SRI BALAJI VIDYAPEETH

(ACCREDITED WITH 'A' GRADE IN THE FIRST CYCLE BY NAAC)

Pillaiyarkuppam, Pondicherry - 607 402

SBV POLICY FOR SPONSORED CLINICAL TRIAL

OF DRUGS AND DEVICES

2019

Revised Edition of 2018

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(DEEMED -TO –BE- UNIVERSITY)

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DOCUMENT REVISION HISTORY:

Date	Version Number	Brief Description of change	Change Request Number
13-08-2018	ORIGINAL	Not applicable	-
17-12-2019	First revision	Fee structure for clinical Trial application was fixed ; Composition of committee has been changed. Fee for application has been fixed	SBV - CTD - PL-2018 Pages 5, 8, 13

TITLE AND APPLICABILITY: SBV POLICY FOR SPONSORED CLINICAL TRIAL OF DRUGS AND DEVICES – 2019

The policy for sponsored Clinical trial of drugs and devices would henceforth be known as SBV POLICY FOR SPONSERED CLINICAL TRIAL OF DRUGS AND DEVICES – 2019

PREAMBLE

Clinical Research and Trials play a vital role for the drug development. Sri Balaji Vidyapeeth (SBV), Puducherry and its constituent colleges are receiving several proposals from Pharmaceutical Companies and Contract Research Organizations for conducting clinical trials in various fields. Keeping the statutory and ethical requirements in focus, the present guidelines has been provided for screening, evaluation and conduct of sponsored clinical trials at SBV.

SCOPE

This guidelines is addressed to investigators, pharmaceutical manufacturers and other sponsors of clinical trials for generation of data intended for inclusion in the regulatory submissions of medicinal products.

A proposed clinical trial/project shall aim to

- evaluate a new chemical entity or drug
- investigate a new use/indication of the existing drug
- test new medical devices

PURPOSE