / noncompliance /deviation and inform the PI to ensure that deviations / noncompliance / violations do not occur in future and follow SVIEC recommendations.
  - SVIEC will enlist measures that the PI would undertake to ensure that deviations /noncompliance /violations do not occur in future.
  - call for additional information
  - Suspend the study till additional information is made available and is scrutinized
  - Suspend the study till recommendations made by the SVIEC are implemented by the PI and found to be satisfactory by the SVIEC
  - Suspend the study for a fixed duration of time
  - Inform the Director, SITE
  - Revoke approval of the current study
  - Inform DCGI / Other relevant regulatory authorities
  - Keep other research proposals from the PI/ Co-PI under abeyance
  - Review and / or inspect other studies undertaken by PI/Co-PI
- File the SVIEC acknowledged deviations/violations and waivers forms submitted in relevant file and send one copy to the sponsor/CRO.

Safety Information

- Safety information can be any information recently reported or obtained from sponsor/CRO particularly regarding risks associated with the research.
- Safety information is categorized as Serious Adverse event (SAEs) and unexpected event reports of both onsite and offsite.

- The Principal Investigator must review safety information received from the sponsor.
- It is recommended that the PI review of safety information must be documented.
- The Investigator must submit Serious Adverse Events (SAEs) and unexpected events reports, both onsite and offsite, including follow up reports for active study participants.
- Report all safety information to the SVIEC according to the SVIEC and regulatory requirements (eg. Investigational New Drug [IND] submissions, Council for International Organizations of Medical Sciences [CIOMS] reports, Suspected Unexpected Serious Adverse Reaction (SUSAR), Periodic Safety Update Report(PSUR), Data Safety Monitoring Board [DSMB] reports).
- File the safety reports and any associated SVIEC correspondence, if any, in the SMF.
- Copies of the associated SVIEC correspondence should be provided to the sponsor according to sponsor requirements.
- Report any other information to the SVIEC that may adversely affect the safety of the participants or the conduct of the research study.

a. Off Site Safety Reports

- Off Site SAEs are adverse event reports that are serious, expected, unexpected related and unrelated (definitely, probably and possibly) to the drug and need prompt reporting to the SVIEC/DSMSC/Sponsor.
- The SAEs that are expected (if listed in the informed consent and IB) or unexpected but unrelated to the drug (classified as per the Offsite SAE Classification form – as per SVIEC SOP) have to be logged by the PI and to be

submitted timely. The following log will be maintained continuously until the end of the study.

- SVIEC/DSMSC will accept the log of the SAEs every 3 months and/or at the time of continuing review/ annual status report.
- Those off site SAEs which qualify for prompt reporting, (classified as per the Offsite SAE Classification form – as per SVIEC SOP) will be reported to SVIEC /DSMSC
- Sponsor/CRO will send two sets of the offsite SAE, CTC will submit one to the SEC/DSMSC (as per the SVIEC SOP) and file acknowledged (Stamped, signed and dated by the SVIEC /DSMSC) copy in the SMF and send a copy to the sponsor/CRO.
- PI's must review the SAE listings in detail and report if a trend is observed and communicate the same to SVIEC/DSMSC.
- PI/Co I may receive email or letter as applicable, if any queries are raised by the SEC/DSMSC Secretary. PI/Co I must reply to the query immediately.

b. Onsite SAE reporting:

Kindly Refer SOP for Safety Reporting

Annual Report/ Continuing Review report

- The purpose of Annual report/ continuing review report is to monitor the progress of the study which was previously approved; not only for the changes but to ensure continued protection of the rights and welfare of research subjects.
- PI/Co I/CTC must submit continuing review report/annual report to the SVIEC annually, subsequent to the date of SVIEC approval to renew approval before two months of expiry.

- All information must be provided to SVIEC/DSMSC, as requested in the continuing review application form (Refer SVIEC SOP)
- The Investigator/CTC should submit the continuing review application well in advance i.e. 12 months after SVIEC final approval.
- CTC should submit three hard copies of the report (1+2) and a soft copy.
- CTC should obtain a copy of the annual/continuing review report acknowledged by SVIEC, and file the same in SMF and send a copy to sponsor (via email/fax).
- The SVIEC Secretary will notify Principal Investigator in case committee recommended modifications, and PI will be requested to resubmit the relevant documents within 1 month for the approval till then the project is suspended.
- Principal Investigator will be communicated about the decision within 14 working days after the minutes are finalized.
- The PI will receive a letter from SVIEC/DSMSC, if the continuing review report/annual report is approved / accepted.
- The letter should be file in the SMF and a copy should be provided to the sponsor.

Note: If there is delay in approval of the continuing review report subsequently from the date of SVIEC approval, the PI cannot recruit any patient during that phase, till SVIEC/DSMSC, approve the continuing review report.

Study Termination

a. Premature Termination / Suspension /Discontinuation of the study

- Research studies are usually terminated as per the recommendation of the SVIEC,PI, Sponsor or other authorized bodies wherein subject enrolment and subject follow-up are discontinued before the scheduled completion of the study.

- The SVIEC/Sponsor/PI/ other authorized bodies can prematurely terminate the study for the following reason but not limited to:
    - Protocol non-compliance/violation due to any reason.
    - Slow recruitment
    - Frequency of SAEs occurring at trial site may require the study to be prematurely terminated for the safety of the patients.
    - Sponsor find treatment not effective
    - Lack of funds, lack of adequate market potential, competing drugs have received marketing approval ahead of the test compound, etc.
    - Overall trial enrolment was met, so all sites are being closed, even if some sites have not completed their enrolments.
- Based on the above mentioned reasons SVIEC secretary can send a notification letter for termination/suspension/discontinuation or query letter to request additional information to the PI.
- In case Sponsor is terminating the study, PI will receive a letter from Sponsor/CRO for the termination/suspension/discontinuation with the explanation for the same.
- PI and CTC will prepare the protocol termination package along with covering letter, Premature Termination Report (Refer SVIEC SOP) signed and dated by PI and another material (e.g. letter received from the Sponsor/PI/SVIEC)
- CTC must obtain acknowledgment of the SVIEC member secretary on the covering letter and file it in the SMF.
- PI/CTC must reply immediately in case of any query generated or any further information requested from the SVIEC.

- PI will receive acceptance letter from the SVIEC, CTC will keep the original letter of the Premature Termination/suspension/discontinuation report in the study file and send the file to archive (Refer SOP; Archival of Essential Documents). Inform the same to Sponsor/CRO.

Study completion

- On the Study completion the PI/ CTC will notify the SVIEC of the study completion using study completion form (Refer SVIEC SOP)
- Additionally PI and CTC must submit letter provided by the sponsor/CRO to give adequate and sufficient information.
- CTC must submit one hard copy + soft copy of Study Completion Reports

Applicable Staff

This SOP applies to all the personals of the clinical research team and others who may be responsible for the interaction with the SVIEC.

These include the following:

- Investigator
- Research Team (listed in the delegation log)
- CTC
- SVIEC staff/member

13.4 Managing Biological Samples:

Purpose

This SOP describes the procedures for collection, preparation, storage and shipment of biological sample.

Scope

This SOP will apply to all biological samples collected, processed, stored and shipped by SITE, unless alternate directions are provided by the sponsor or Contract Research Organization (CRO).

Procedure

Collection of Samples

Study Nurse or the person delegated in the duty delegation log will collect the biological samples on scheduled visit as described in the protocol.

After collecting the sample, the study nurse or delegated person will record the details in the biological sample collection form

Preparation of Samples

- The sample either is stored as collected and/or processed as mentioned in the protocol or laboratory manual provided by the sponsor/CRO.
- Using a permanent marker, study nurse or CTC will record the patient initials, patient ID and the date and time when the sample was obtained on each sample labels.
- In case of any damage to sample or if samples is unusable immediately inform to Sponsor/ CRO (in case of sponsored study) and report deviation to SVIEC and document the same in the source note, if required.

Storage of Samples

- Before shipments, site personnel will store both urine and plasma samples at a temperature of at least - 20ºC – or at a temperature mentioned in the protocol
- Other biological samples should be stored as mentioned in the protocol.

Shipment of Samples

Site personnel will

- Call the courier person as agreed by the sponsor/as mentioned in the protocol and schedule the date and time for shipping the sample.
- Inform the courier person to bring the required materials for shipment as mentioned in the protocol.
- Complete all the biological sample inventory form available in the collection kit listing all the samples in the shipment.
- Keep a photocopy of the Biological Sample Inventory page in the TMF.

Applicable Staff

This SOP applies to all the existing personals of the clinical research team and any new member appointed who may be responsible for study related activities as mentioned in this SOP (per the delegation log). These include following

- Investigator
- Research Team (listed in the delegation log)
- Study Nurse

13.5 Managing Investigational Products (IPs):

Purpose

To describe the process and requirements for the receipt, storage, dispensing, and return or destruction of Investigational Product (IP) at site.

Scope

This Standard Operating Procedure (SOP) will apply to all studies being conducted at SITE.

Any new trial which is initiated during active period of the SOP will be covered under the SOPs, unless otherwise indicated. If necessary a study specific SOP may be prepared.

Procedure

Prior to receipt of Investigational Product (IP)/ Study Drug

- PI must identify an area with restricted access and appropriate temperature control for IP storage. This is area will be known as 'IP Storage Room'.
- Assign team members who would be responsible for IP receipt, storage, dispensing, accountability and recording the temperature for the storage area and returning or destruction of the IP/ study drug.
- The person must be identified on the study delegation log.

Receipt of Investigational Product (IP)/ Study Drug

- Upon receipt of the IP shipment at the site, the CTC/delegated member will unpack the IP box and check the IP inventory against the shipping form.
- Checking the inventory will include the following:
    - Checking the packaging numbers
    - Unique Kit numbers/IP number
    - Lot/batch numbers
    - Number of IPs in the container (s)
    - IP expiry date
- Any discrepancies (e.g. tampering/ breakage of the IP kit, mismatch in the number of kits, temperature excursions etc.) identified must be documented and informed to the sponsor/CRO point of contact immediately and seek advice for the next steps.

- Such IP must be stored separately and must be dispensed only after confirmation from the sponsor/CRO/designee. This must be done by the person designated for IP accountability.
- If the inventory matches the drug received, the pharmacist/delegated person will sign and date (note: mention logger temperature present in the IP container on the receipt form) on the shipping receipt or Investigational Product Receipt Form, return a copy to the sponsor, and file the original in the Trial Master File (SMF).
- Shipment inventory must be done as per the study specific procedure (e.g. IVRS or IWRS, accountability log etc.)
- The IP must be immediately transferred to the designated storage area at conditions as mentioned in the protocol.
- The temperature of the storage area must be recorded with a calibrated thermometer for the temperature range once daily or as mentioned in the protocol. It is strongly recommended that accurate temperature must be recorded.
- If available maintain the hard copy of auto generated temperature logger.

IP / Study Drug Storage

- Temperature of the IP storage area must be maintained on a 24-hour basis for recording temperature. The temperature will be recorded once daily or as mentioned in the protocol, except on holidays and Sundays. The capture of minimum and maximum values of temperature will be recorded if only specified by the sponsor/CRO.

- In case a temperature excursion is noted, the CTC/designated study team member must inform Investigator and the following telephonically followed by email at the earliest:
    - Inform the sponsor / CRO and document the same
    - Try to identify the cause of temperature excursion
- Take remedial actions in consultation with sponsor/CRO
- IP that has undergone a temperature excursion must be kept separately and must not be dispensed till a confirmation from sponsor/CRO is obtained i.e. the IP is “fit for use”.

IP / Study Drug Dispensing

- IP must be dispensed by the CTC/delegated member to subjects randomized on the study after fulfilling the eligibility criteria in accordance with the protocol.
- Upon dispensing the IP the CTC/delegated member must note following in the source note and IP package:
    - Trial/Study ID number (both source notes and IP package)
    - Initial of the subject (both source notes and IP package)
    - Date of IP dispensing (both source notes and IP package)
    - Batch number and quantity of IP dispensed (in the source note)
    - Expiry date (in the source note)
    - This information must be captured in Real time basis on the IP stickers available on IP containers, in the subject source notes as well as in the Drug Accountability Logs.

- The CTC/delegated member will maintain a record of drug dispensed to and retrieved from each subject. To accomplish this, the CTC/delegated member will use the CRF, if any and only if provided by the sponsor/CRO.
- The CTC/delegated member will explain to each subject the drug accountability needs for
- The study (e.g., the need for the subject to return unused, partially used, and empty packages).
- Requests for IP resupply must be done as per the study specific procedures.

IP/ Study Drug Return

- The study subject will return all drug and study-related supplies to CTC/delegated member on the specified visit mentioned in the protocol.
- The CTC/delegated member will count the returned drug and compare this with the amount of drug expected to have been used since the previous study visit.
- CTC/delegated member must document IP returned by the subject in the subject's source file as well as in the drug accountability logs as per the study requirement.
- In case of missing IP or extra IP, the CTC/delegated member must obtain the information from the Subject and document the clarification provided in the source notes, drug dispensing log and CRF. This documentation should be done in real time basis
- The CTC/delegated member will keep the Drug Dispensing Log and the drug accountability CRF pages updated, regardless of when the monitor will perform final accountability.

- The CTC/delegated member will store the returned drug separately in a secure area until it is verified by the CRA/Monitor.
- Whether the drug is to be returned to the sponsor or destroyed on-site will be determined by the instructions in the protocol.
- The documentation of the destruction/ return must be maintained in the SMF.

Return of IP to Sponsor

- As specified in the protocol, the IP will be returned to the sponsor at intervals or at the end of the study. The CTC/delegated member will follow the protocol or other instructions from the Sponsor or CRO to decide whether empty containers must be returned.
- The CRA/Monitor will perform the independent drug accountability review and will seal the drug that need to be shipped back to the Sponsor/CRO.
- The CRA/Monitor will arrange the preferred courier for the shipment of used and/or unused IP back to the sponsor/CRO.
- The CTC will arrange for a gate pass for the shipment that needs to send back to sponsor/CRO.
- Unless instructed otherwise by the CRA/Monitor, the CTC/delegated member will:
- Perform an inventory of the drug supplies.
- Compare inventory with the study medication records.
- Document discrepancies in the CRF or in a memo to file.
- Complete the Drug Return/Destruction Form (in presence of monitor) or similar form provided by the sponsor or CRO.

- Include a copy of the signed and completed Drug Return Form with the drug shipment and place the original in the study file.

IP Record Retention

At study completion, the CTC will file all drug records with other regulatory documents in accordance with the record retention policy mentioned in the protocol.

Applicable staff

This SOP applies to those members of the study team involved in the process receipt, storage, dispensing, and return or destruction of Investigational Product (IP).These include the following:

- Principal Investigator (PI)
- Clinical Trial Coordinator (CTC)
- Pharmacist
- Research Nurse
- Support Staff

13.6 Travelling Reimbursement to Study participants:

Purpose

This SOP describes the procedures involved in reimbursement to the study subject for their involvement in the research and research related activities as agreed in CTA and mentioned in ICF.

Scope

This SOP applies to all study team member who are engaged in study related activities and delegated in the delegation log for research related reimbursement (if applicable) to all subject participated in the studies being conducted in Site.

Procedure

Information regarding reimbursement

Subjects may be paid for the inconvenience and time present, and should be reimbursed for expenses incurred, in connection with their participation in research. They may also receive free medical services. However, payments should not be so large or the medical services so extensive as to induce prospective subjects to consent to participate in research against their better judgment (inducement). All payments, reimbursement and medical services to be provided to research subjects should be approved by the SVIEC. Care should be taken:

- When a guardian is asked to give consent on behalf of an incompetent person, no remuneration should be offered except a refund of out of pocket expenses;
- When a subject is withdrawn from research for medical reasons related to the study the subject should get the benefit for full participation;
- When a subject withdraws for any other reasons he/she should be paid in proportion to the amount of participation.
- Reimbursement must be done as agreed by the investigator and sponsor/CRO in the Clinical Trial Agreement (CTA) and as defined in the Informed consent document.

Procedure for reimbursement

CTC as designated will reimburse the amount to the patient as mentioned below:

- Should open a particular study account in the SITE accounts department and maintain the account number. Always deposit the cheque in the same account received by the sponsor/CRO.
- Keep a track of patient's visits as mentioned in the protocol, travel, concomitant medication prescribed for adverse event (if any), and if any unscheduled visit scheduled during the study period for reimbursement.
- Must reimburse travel cost, upon presentation of receipt of a valid ticket (if available or as agreed in the CTA) or bills of the protocol specified visits or unscheduled visits if any.
- Must collect the original bills from the patient for above listed things for reimbursement
- Payment voucher must be prepared for the same; it will include patient hospital case number, name, amount to be paid, study account number and reason for reimbursement.
- Investigator or designee will approve and sign the voucher. Patient will sign or put his/her thumb impression in case patient is illiterate on the copy of the voucher (patient will sign/thumb while submitting the voucher to the accounts department).
- Copy of signed voucher (by investigator/designee and subject) and bills should be filed in a separate file.
- Original voucher and bills will be forwarded to the concerned authority as per the hospital policy for approval.
- The voucher and bills will be forwarded to the accounts department of the SITE.

The competent authority from accounts department will sanction and release the amount.

In case of Serious Adverse Event (SAE) which found to be related to the IP, PI/ Co I will make sure that subject should get reimbursed for every expense occurred during the management of the adverse event.

CTC will always keep a copy of the updated account statement to make sure the account has sufficient balance for reimbursement.

CTC should send the expense invoices to sponsor on regular intervals, to receive the amount on time.

Applicable Staff

This SOP applies to all the existing personals of the clinical research team and any new member appointed who may be responsible reimbursing the study subject as mentioned in this SOP (as per the delegation log).

These include the following:

- Investigator
- CTC
- Research Team (listed in the delegation log)

13.7 Site Initiation, Activation, Conduct and Closeout

Purpose

To describe the process, that ensures that the site is organized and prepared for the proper conduct of the research study at SITE. This standard operating procedure (SOP)

also describes the processes to be followed at site initiation, activation, conduct and closeout of research study at Site.

Scope

This SOP will apply to all Pharma sponsored research study initiation, activation, conduct and close-out at Site.

Procedure

A research study should be initiated at a site only after investigator and Sponsor/CRO involved in the study is satisfied that essential documents, agreements and approvals are all in place. The site initiation process is designed to ensure that;

- Site has all essential documents in place for the site to conduct the study in compliance with the approved protocol and applicable regulatory guidelines.
- Site is aware of all the sponsor's procedures and SOPs for study conduct (such as safety recording and reporting, amendments, notification of any urgent safety measures/ violations or serious breaches) and has read and understood each.
- Site is met with all the required regulatory and sponsor requirements.

Preparing site for Site Initiation Visit

a. *For preparing the site for initiation the investigator(s) or Clinical Trial Coordinator (CTC) should:*

- Confirm the available date and time with the clinical research team that must attend the meeting and arrange the most suitable meeting date, time and place.
- Request an agenda for the visit from the sponsor; circulate the same to each team member.
- Confirm that investigator and team has reviewed the Protocol and Investigator's Brochure (IB) and any up-to-date information on investigational product (IP).

The Investigator(s) must prepare a list of questions if any to be asked in the SIV.

- Ensure that the procedures stated in the study protocol are applicable at the site and fully understood.
- Confirm that all documents required by Institutional Ethics Committee (SVIEC) are available.
- Confirm that the clinical trial agreement (CTA), indemnification letter and budget are finalized and signed.
- Notify appropriate departments regarding the sponsor/CRO visit (e.g., Laboratories, pharmacy, CT scan, bone scan and x-ray, etc).
- File all essential documents in TMF (or sponsor-supplied Investigator Study File), and compile any outstanding documents to provide to the Clinical Research Associate (CRA) at the initiation meeting.

During the Site Initiation Visit

a. During the initiation visit the investigator(s) or Clinical Trial Coordinator (CTC)

should ensure that -

- The Investigator's Trial Master File (TMF) contains the following mentioned applicable items and all the required regulatory documents:
    - Signed protocol and Investigator Statement
    - Signed and executed Investigator contract
    - CVs and licenses of key site study staff
    - Financial Disclosure forms
    - Investigator Undertaking (IU)
    - SVIEC approval letter for the protocol
    - SVIEC membership roster (updated)

- SVIEC approved informed consent form
- Institutional and/or other regulatory authority approvals
- Valid clinical/other laboratory licensure
- Laboratory normal value ranges
- Notice that indicates the study has been submitted to the regulatory authorities (if applicable).
- Investigator Brochure, if applicable.
- Case Report Forms (CRF)
- Investigational product inventory management forms
- Any other essential documents.

- Provide the study members name involved in the study and their responsibilities inthe duty delegation to the monitor/CRA.
- Provide original and updated curriculum vitae of all study personnel / Investigators involved, as per sponsor requirements (if not provided earlier).
- Ensure that the names and contact numbers of the relevant medical and study personnel of the sponsor are available and documented clearly.
- Ensure that all relevant study site personnel fill out the Site Personnel/Signature Log and Training Log.
- Check that the procedures and plans for storage, dispensing and return of IP have been agreed and finalized with the Sponsor and Pharmacist (if applicable).
- In case of paper CRF's: Check that the quantity of CRFs that have been requested or shipped to the study site are sufficient for the number of Participants/patients that are likely to be recruited into the study also allowing for the archiving of one set of intact, unused CRFs

- Check that other related supplies are available or are to be shipped to the study site at a later date, and that they are available in sufficient quantities.
- Check that laboratory facilities and arrangements for the dispatch of samples to the central laboratory are organized and that any specialized equipment that may be required will be available throughout the period of the trial, e.g. collection kits, centrifuge machine, freezer, etc.
- Ensure that monitor/CRA gives sufficient time to CTC for CRF completion training.
- Ensure and understand the requirements of the sponsors/CRO regarding source documents and raw data, which will be required during monitoring visits to enable the monitor/CRA to perform source data verification at each monitoring visit.
- Ensure that the procedures relating to the archiving of study records at the end of the study is agreeable to the sponsor.
- During the initiation visit the Investigator or delegate (for investigator initiated study)and monitor/CRA (for sponsor study) will provide a protocol-specific training session to all the members of the research team who will be involved in the research study.
- The investigator or monitor/CRA will ensure that the attendance sheets and other documentation are completed.

b. The protocol-specific training session will include, but is not limited to, the following:

- Aim and Objective of the protocol
- Time and events schedule for the protocol

- Subject recruitment
- Obtaining informed consent
- Procedure for dispensing the IP
- IP storage and records
- Protocol-specific forms and procedures
- Source documentation
- Adverse event reporting
- Additional information from the Investigator's Meeting (IM)
- Any other relevant information

c. The Investigator, monitor/CRA and CTC will:

- Develop a recruitment plan for subjects
- Identify a back-up to the primary CTC

Study Activation and Initiation Visit Follow-Up

a. In preparation for study activation

- Confirm that the sponsor sends a written summary of key discussions and agreements made during the site initiation visit. Follow-up if necessary.
- Confirm readiness of the site to start the study.
- Confirm the receipt of all study-related materials such as CRFs, laboratory supplies, investigational product(s).
- Distribute protocol summaries and worksheets, if not done previously (the sponsor may provide study-related worksheets, however the site can prepare one).
- Notify all appropriate departments that the study is ready to enrol participants.

- Initiate study recruitment strategies and begin enrolling study patients/participants.

Study conduct

a. Once the site is activated and starts recruiting patients, the Investigator and CTC will ensure the following:

- All study activities are accomplished according to the protocol and applicable regulatory regulations.
- Subjects sign the correct version of the consent form before any study-related procedures are accomplished.
- Medical History along with physical examination and Vital signs will be captured by Principal Investigator and Sub investigator after voluntarily signing of ICF by patient
- Data collected in the Case Report Form (CRF) are supported by source documents.
- Protocol deviations/non-compliance/violations/waivers if any should be notified to the SVIEC (Refer SOP for SVIEC communication) and the same must be documented in the source documents and appropriate CRF.
- Adverse events are reflected in the source documents and captured in the CRF.
- Serious Adverse events (SAEs) are reported to the Sponsor/CRO and SEC within specified time frame (refer SOP for SAE reporting).
- SUSAR and CIOMS should be notified in the timely manner to the SVIEC.
- The IP is being dispensed correctly and IP accountability records are being maintained.

b. While the study is ongoing, the CTC will ensure the following:

- The Sponsor/CRO is informed of all significant study events and staff members are documenting critical interactions with the Sponsor/CRO.
- Biological samples are being obtained, handled, stored, and shipped appropriately.
- Study supplies remain adequate.
- Study records remain confidential.
- All equipment is calibrated regularly and maintenance records are being kept.

Premature Termination or Suspension of a Study

a. If the research study is prematurely terminated or suspended for any reason, the investigator/institution should:

- Immediately inform the SVIEC regarding the premature termination of the study in the format specified in the SVIEC SOP.
- Promptly inform the trial participants and include, where appropriate, the reason for suspension / early termination of the study.
- Assure appropriate therapy and follow-up for the participants, and, where required by the applicable regulatory requirement(s), should inform the regulatory authority (ies).
- The PI should maintain documents as specified in the TMF list and take measures to prevent accidental or premature destruction

In addition:

b. If the PI terminates or suspends a research study without prior agreement of the sponsor, the PI should:

- Promptly inform the sponsor and the SVIEC regarding the termination.
- Provide the sponsor and the SVIEC with a detailed written explanation of the termination or suspension.

c. If the sponsor terminates or suspends a research study, the PI should:

- In case the sponsor chooses to or is required to terminate prematurely or suspend the research study, then the sponsor should notify the investigator(s), institution(s), the ethics committee and the regulatory authorities accordingly. The notification should document the reason(s) for the termination or suspension by the sponsor or by the investigator / institution.

Site close-out

a. Preparing the site for study close-out visits

- After the last patient has completed all scheduled visits associated with the study, arrange a mutually convenient date and time with the monitor/CRA to conduct the study close-out visit.
- Request the monitor/CRA for the visit agenda so key research personnel such as PI, Co I, CTC, research nurse and other team members will be available, as appropriate.
- Ensure all regulatory documentation and case report forms (CRFs) not previously monitored are complete and available for review.
- Ensure all data queries received to date have been resolved.
- Inventory IPs supply and complete final accountability records. If previously instructed to return or destroy IP, assure all required documentation is filed in the appropriate TMF for monitor/CRA review.

- Arrange monitor/CRA meeting with the PI and/or Co I and CTC to discuss any outstanding issues.
- PI will ensure that all outstanding payments are cleared as per CTA.

b. Managing the study close-out visit

- Ensure all documentation (e.g., regulatory correspondence) is filed appropriately and ready for the monitor/CRA to review during the close-out visit.
- Discuss all open study-related issues and what steps will be taken to resolve them in order to satisfy the sponsor/CRO requirement(s).
- Review with the monitor/CRA the list of outstanding issues related to regulatory documents, source data verification, IP reconciliation, and any requirements for data retention and storage.
- Discuss any concerns regarding the possibility of a quality assurance audit and/or inspection by SVIEC or external regulatory bodies. Include the CTC as appropriate.
- If the study involved electronic data capture, determine when hard copies/CD of all CRFs will be provided to TMC, if applicable.
- The PI is responsible for ensuring the appropriate follow-up, per the protocol, for any participant experiencing an ongoing unanticipated problem (e.g., serious adverse event) at study end and providing this information to the sponsor/CRO, assuring all requirements have been met.
- Arrange meeting of the PI and monitor/CRA to discuss any future considerations (e.g., publication of study data or future studies).

c. Follow-up after the study close-out visit

- For any remaining IP(s), ensure the item(s) is returned to the sponsor/CRO per their requirements.
- If the randomization code for any IP was broken for any reason, ensure complete documentation has been filed.
- Ensure return or destruction of all other study-related materials, such as unused lab kits and CRFs.
- Ensure any equipment on loan from the sponsor is returned or if mutually agreed by both the parties can be retained at the site.
- After all data queries have been resolved, check TMF, subject files and other study files for completeness.
- Arrange for transfer of study documents to secure storage.
- Submit the Final Closure Report to the SVIEC, in accordance with SVIEC SOP for Study Completion or Closure.
- Verify participant reimbursement or compensation if any have been distributed per the study budget, as outlined in the Informed Consent and CTA.
- If the informed consent and CTA, protocol or contract state subjects will be informed of their treatment arm, ascertain from the sponsor how and when this will be completed.

Applicable Staff

This SOP applies to all the personals of the clinical research team and others who may be responsible for site initiation, activation, conduct and close-out at TMC.

These include the following:

- Investigator

- Research Team
- CTC
- Research Nurse
- Support staff

13.8 Study Team Training and Study Handover

Purpose

This SOP defines the procedure and recommendation of training of study team members and adequate handover to CTC/study team member, to ensure that the patient safety, protocol compliance, data integrity and overall quality assurance at the investigational site is protected and integrated as per the applicable regulations and guidelines.

Study team member must understand the responsibilities of the trials conducted at site and be appropriately qualified by education, training and/or experience to perform his or her research-related task(s). Some training may be obtained through internal hospital accepted training and certification program(s) or through external hospital accepted training and certification program(s).

The purpose of a handover is to ensure continuity of operations when the study team member, usually responsible, is not available due to temporary or permanent absence. A handover can be supported by a discussion to explain the status of the tasks, a summary of the work status in an email/ memorandum or, a more detailed file.

Scope

This SOP will apply to all study team members conducting studies in SITE.

Procedure

Study Team Training

- On appointment, all study team members will be given an appropriate study depending on the job specification to possess the right experience and qualifications and further training may be provided to bring them up to the required level for specific tasks. Duty delegation /job responsibility document will be given to every Clinical Trial Coordinator (CTC)/ team member.
- The Investigators, CTC and other study team members must undergo training which will enable them to understand their responsibilities, applicable regulations, guidelines and research studies and training should be documented in the training log.
- Each Investigator, CTC and study team members will review and learn the site's SOPs. It is recommended that SOP training must be included in the orientation of new clinical research personnel. All applicable clinical research personnel should be knowledgeable of new or revised SOPs.
- Good Clinical Practice (GCP) is a universal standard in clinical research that must be followed in every research protocol. GCP training and education are recommended for research team members, especially the Investigator and CTC. However, any member of the research team with a significant role in the conduct of a research study must be knowledgeable in GCP. All members of the clinical research team should GCP trained and certified.
- If scheduled, PI and CTC will attend the Investigator Meeting (organized by Sponsor) and complete all required training for a study. If PI is unable to attend

the meeting, PI can recommend other study team member(s) to attend the IM. PI should be informed regarding the study contents discussed in IM.

- Before study initiation Sponsor/CRO will organize SIV meeting at site to train all study team members and all study team members should attend the meeting for thorough understanding of the study.
- PI and study team member(s) should be prepared to demonstrate all training received.
- CVs, GCP and other training certificates should be updated as required. It is recommended that an assessment of the employee's knowledge of the regulations and guidelines can be conducted upon recruiting and on a regular basis. It is recommended that an assessment of any additional protocol-specific skill requirements be conducted prior to activation of each new study.

Study Handover

If any study team member is planning for leave or to resign, he/she must ensure that the proper handover is given to concern person identified by the PI, the identified person should be briefed in time before the person goes on leave to allow for any follow up questions.

Prior to leaving the study, the existing study team member should complete the following:

- Training on protocol and procedures e.g. SOPs and explanation of relevant documents
- Information regarding study subjects, study documents and all study related activities
- Outstanding data entry and/or data queries

- Training to complete source documents
- Explanation on the objectives & priorities
- Notification to the sponsor of the study team changes
- Notification to the active subjects of the study team changes if the research team contact information will change for the subjects.
- Provide a list of study-specific contacts (e.g., sponsor, monitor, vendors involved etc.)
- Provide a list of outstanding issues
- The leaving person has to make sure that the documentations concerned for the tasks is up to date and easily available, and if needed, revise it when preparing the handover.

If there is a change in PI, the following documents need to be revised and completed;

- Inform Sponsor and IEC regarding the change in PI in the Study team.
- Consider revising the protocol and informed consent form, as appropriate. Also consider notifying current subjects; correspondence sent to all subjects must be approved by the IEC, if applicable.
- Update the Form FDA 1572 or the Investigator Agreements, Investigator Undertaking and other required forms
- Update the Duty Delegation log
- Ensure that the new PI has completed the SOP required training and study-specific training. Written hand over should be given in order to ensure the continuity of work. The format can be a briefing note, a check list, or a schedule prepared to give all information.

When the study member returns from leave a hand over should be prepared to give updates on the status of the tasks.

The existing and new study team member should document the study handover in a note to file or other documentation in the TMF. The note should contain some of the items above and the date of the handover. The new study team member should obtain documented study-specific training and any required approvals prior to being added to the duty delegation log.

Applicable Staff

This SOP applies to all the existing personals of the clinical research team and any new member appointed who may be responsible for training and study handover as mentioned in this SOP(as per the delegation log).

These include the following:

- Investigator
- Research Team (listed in the delegation log)
- CTC

CHAPTER 14
Institutional Animal Ethic Committee (IAEC)

IAEC has been constituted in 2006 to fulfil purpose of Education and Research for Educational purpose on small animals and registration number is 947/PO/ReRc/S/06/CPCSEA. It is renewed for every three years.

14.1 Standard Operating Procedure for Institutional Animal Ethic Committee:

- The Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) has been constituted under the provisions of the Prevention of Cruelty to Animals (PCA) Act, 1960. It gives the guidelines for the conduct of animal experiments.
- Animals are maintained in a proper and healthy manner.
- Animals are not subjected to unnecessary pain or suffering before, during and after performance of experiments on them.
- There is no unnecessary sacrifice of animals for the sake of science. There should be no duplication of research.
- Animals are kept in disease free condition to ensure proper data collection.
- Animals are procured from registered breeders.
- Experiments on large animals are to be avoided whenever it is possible to achieve the same results by experiments on small laboratory animals.
- For effective implementation of these rules and guidelines, the Institutional Animal Ethics Committees (IAEC) has been constituted in institutions conducting experiments on animals. This is a scientific body nominated by the Head of the Institution. The IAEC is required to examine proposals for conducting experiments on small animals, which would chiefly examine the necessity of

performing the experiment, and ensure that experiments are not performed in a routine manner. All decisions are to be taken with the approval of the Committee. The Standard Operating Procedures (SOP) for Institutional Animal Ethics Committee for experimentations on animals will help the Principal Investigators, Animal Ethics Committee members and scientific researchers, for better understanding of the ethical procedures involved in animal experimentations.

14.2 Function of IAEC:

- IAEC should provide independent, competent and timely review of the ethics of a proposed study before the commencement of the same and regularly monitor the ongoing studies.
- IAEC will review and approve all research proposals involving animal experiments with a view to assure quality maintenance and welfare of animals used in laboratory studies while conducting research.

14.3 Composition of IAEC:

Institutional Animal Ethics Committee shall include members as follows:

- A scientist from different biological discipline cum chairperson
- A scientist from different biological discipline
- A Biological Scientist
- One veterinarian involved in the care of animals
- A scientist in charge of animal House facility cum member secretary
- A scientist from outside the institute
- One non-scientific socially aware person
- One main nominee of CPCSEA

- One link nominee of CPCSEA

Specialist may be co-opted while reviewing special projects using hazardous agents such as radio-active substance and deadly micro-organisms. The Chairperson of the committee and member secretary shall be nominated by the institution from amongst the nine members. Members against serial no. 6, 7, 8&9 will be nominated by CPCSEA with a provision of a link nominee for CPCSEA nominee.

14.4 Authority under which IAEC is constituted and duration:

- Five names against serial numbers 1-5 will be sent from the institute to CPCSEA.
- The duration of IAEC will be for a period of 5years.
- The IAEC will be reconstituted at the time of renewal of registration to CPCSEA.
- Changes can be made in deserving cases with the approval of CPCSEA

14.5 IAEC Requirements:

- The duration of appointment will be 5 years (coinciding with renewal of registration).
- The committee will be reconstituted at the time of renewal of registration and at least half of the members will be replaced.
- A member can be replaced in the event of long-term non-availability (three consecutive meetings) or death.
- Members should maintain 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.
- Conflict of interest should be declared by members of IAEC.
- A member can tender resignation from the committee.

14.6 Quorum Requirement:

The minimum of six members shall be required to form quorum of the IAEC meetings.

All decisions shall be required to be undertaken in the meetings of IAEC and not by the method of circulation of project proposals. Presence of main nominee of CPCSEA nominee is a must. It shall be a must for the establishment to invite all nominees of IAEC for attending the meeting and the meeting notice shall invariably be issued by Registered Post at least 15 days before the date of the meeting. Link nominee can attend in case main nominee conveys his unavailability in writing to the Chairperson of IAEC. Socially aware member's presence is compulsory in all cases referred to CPCSEA and their presence is mandatory at least in one meeting of IAEC of the establishment in a calendar year. It shall be the duty of establishment to inform to CPCSEA about the continuous absence of nominees of CPCSEA in a calendar year.

14.7 Conduct of meeting:

The Chairperson of the IAEC shall be responsible for conducting at least two meeting of IAEC in a calendar year with the help of the Member Secretary of IAEC. If, for reasons beyond control, the Chairperson is not available, or has conflict of interest, an ad-hoc Chairperson will be elected from amongst the members present. 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 them approved by the Chairperson & nominee of CPCSEA before communicating to the Principal Investigator. A copy of minutes is required to be sent to Member Secretary CPCSEA within 15 days of the meeting, otherwise, the meeting will not be considered valid.

14.8 Participation of Investigators/Experts in IAEC:

IAEC may call upon subject experts who may provide special inputs of selected research protocols, if need be. They are required to give their specialized views but not to take part in the decisions making process which will be made by the members of the IAEC only. Investigators whose proposals are to be discussed can also be called to present their case to the IAEC.

14.9 Application Procedure:

- All proposals should be submitted in the prescribed application form (**Appendix 8**).
- All relevant documents with checklist should be enclosed with application form.
- Required number of copies of the proposal along with application and documents in prescribed format duly signed by Principal Investigator (PI) and Co- investigators/ Collaborators should be submitted to IAEC.

14.10 Review Procedure:

- The meeting of the IAEC should be held on scheduled intervals as prescribed in the concerned SOP of the IAEC and additional meetings may be held if there are reasons to do so.
- Even if there are no projects, it is mandatory to call for an IAEC meeting at least once in a year to discuss matters related with maintenance of the animals in the animal house. The member secretary must be present with all available records at every IAEC meeting.
- The copy of the application/ proposals will be sent to CPCSEA nominee and to all the members 15 days before the meeting.
- The date of meeting will be intimated to the Principal Investigator who should be

available to offer clarifications if necessary.

- The decision will be taken by consensus after discussion. Negative view point will be recorded in the minutes. If consensus is not reached, the case will be referred to CPCSEA.
- Independent Consultants/Expert will be invited to offer their opinion on specific proposals if needed.
- The decisions will be recorded in minutes, approved by chairman and will be signed by all the IAEC members present.

14.11 Decision Making:

- Decision will be taken by discussion before arriving at consensus.
- A member having conflict of interest should inform the chair person and withdraw during the decision procedure of concerned application. It should be recorded in minutes.
- The quorum of the meeting should be complete at the time of decision making.
- Only members shall take decision. Experts/ invitees/ investigators will only offer their opinion.
- Decision may be to approve, reject or revise the proposal. Specific suggestions for modification and reasons for rejection should be given.
- In case of conditional decisions, clear suggestions for revision and procedure for re-review the application should be specified.
- Modified proposals may be reviewed by an expedited through identified members
- Procedures for appeal by the researchers should be clearly defined.

14.12 Communication:

- The decision of IAEC will be communicated by Member Secretary in writing.
- Suggestions for modification will be communicated by IAEC. If revision is to be made, the revised document in required number of copies should be submitted within a fortnight.
- Reasons for rejection will be informed to the researchers. Schedule/ plan of ongoing review by the IAEC should be communicated to the Principal Investigator.

14.13 Follow Up Procedure:

- Reports of ongoing research projects should be submitted every 6 months, before next IAEC meeting.
- Final report should be submitted at the end of the study.
- All Serious Adverse Events (SAEs) & the interventions should be intimated.
- Protocol deviation, if any should be informed with adequate justification.
- Any amendment to the protocol should be resubmitted to IAEC for renewed approval.
- Premature termination of the study should be notified with reasons along with summary of the data obtained so far.
- Change of Investigators / sites should be informed for approval of IAEC.
- Any new information related to the study should be communicated.

14.14 Record Keeping and Archival:

All of the following documents must be stored for a period of five years.

- Curriculum Vitae (CV) of all members of IAEC including training programs in animal ethics.

- Minutes of all meetings duly signed by the Chairperson and CPCSEA nominee, copy of all correspondence with members, researchers and other regulatory bodies.
- Copy of existing relevant National and International guidelines on research ethics and laws along with amendments.
- All study related documents (study projects with enclosed documents) should be archived for minimum of five years after the completion of study. A copy of filled Proforma related to the projects shall remain with the Principal Investigator for minimum of five years.

14.15 Updating IAEC Members:

- All relevant information on Animal ethics will be brought to the attention of the members of IAEC by the Member Secretary.
- Institute Members will be encouraged to attend National and International training programs/conferences/seminars in the field of research related to the animal ethics.
- To help in improving the quality of research projects/animal ethics committee submissions and review.

14.16 Reporting to CPCSEA:

- IAEC will send a copy of minutes of IAEC meeting within 15days.
- Inspection report of animal house by IAEC members will be sent once in a calendar year. If action is required, the ATR should be provided in stipulated time.

14.17 Reimbursement to CPCSEA Representatives:

CPCSEA representatives on IAEC or authorized persons sent for inspection of the

establishment are required to be paid Rs 5000/- each as sitting fees per day along with reimbursement of actual expenditure incurred in this regard (if not provided by the establishments / organizations).

14.18 Renewal Fees Payable to CPCSEA:

Renewal fees for the purpose of Research for education and commercial are as follows:

- For small or large animals for education research: Rs. 2500 each
- For small or large animals for commercial research: Rs. 2500 each

14.19 Execution of experiments:

- Experiments shall be performed under supervision of a qualified person (Veterinarian/ Post graduates in life sciences/ trained laboratory technician) and under the responsibility of the person performing the experiment.
- Experiment shall be performed with due care and humanity.
- Animals intended for the performance of experiments shall be properly looked after both before and after experiments.
- Personnel using experimental animal(s) shall be responsible for the welfare of animal(s) during their use in experiments.
- Investigators shall be responsible for the aftercare and rehabilitation of animal(s) after experimentation, and shall not euthanize animal(s) except in situations as defined.
- The following parameters shall be adopted for application of euthanasia, namely;
    - When the animal is paralyzed and is not able to perform its natural functions or it becomes incapable of independent locomotion or it can no longer perceive the environment in an intelligible manner.
    - If during the course of anaesthesia /experimental procedure the animal has

been left with a recurring pain wherein the animal exhibits obvious signs of pain and suffering.

- Where the non-termination of the life of the experimental animal will be life threatening to human beings or other animals.

- Rehabilitation treatment of an animal after experimentation shall extend till the point the animal is able to resume a normal existence. It is mandatory that the cost of after care and rehabilitation should be met from the contingency of the project.
- Experiments involving operative procedures shall be performed under anaesthesia to be administered by a veterinary surgeon/scientist/technician so trained for the purpose.
- Experiments shall not be performed by way of an illustration/ as a public demonstration.
- No experiment the result of which is already conclusively known shall be repeated without justification.

14.20 Laboratory Animal Ethics:

All scientists working with laboratory animals must have a deep ethical consideration for the animals they are dealing with. From the ethical point of view it is important that such considerations are taken care of at the individual level, institutional level and finally at the national level.

14.21 Documentation:

All research proposals should be submitted with the following documents:

1	Title of the project
2	Names of the Principal Investigator and Co-investigators with designation.

3	Name of any other Institute/Hospital/Field area where research will be Conducted.
4	Endorsement of the name of Head of the Department
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 annexure like Proforma,
	Curriculum Vitae of outside members, undertaking etc. to be used in the study.
8	Any other information relevant to the study.
9	Agreement to submit six monthly progress report and final report at the end of study.
10	The Principal Investigator should provide the details of other ongoing research projects related to the Animal studies (Title of the project, Date of starting and Duration, source and amount of funding).

14.22 Elements of Review:

- Scientific design and conduct of the study.
- Approval of scientific review committee and regulatory agencies.
- Assessment of predictable risks/harms to the animals.
- Protocol and Proforma of the study.
- Plans for data analysis and reporting.
- Adherence to all regulatory requirements and applicable guidelines.
- Competence of investigators, research and supporting staff.
- Facilities and infrastructure in the animal house.

All communications must be addressed to:

Deputy Secretary (AW) and Member Secretary (CPCSEA)

Ministry of Environment, Forest and Climate Change,

Government of India (Animal Welfare Division)

5th Floor, Vayu Wing,

Indira Paryavaran Bhawan, JorBagh Road, New Delhi – 110003.

Telephone No. 011-24695424

Email: <cpcsea-mef@gov.in>

Appendices

Appendix -1A

[FORMAT OF MAJOR/MINOR RESEARCH PROJECT]

A

SYNOPSIS OF

MAJOR/MINOR PROJECT

ON

TOPIC OF RESEARCH PROJECT

NAME OF PRINCIPAL INVESTIGATOR	NAME OF CO-INVESTIGATOR
DESINGNATION-----	DESIGNATION-----
SIGNATURE-----	SIGNATURE-----
NAME OF INSTITUTION-----	NAME OF INSTITUTION-----

CONTENT OF SYNOPSIS

CHAPTER	PARTICULAR	PAGE NUMBER

Title of Research Project

The title of the research project should be brief but informative; it should neither be too short nor too long. A good title will clue the reader into the topic but it cannot tell the whole story. Any name of the institution, the number of cases to be studied should not be included. The hypothesis to be studied can be included.

CHAPTER- 1

1.1 Introduction / Origin of Proposal

Follow the title with a strong introduction. The introduction provides a brief overview that tells a fairly well informed (but perhaps non-specialist) reader what the proposal is about. It might be as short as a single page, but it should be very clearly written.[It includes brief introductory information related to the study which develops conceptual frame work of the researcher]

This may include the highlight of the problem/issue to be resolve. This can be followed by socio- economical status of the health problem, national /international health scenario or the severity to address the problem.

Setting the outline area is a start but researcher needs to get specific about what his/her research will address. What is his proposal about?

Why this work is important? What are the implications of doing it? How does it link to other knowledge? How does it stand to inform policy making? What will we learn from your work? This should show how this project is significant to our knowledge. Why is it important to our understanding of the world? It should establish why I would want to read on. It should also tell me why I would want to support, or fund, the project.

CHAPTER – 2

2.1 Rationale/Hypothesis

Rationale includes the basis upon which project strategy stands. It correlates the existing literature with the proposed plan of study, on scientific ground.

[Hypothesis is mentioned as a tentative prediction or explanation of the relationship between two or more variables. Hypothesis should not be a haphazard guess but should

reflect the knowledge, imagination, and experience of the investigator. Hypothesis can be formulated by understanding the problem, reviewing the literature on it, and considering other factors. A researcher can state the problem and the hypothesis in about 200 words covering all the aspects.]

CHPATER – 3

3.1 Aims and Objectives

[MENTION ALL OBJECTIVES OF THE STUDY]

[All research projects should have objectives and aims and every effort should be made to achieve them. The objectives and aims should be only a few (2-3). They must pertain to the study problem. Usages of terms like "first study", "the only study", etc. should be avoided.]

Note:

- Aim is a broad term which precisely combine overall objective of the project within one sentence
- Objectives are the stepping stone through which researcher is going to achieve the aim; Objectives may be 3-4 in numbers and cover entire theme of the project

CHAPTER – 4

4.1 Review of Literature

[This chapter includes review of the work carried out by the other researchers in the similar area or related area]

- Minimum 15-20 relevant literature reviews should be given.

- Latest articles related to plan of study should be included as reference, as much as possible.

CHAPTER – 5

5.1 Research Methodology

[Methodology in clinical research may varied from non-clinical proposals]

This chapter includes—

a. Study Design
b. Study Settings
c. Sampling
d. Variables
e. Controls
f. Study Methods – Examinations or Investigations
g. Data Collection
h. Data Analysis
i. Ethical Clearance

FOR EXAMPLE-

a. Study Design

The methodology starts with selection of study design. A single study design or a combination can be selected e.g.:

- **Descriptive designs**
  - Cross-sectional study or survey
  - Epidemiological description of disease occurrence Community diagnosis Study of natural history of a disease

- **Observational analytical designs**
  - Prospective study
  - Retrospective study Follow-up study
- **Experimental designs**
  - Animal studies
  - Therapeutic clinical trials - drugs Prophylactic clinical trials- vaccines Field trials
- **Operational designs**

b. Study Settings

A mention about the research setting should be made. This includes information about the institution, facilities available, time of study, and population of study.

c. Sampling

Sampling is selecting a sample of appropriate size for the study. The sample size depends on the study design. The study population can be population of cases, population of people, or population of recipients of certain treatment.

There are many methods for sampling like simple random, systemic and stratified sampling, cluster sampling, etc. Care should be taken to ensure that the sample size is adequate to produce meaningful results. The sample size should be adequate to apply all relevant tests of statistical significance. The samples should be representative of the population and should be reliable. This minimizes sampling errors.

d. Variables

Variables are the factors that can change. These changes can affect the outcome of a research project. Thus, it is important to identify the variables at the planning stage. They should be quantified with a measurable unit. Knowledge of the various variables in

a research project will assist in refining the objectives. Usually, objectives of a research will be to see the effect of independent variables on dependent variables. There are four types of variables.

Independent variables

These are the variables that can be manipulated by the researcher and the effects of that are observed on the other variables. For example; predisposing factors, risk factors and cause.

Dependent variables

The changes occur as a result of independent variables. For example; disease and outcome.

Intervening variables

These may influence the effect of independent variables on the dependent variables. For example, while studying the response of HIV-AIDS to -highly active antiretroviral therapy or HAART, the outcome may be influenced by the presence of anti-tubercular drugs.

Background variables

These are changes that are relevant in the groups or population under study. These need to be included in the study. For example; age, sex, and ethnic origin.

e. Controls

Control groups increase the validity of the research project. They usually consist of units of same population but differ in some respects. Controls are not necessary for all research projects.

As far as possible they should be used in all analytical studies, drug trials, and intervention programs.

f. Study Methods

Here the researcher will have to describe the method of data collection, which may be in the form of:

1. Questionnaire
2. Interviews
3. Medical examination
4. Laboratory investigations
5. Screening procedures

A sample of the pro-forma should be prepared and attached.

g. Data Analysis

Data analysis is an important part of a research project. A good analysis leads to good results. The plans for data analysis should be mentioned under the following heads Statistical methods, Computer program used, and Data sorting method. A general Statement “appropriate statistical methods will be used." Must be avoided.

h. Ethical Clearance

Wherever necessary, ethical committee clearance from the institute should be obtained after the approval of the project. The certificate/letter should be submitted to the research cell before commencing the work. Ethical clearance is required in all human and animal studies.

CHAPTER – 6

6.1 Plan of Work

It include phase wise distribution of work plan (methodology) and, description of each protocol/study/scheme/process, with standard references (Details of methods)

CHAPTER – 7

7.1 Timeline

[Divide the proposed time period of the project in smaller sections of 5-6 and place the tentative work plan as per progress of the project]

[Provide information about estimated timetable (if possible in table form), indicating the sequence of research phases and the time that researcher will probably need for each phase. Take into account that at this stage, it can only be estimated, but make clear that researcher have an idea about the time span that will be needed for each step.]

Example: (A project of three year duration)

Months	Work Plan
01-Mar	Procurement of equipment, chemicals and other consumables.
04-Oct	Wet Lab Experiments: Synthesis and characterization of developed product
Nov-18	In-vitro Experiments: Investigating tissue
19-26	In vivo studies using Wistar rats animal model and investigations
27-30	Feedback protocol development and reassessment
31-36	Check overall progress of work and revised strategies if necessary. Documentation and paper/patent filing.

Months	Work Plan
01-Mar	Procurement of equipment, chemicals and other consumables.
04-Oct	Wet Lab Experiments: Synthesis and characterization of ……
Nov-18	In-vitro Experiments: Investigating tissue ……

CHAPTER – 8

8.1 Expected Outcomes

[This Includes Expected Result of The Study]

CHAPTER – 9

9.1 Preliminary Work Done By the Investigator

(Provide details with available references of investigators)

CHAPTER – 10

10.1 BIBLIOGRAPHY (In Vancouver Style)

Example of references in the Vancouver style

Eg. Kwan I, Map stone J. Visibility aids for pedestrians and cyclists: a systematic review of randomized controlled trials. Acid Anal Prev.2004;36 (3):305-12.

BUDGET

Name of the Institute :

Name of Principal Investigator :

Designation :

Department & Institute :

Email Id and Phone No :

Name of Co-Investigator :

Designation :

Department & Institute :

Email Id and Phone No :

Period of Research Project (Duration) :

Budget :

A. Recurring Expenditure:

Sr.	Components	Year-wise /month-wise	Total
1	Salary for Personnel (Research assistant, Research associate, staff, etc.)		
2	Chemicals		
3	Glass wares		
4	Travel		
5	Stationary		
6	Cost of Diagnostic test		

7	Miscellaneous (postage, printing, Photocopying etc)		
Total			

B. Non-recurring expenditure:

Sr.	Components	Year-wise /month-wise	Total
1	Equipments		
2	Computer (in any)		
3	Any software		
4	Any other capital		
Total			

C. TOTAL BUDGET: A + B = ____

- **Along with the proposal a short CV of PI and co-PIs (Max. 2-page) is required to attach.**

Appendix 1B

Declaration Form

I, _____ Principal investigator for the minor/major research Project entitled_____ have read the terms and conditions mentioned in the approval letter No. _____ Dated _____solemnly accept to follow.

I Undersigned undertake that if my research project is funded by Sumandeep Vidyapeeth, I will complete the project successfully and time bound in order to generate possible research paper to be published and in no case, I will leave the project In between as unfinished.

I understand that if I do not follow the terms and conditions and do not provide the required documentation, the funding may be discontinued and the sole responsibility will be of Principal Investigator.

Signature _____

Name of Principal investigator _____

Appendix 1C

Performa fore Progress Report

Name of PI/Department/Institute	Title of the Project	e-mail id	Telephone/ Mobile/ fax numbers

1 Project Title :

2 SVRFS Project Fund Sanctioned Amount (in Rs.) :

3 SVRFS Sanction Order No. & Date :

4 SVIEC Approval number (if any) & Date :

5 Date of initiation of the Project :

6 SVRFS Grant Received (Amount and date) :

7 SVRFS Grant Consumed (Amount and date) :

8 SVRFS Grant Balanced (Amount and date) :

SR. No.	Components	Details
1	**Work done so far** METHODOLOGY & SYSTEMS APPROACH ADOPTED (Including Survey, Community Mobilization & Social Engineering, Technology Identification, Demonstration & Training Component, Objective wise achievements etc.) a. Scheme/studies performed (in continuation of	Attach additional sheet/s as per requirement

	previous report, if any)	
	b. Data collection	
	c. Results obtained	
2	In terms of clinical utility/low cost/Design /environmental friendly/New technology generation/ publication, conference presentation, etc.)	
3	PROGRESS INDICATORS FOR MONITORING	
	(Qualitative & Quantitative Analysis – personnel	
	trained, clinical benefits, skill up gradation, publications etc as the case maybe)	
Plan of work for next semester		
4	(Study design and rationale of the same)	
5	Any other information	
6	Overall remarks of the PI/Guide	

Details of publications related to your project, (if any)

Name of faculty & Department	**Publication Title & Journal Name**	**Year & Month of acceptance**	**Issue, volume number & Page No**	**ISSN No/ Impact factor (if any)**	**National / International &Web link**	**Indexing (Pubmed/ WoS /Scopus/ UGC care)**	**E-Journal (Online)/Print/Both**
(Corresponding author Only)					National Journal means- Head office is in India)		

Details of conference proceeding/workshop related to your project, (if any)

Name of presenter & Type of presentation	Title of the presentation	Date & Venue of the conference	National/ International	Indexing (Pubmed/Elsevier/S (Pubmed/WoS/Scopus/ UGC care)	Any Achievement	Remark
(Corresponding author Only)						

Name of PI

Signature of PI

Date

Name of HOI/HOD

Signature of HOI/HOD

Date

Appendix 1D

Utilization Report and Certificate

(To be submitted with proofs along with progress report) (Financial Year Wise)

(Period: From _____ To_____)

Sr. No.	Particular	Details
1	Title of the Research Project	
2	Name of Principal Investigator	
3	Department & Institute of Principal Investigator	
4	Email ID & Phone Number	
5	SVRFS Fund Sanctioned	
	Sanction Letter No. & Date	
6	SVIEC/SVIAEC/NOC Approval Date / Number	
7	Revised Fund (if applicable)	
	Letter No. & Date	
8	Date of Commencement of Project	
9	Seed Money Fund Received	
	Approval Letter No. & Date	
10	Actual expenditure incurred (SVRFS Approved Amount) (Give details in **Annexure-1)**	
11	Fund utilized, till date (INR). (SVRFS Approved Amount)	
12	Balance amount available (INR) (Seed Money Amount)	
13	Balance fund carried forward/refunded	
	(If refunded) Cheque No. & Date	

Certified that out of Rs._____ sanctioned for the Research project entitled " _____" , a sum of Rs. _____ has been utilized towards the purpose for which it was sanctioned and that the balance of Rs. _____ has been carried forward/refunded to the Institution (if applicable) by Cheque No. _____ dated _____.

Signature of Principal Investigator with date	**Signature of Account officer with date**	**Signature of HoI with date**

Annexure-1

Statement of Expenditure

(Period: From _____ To_____)

Expenditure	Amount	Remark
Recurring;		
1. Salaries:		
2. Materials & consumables, stationary etc		
3. Chemicals		
4. Travel		
5. Overhead expenses		
6. Any other		
[A]		
Non-recurring:		
1. Infrastructure		
2. Equipments		
3. Any other		
[B]		
Total [A+B]		

Signature of Principal Investigator

with date

Signature of HoI

With date

Appendix 1E

Project Completion Report

SVDU Funded Research Project

COMPLETION REPORT

PROJECT TITLE & SANCTION No.

Submitted

to

Department of Central Research and Innovation

Name of the PI

&

Designation

&

Department & Institute

Pro-Forma for Report for Utilization of Financial Support

CONSOLIDATED STATEMENT OFEXPENDITURE

(For the Year of Project Starting to Project Completion)

Name of PI	Designation	Department & Institute	e-mail id	Mobile No.

1. Project Title :
2. SVRFS Project Fund Sanctioned Amount (in Rs.) :
3. SVRFS Sanction Order No. & Date :
4. SVIEC Approval number (if any) & Date :
5. Date of initiation of the Project :
6. SVRFS Grant Received (Amount and date) :
7. SVRFS Grant Consumed (Amount and date) :
8. SVRFS Grant Balanced (Amount and date) :

1st Instalment Amount & Date	2nd Instalment Amount & Date	3rd Instalment Amount & Date	4th Instalment Amount & Date	5th Instalment Amount & Date	Total Amount	Remarks

Statement of Expenditure:

Sr. No	Sanctioned Budget Heads	Allocation of Funds (in Rs)	Expenditure incurred (Instalments) (in Rs)						Remarks, if any
			1st	2nd	3rd	4th	5th	Total	
1	Equipment								
2	Recurring item								

	(labs tests/medical								
3	Any other expense								
4	Total amount								

Signature Head of Department **Signature of CFO** **Name &Signature of PI**

1. Self-assessment of the Impact of financial support:

(Please specifies if any of the following activity emerged/ improved as a consequence of the financial support)

a. Any new research project that emerged on the basis of the SVDU funded project(Yes/No)

   If yes……..A short paragraph can be provided.

b. Did the newly created facility/infrastructure lead to betterment of quality of research publications

c. Any training program/ workshop organized by the department during the period of report, involving this project)

2. If any complications faced during the project execution/grant utilization?

3. Comments/suggestions of the PI

4. Submit the details of the report as per the **Annexure II**

Annexure II

S.No.	Components	Details Attach additional sheet/s as per requirement
1	**Significant Achievement/Special Features/ Highlights of the Project** (Innovativeness in terms of clinical utility/ low cost/Design /environmental friendly/New technology generation/, etc.)	
2	**Overall progress indicators** (Qualitative & Quantitative Analysis – personnel trained, clinical benefits, skill up gradation, publications, conference presentation etc. as the case may be	

Name of faculty & Department	Publication Title & Journal Name	Year & Month of acceptance	Issue, volume number & Page No	ISSN No/ Impact factor (if any)	National/ International& Web link	Indexing (Pubmed/ WoS/Scopus/ UGC care)	E-Journal (Online)/Print/Both
(Corresponding author Only)					National Journal means- Head office is in India)		

Details of publications related to your project, (if any)

Name of presenter & Type of presentation	Title of the presentation	Date &Venue of the conference	National/ International	Indexing (Pubmed/WoS/ Scopus/ UGC care)	Any achievement	Remark
(Corresponding author Only)						

Details of conference proceeding/workshop related to your project, (if any)

Details of Equipment acquired under SVDU funded research project

Name of the Equipment	
Model Number	
Complete Specifications	
Details of Manufacturer	
Name	
Address	
Phone	
Fax	
Email	
Details of Local Agent / Supplier	
Name	
Address	
Phone	
Fax	
Email	
Cost (in Indian Rupees)	
Used for	

Appendix 2

Guidelines on Publication

1. Introduction:

Sumandeep Vidyapeeth Deemed to be University (SVDU) framed the guidelines on publication to advice all concerns pertaining to the scientific publication. A Committee on Publication guide line is constituted to promote higher standard in scientific publications carried out by researchers, faculty members and students of the SVDU. This committee aims to find practical ways of advice to the authors, editors, editorial board members dealing with issues of scientific research, scientific publishing, scientific presentation, text books, electronic books and various types of misconduct and other ethical issues.

2. Objectives:

Main objectives of Publication committee are to ensure intellectual honesty in all medical and paramedical publications. In order to maintain highest professional and ethical standards of all publications, accountability, transparency, declaration of conflict of interest, redundant publication, plagiarism, role of editors, the guidelines are intended to provide procedures to manage allegations of publication misconduct.

3. Standard Guidelines of Regulatory Authorities:

The Committee has considered following publications of the Regulatory authorities during framing the guidelines for the research Publication.

i) UGC Regulations for Promotion of Academic Integrity and Prevention of Plagiarism in Higher Educational Institutions.

ii) ICMR Policy on Research Integrity and Publication Ethics.

Researchers may also refer the guidelines of international committee of Medical Journal

Editors (ICMJE) and committee on Publication Ethics (COPE) pertaining to the ethical matter to ensure the substantial intellectual role of the author or authors included their name in the research/Book publication.

4. Authorship:

The award of authorship should balance intellectual contributions to the conception, design, analysis and writing of the study against the collection of data and other routine work. If there is no contribution by the particular individual in the research/scientific writing, he/she should not be credited with authorship.

a) The first author should be the researcher/faculty/student who has ethical approval on his/her name for conducting the study.

b) Authorship can be provided to other collaborators who have been helping in data collection, analysis and report writing.

c) The corresponding author should be the supervisor of the student or the faculty who has designed the study helped in data collection and analysis.

d) In case the faculty who had contributed to the project had resigned during the publication process, his name should be included and his signature has to be obtained prior to publication.

e) In case of a student who designed and carried out the study has left the institute without publishing the research work, the Guide/Head of Dept. / Supervisor can publish his/her research work as the corresponding author with the student being shown as the first author.

f) In case the student has left the institute without publishing his/her research work, permission from the student must be obtained to publish that scientific work with his/her name as first author and the guide as the Corresponding author.(Proof of permitting to be the correspondence author should be obtained).

g) The supervising faculty / guide should be the corresponding author and the student who has completed the research work and has the ethical approval on his/her name should be the first author.

h) The details of author's affiliation must be mentioned.

5. Review:

a) Peer-reviewers are external experts chosen by editors to provide written opinions with the aim of improving the study. The method of reviewing the articles varies from journal to journal, but some use open procedures in which the name of the reviewer is disclosed.

b) Suggestions from authors as to who might act as reviewers are often useful, but there should be no obligation on editors to use those suggested name.

c) The duty of confidentiality in the assessment of a manuscript must be maintained by expert reviewers, and this extends to reviewers' colleagues who may be asked (with the editor's permission) to give opinions on specific sections.

d) The submitted manuscript should not be retained or copied.

e) Reviewers and editors should not make any use of the data, arguments, or Interpretations, unless they have the authors' permission.

f) Reviewers should provide speedy, accurate, courteous, unbiased and justifiable reports.

g) If reviewers suspect misconduct, they should write in confidence to the editor. Journals should publish accurate descriptions of their peer review, selection, and appeals processes.

6. Duties of Editors:

a. Providing guidelines to authors for preparing and submitting manuscripts.

b. Treating all authors with fairness, courtesy, objectivity, honesty, and transparency.

c. Establishing and defining policies on conflicts of interest for all involved in the publication process, including editors, staff, authors, and reviewers.

d. Protecting the confidentiality of every author's work

e. Establishing a system for effective and rapid peer review

f. Provide direction for the journal and build a strong management team.

7. Conflicts of Interest:

Conflicts of interest comprise those which may not be fully apparent and which may influence the judgment of author, reviewers, and editors. They have been described as those which, when revealed later, would make a reasonable reader feel misled or deceived. They may be personal, commercial, political, academic or financial.

Conflicts of interest must be declared to the editors by researchers, authors and reviewers.

Editors should also disclose relevant conflicts of interest to their readers. If in doubt, disclose, sometimes editors may need to withdraw manuscript submitted for publication.

8. Redundant Publication:

Redundant publication occurs when two or more papers, without full cross reference, share the same hypothesis, data, discussion points, or conclusions.

Re-publication of a paper in another language is acceptable, provided that there is full and date disclosure of its original source at the time of submission.

9. Citation manipulation:

Excessive citation of an author's own research by the author (self-citation) with the

intention of increasing the number of citations for self should be avoided/ limited to appropriate number.

Other citation manipulations like honorary citation, Editor Self-citation, reviewer self-citations are discouraged.

10. Plagiarism:

Plagiarism is the representation of another author's language, thoughts, ideas, or expressions as one's own original work in educational contexts. It also includes research grant applications to submission under “new” authorship of a complete paper, sometimes in a different language. It may occur at any stage of planning, research, writing, or publication. It applies to both print and non-print.

All sources should be disclosed, and if a large amount of other people’s written or illustrative material is to be used, permission must be sought. Anti-plagiarism guidelines of SVDU should be strictly adhered to.

11. Guidelines for submission of Publication:

- The Manuscript for publication should be according to the guidelines of the respective journal in which article is planned for publication.
- The Manuscript for publication should be checked for plagiarism as per the guide lines of the UGC Plagiarism regulation 2018.
- The SVDU utilizes the “URKUND” software for the Plagiarism check. More than 10% is not accepted in that case the author should rewrite the manuscript with modifications to reach less than 10% and resubmit the article manuscript along with the copy of plagiarism report.
- The Manuscript will be evaluated and scrutinized by the subject of the SVDU Publication Guidelines Committee. Once approval is given the Manuscript will be

sent for publication.

- The committee should complete the work within one month of submission, otherwise it will be presumed as approved by Committee. In case of Acceptance or Rejection it is the duty of the Author to inform the SVDU Publication Guideline committee.
- The article should not be submitted to any predatory journal for publication.
- In case data of research carried out at the earlier institute is to be published after joining SVDU, permission from the earlier institute where research was carried out is mandatory before publishing under the SVDU. Name of both the institutes (earlier and present) should be in the publication.
- In all publications authors should mention in the address bar "Sumandeep Vidyapeeth Deemed to be University, Piparia, Vadodara" If they fail to do so such publications will not be considered by the institute for any award or recognition.

12. Presentation of Research Data at Conference:

- Permission for presenting data of research carried out at SVDU at conferences needs permission of the SVDU Publication Guideline committee. The committee must give this within 15 days.
- All Research projects carried out at SVDU is the property of SVDU. In case the data is to be presented after leaving the institute permission is needed from the SVDU Publication Guideline committee.
- The data of research carried out at the earlier institute is to be presented after joining SVDU permission from the earlier institute where research was carried out is mandatory to be taken before presenting at any conference.

13. Misconduct:

- The general principle confirming misconduct is an intention to cause others to regard as true that which is not true. The examination of misconduct must, therefore, focus, not only on the particular act or omission but also on the intention of the researcher, author, editor, reviewer or publisher involved.
- There must to an investigation to find the truth of the misconduct done to safeguard the rights of the concerned parties.

14. Investigating Misconduct:

- Editors should not simply reject papers that raise questions of misconduct; they are ethically obliged to pursue the case. If editors are convinced that the misconduct is serious, in that case they should immediately pass this on to the employers.
- If accusations of serious misconduct are not accompanied by convincing evidence, the editors should confidentially seek expert advice.
- The publication committee can arrange a meeting to resolve the case of misconduct on the basis of the application. The committee may take the legal opinion to resolve the case. The authors should be given sufficient opportunity to respond to accusation of serious misconduct. The committee may refer the UGC regulations to resolve the case of plagiarism and refer the case to the legal team appointed by the employer to take the decision in case of serious matter of misconduct of redundant publication, self-citation, other manipulation of citation etc.

15. Documents to be submitted to the Publication committee for approval:

The person sending the research manuscript for publication should submit the following document to the publication Guideline committee:

a) Draft of Publication

b) Ethical approval letter

c) Plagiarism certificate

In addition, researcher/faculty/student has to submit the following duly filled and signed formats to the publication Guidelines committee;

15.1 Format of authorship consensus:

Order of Authorship	Name & Designation	Department	Contribution to the scientific work	Signature
1				
2				
3				
4				
5				
6				

*Corresponding Author must be mentioned

15.2 Details of the proposed journal for publication:

Name of the Proposed journal	Publisher's detail	ISSN/ISBN	Indexing status	Impact Factor	National/ International

16. Format for scrutiny by publication committee:

S.No	Item	Yes	No
1.	Draft of Publication		
2.	Ethical approval letter		
3.	Plagiarism certificate		
4.	Format of authorship consensus		
5.	Details of the Proposed journal for publication		

17. Proposal format for authoring Book for approval by publication Guidelines committee:

S.No	Item	Details
1	Name of the Institute /Department	
2	Title of the Book	
3	Details of chapters (Number & name of chapters)	
4	Author Name & Designation (If Single author)	
5	Author Names& Designation with chapter Number (If Single author)	
6	Time line (in months /Years)	
7	Proposed Publisher	

Appendix-3

Application Form for Research Incentive Claim (RIC) for Publication

Name of the Claimant (Authorship)		:
Contact No		:
Email ID of all authors (IN CAPITALS)		:
		:
		:
		:
Designation & Department		:
Name of the Institute		:
Title of Research work		:
SVIEC / IAEC Approval No.& Date/Patent (HARD COPY)		:
Name of Journal/ Book	:	
Whether Indexed	:	☐ Yes ☐ No
If Indexed	:	☐ Pubmed ☐ UGC care list ☐ Scopus ☐ Web of Science
ISSN/ISBN No.	:	

Type of Publication	**:**	☐ Print	☐ Online ☐ Both	
Type of work	**:**	☐ Research Article	☐ Systemic Review	☐ Chapter
		☐ Case study	☐ Meta-Analysis	☐ Patent
		☐ Book		
Journal Impact factor ***(Clarivate Analytics Only)*** For information, Visit the link	**:**			
Amount Claimed (INR)	**:**			
IDFC Bank Account No.	**:**			

Declaration by the claimant: -

Hereby give an undertaking that:

- The above information is true to the best of my knowledge and belief.
- The aforesaid work has been carried out at Sumandeep Vidyapeeth or in collaboration with another Institution/Research Institute.
- Sumandeep Vidyapeeth has right to retrieve the dispersed incentive amount in case he/she provides wrong information, contrary to the RIC policy.

Date **:** _____

Signature of Claimant **:** _____

Note:

1. Attach the hard copy of Research Paper along with Ethics Approval and proof of indexing of article /Book/ Book Chapter (possessing all publication details and authorship of your claim).
2. Incomplete / wrong information in application form will be rejected for the claim.

Name of the Institute Remarks Forwarding date Signature of Principal / Dean	
Signature of IQAC coordinator **(Coordinator MUST ensure the claimed data for IQAC data base)**	

For Office Use Only:

1. Amount sanctioned :
2. Remarks of Chief Research Officer :

_____

Signature of Research Director

Appendix 4

Form for Sumandeep Vidyapeeth Research Award (scoring Sheet)

Sr. No	Particulars	A	B	C
		Per activity – Points	Total no.	Total score (A×B)
Internally Funded Research Project				
1	As Principal Investigator in completed Research project	5		
Externally Funded Research Projects (Sanctioned / Ongoing / Completed)				
2	As a Principal Investigator	15		
Consultancy Projects (Sanctioned / Ongoing / Completed)				
3	As a Principal Investigator	10		
Intellectual Property Rights				
4	Patent / Patent Design (Published / Awarded)	10		
5	Copy right Awarded	5		
6	Scientific Publications in journals indexed in PubMed / Scopus / Web of Science	10		
	Scientific Publications in journals indexed in UGC CARE	2		
Book Publication				
7	Book Published (First Author)	5		
	Chapter Published (First Author)	2		
Any Academic / Scientific Award				
8	SVDU / State / National / International Level	5		

Oral Presentation of Research Paper (Podium / Poster)				
9	First Prize – State / National / International	5		
Editor in Scientific Journal				
10	Nominated as Editor in scientific Journal indexed in PubMed / Scopus / Web of Science	5		

_____

Signature of Applicant

Note:

1. The filled scoring sheet along with documentary evidence shall be sent in single PDF to researchcell@sumandeepvidyapeethdu.edu.in

Appendix 5

Standard Terms and Conditions

In addition to the specified General Consultancy rules, the following terms and conditions will apply to consultancy projects taken under all categories by SV, unless otherwise mutually agreed to in a separate document.

1) **Declaration:** All consultancies work undertaken by SV, Vadodara as part of the project will be in good faith and based on material / data / other relevant information given by the Client requesting for the work.
2) **Confidentiality**: Due care will be taken by SV, Vadodara to maintain confidentiality and discretion regarding confidential information received from the Client, including but not limited to results, reports and identity of the client.
3) **Reports**: Any test or other consultancy report given by SV, Vadodara will be based on work performed according to available standards and / or open domain literature. In any event, this report may not be construed as a legal document, certificate or endorsement and may not be used for marketing of the products or processes, without prior consent from SV, Vadodara. The SV reserves the right to retain one copy of the report and use the results of the project for its internal teaching and research purposes.
4) **Work Performance**: Every effort will be made to complete the specified work according to the planned time schedule. However, SV, Vadodara will not be held responsible for delays caused beyond its reasonable control.
5) **Conflict Of Interest**: SV, Vadodara may take up work for other clients also in the same area, provided, to the best of the SV's knowledge, there is no conflict of interest in undertaking such projects.

6) **Payment**: The payment of consultancy work to SV, Vadodara are to be made in advance and in full before the start of the project, through a demand draft / crossed valid cheque, drawn in favour of "Consultancy Services SV" and sent to the office of Director Research Cell. The charges will also include any applicable tax as prescribed by the Government of India from time to time.

7) **Termination**: The consultancy project work may be terminated by either party by giving the other party a notice period of 30 days. However, both parties will meet any residual obligations in connection with the project.

8) **Liability**: SV, Vadodara shall not be held liable for any loss, damage, delay or failure of performance, resulting directly or indirectly from any cause, which is beyond its reasonable control.

9) **Intellectual Property Rights**: All rights pertaining to any intellectual property generated / created / invented in the due course of the project, will be the joint property of SV, Vadodara and the Consultant(s). Terms and conditions regarding transferring / assigning / selling these rights to the client shall be governed by a separate written and mutually agreed to document, if required.

10) **Royalty:** Out of the sales made for a patent emerging from consultancy work, an annual royalty (to be divided equally between the consultant and the SV, Vadodara) of a fixed percentage (to be decided by the Vice Chancellor) will be paid to the Institution by the client.

11) **Resolution of Disputes:** Any disputes arising out of the project shall be amicably settled by both the organizations. The arbitration power shall lie with Registrar, SV Vadodara in case of any dispute and the decision taken by the Vice- Chancellor shall be final.

Appendix 6

Form for Approval of Consultancy Project

1. Name of the Department/Office/Branch : _____
2. Title of the Consultancy Project : _____
3. Consultancy Project Category: I / II /III : _____
4. Duration of the Consultancy Project (Year/Month/Days): _____
5. (i) Date of Commencement : _____

   (ii) Expected Date of Completion : _____
6. Detailed Project Report (DPR) attached: YES /NO
7. Client's Name and Address : _____
8. Type of Client (Tick): Private Sector/ Govt. Sector/ Public Sector /Foreign Agency /

   Others (Please Specify) : _____
9. Payment to be received in: FULL /Part : _____
10. Indian Currency /Foreign Currency : _____
11. Whether MoU/ Agreement Signed with Client (Attach, if any):

    Signed / Not Signed : _____
12. Consent Letter from the Client attached: YES /NO : _____
13. Consent Letter from the Consultant(s) attached: YES /NO : _____
14. Whether Eligibility criteria as Consultant(s) fulfilled as per Consultancy Rules of the

    Institution: Yes / No : _____

    If Yes, attach in DPR the detailed proof(s) in support of claiming the eligibility as

    Consultant(s).
15. Consultant(s) Certificate(**Appendix 7)** attached: YES/NO : _____
16. Details of Persons involved in the Consultancy Project: (Should be attached with DPR)

Name of Consultant(s)	Designation	Institution	Signature

17. Budget (should confirm to the amount of contract/agreement with the Client) (should be attached with DPR) also attach a separate sheet giving complete tentative detail (if any).

Item	Budgeted Amount
Total money received from client (X)	
Service Tax (Y)	
Total Contracted Amount (Z=X-Y)	
SV Share (U= 0.4Z)	
Remaining Amount (RA= Z-U)	
Total Expenditure* (E)	
Balance Amount for Distribution (D = RA-E)	
To Consultant (0.9D)	
To Institute Development Fund (0.1D)	

Signature of the Principal Consultant (with date)

Forwarded by Head of Institute:

_____

DIRECTOR RESEARCH CELL, SVDU

Consultancy Project No.:_____Dated: _____

Recommendations of Research Committee: Approved / Not Approved /

Suggestions for improvement

_____

Convener **Member(s)**

_____

Appendix 7

Consultant(s) Certificate

1. Certified that this consultancy assignment shall not clash with my teaching/office work in the department/office or any other official duty at the SV.
2. That the interest of my Institution/ department in the SV shall not suffer.
3. That the time spent on consultancy and related assignments shall be limited to the non-working days /holidays and the duration of my total consultancy work in a calendar year shall not be more than 60days.
4. That the total annual income of my all consultancy work shall not exceed my gross salary for six months in a financial year.

(Consultant's Signature)

Address (Office)

(Countersigned with official stamp) Head of the Institute

Appendix 8

Application for Permission for Animal Experiments

Application to be submitted to the CPCSEA, New Delhi after approval of

Institutional Animal Ethics Committee (IAEC)

Section I

1	Name and address of establishment	
2	Registration number and date of registration.	
3	Name, address and registration number of breeder from which animals acquired (or to be acquired) for experiments mentioned in parts B & C	
4	Place where the animals are presently kept (or proposed to be kept)	
5	Place where the experiment is to be performed (Please provide CPCSEA Reg. Number)	
6	Date on which the experiment is to commence and duration of experiment.	
7	Type of research involved (Basic / Educational/Regulatory/Contract Research)	

Signature:

Name and Designation of Investigator:

Date:

Place:

Section II

Protocol form for research proposals to be submitted to the committee/Institutional Animal Ethics Committee, for new experiments or extensions of ongoing experiments using animals other than non-human primates.

1. **Project / Dissertation / Thesis Title:**
2. **Principal Investigator / Research Guide / Advisor:**
    a. Name
    b. Designation
    c. Department / Div/Lab
    d. Telephone No.
    e. E-mail Id
    f. Experience in lab animal experimentation
3. **List of names of all individuals authorized to conduct procedures under this proposal.**
    a. Name
    b. Designation
    c. Department / Div/Lab
    d. Telephone No.
    e. E-mail Id
    f. Experience in lab animal experimentation
4. **Funding source / Proposed Funding Source with complete address (Please attach the proof)**
5. **Duration of the animal experiment**
    a. Date of initiation (Proposed):
    b. Date of completion (Proposed):

6. **Described detailed of study plan to justify the uses of animals (Enclosed Annexure)**

7. **Animals required**

    a. Species and Strain:

    b. Age and Weight

    c. Gender

    d. Number to be used (Year-wise breakups and total figures needed to be given in tabular form)

    e. Number of days each animal will be housed

8. **Rationale for animal usage**

    a. Why is animal usage necessary for these studies?

    b. Whether similar study has been conducted on in vitro models? If yes, describe the leading points to justify the requirement of animal experiment.

    c. Why are the particular species selected?

    d. Why is the estimated number of animals essential?

    e. Are similar experiments conducted in the past? If yes, why new experiment is required?

    f. Have similar experiments been made by any other organization in same or other in vivo models? If yes, enclose the reference.

9. **Description of the procedures in detail**

    a. Describe all invasive and potentially stressful non-invasive procedures that animals will be subjected to in the course of the experiments.

    b. Furnish details of injection schedule substances

    c. Doses:

    d. Sites:

e. Volumes:

f. Blood withdrawal details

g. Volumes:

h. Sites:

i. Radiation (dosage and schedule) :

j. Nature of compound/Broad classification of drug/NCE:

10. Does the protocol prohibit use of aesthetic or analgesic for the conduct of painful procedures? If yes, Justify.

11. Will survival surgery be done? If yes, the following is to be described.

a. List and description of all such surgical procedures (including methods of asepsis)

b. Names, qualifications and experience levels of personnel involved.

c. Description of post-operative care

d. Justification if, major survival surgery is to be performed more than once on a single animal.

12. Describe post- experimentation procedure

a. Scope for Reuse

b. Rehabilitation (Name and address, where the animals are proposed to be rehabilitated)

c. Describe method of Euthanasia

d. Method of carcass disposal after euthanasia

13. Describe animal transportation methods if extra institutional transport is envisaged.

14. Use of hazardous agents (use of recombinant DNA based agents or potential human pathogens require documented approval of Institutional Biosafety Committee (IBC). For each category, the agents and the biosafety level required, appropriate therapeutic

measures and the mode of disposal of contaminated food, animal waste and carcasses must be identified):

If, your project involved use of any of the below mentioned agent, attach copy of the approval certificates of the respective agencies:

a. Radio-nucleotides (AERB):
b. Microorganisms/ Biological infectious agents (IBSC):
c. Any other Hazardous chemicals/drugs:
d. Recombinant DNA (RCGM)

Investigator's Declaration

1. I certify that the research proposal submitted is not unnecessarily duplicative of previously reported research.
2. I certify that, I am qualified and have experience in the experimentation on animals.
3. For procedures listed under item 10, I certify that I have reviewed the pertinent scientific literature and have found no valid alternative to any procedure described herein which may cause less pain or distress.
4. I will obtain approval from the IAEC/ CPCSEA before initiating any changes in this study.
5. I certify that performance of experiment will be initiated only upon review and approval of scientific intent by appropriate expert body (Institutional Scientific Advisory Committee / funding agency / other body.
6. I certify that I will submit appropriate certification of review and concurrence for studies mentioned in point 14.
7. I shall maintain all the records as per format (Form D) and submit to IAEC.
8. I certify that, I will not initiate the study before approval from IAEC / CPCSEA received in writing. Further, I certify that I will follow the recommendations of IAEC / CPCSEA.
9. I certify that I will ensure the rehabilitation policies are adopted (wherever required).

Signature

Name of Investigator

Date:

Certificate

This is to certify that the project proposal no. _____entitled_____ submitted by Dr./Mr./Ms_____ has been approved/recommended by the IAEC of _____ (organization) in its meeting dated _____and has been sanctioned _____ (animals) under this proposal for a duration of next _____months.

Authority by	Name	Signature	Date
Chairman			
Member Secretary			
Main Nominee of CPCSEA			

(Kindly make sure that minutes of the meeting duly signed by all the participants are maintained by office)

Department of Central Research & Innovation

Sumandeep Vidyapeeth Deemed to be University
At Post Piparia, Taluka-Waghodia,
District-Vadodara. Pin-391760

www.sumandeepvidyapeethdu.edu.in

02668-245262/64/66, Ext.2746/2747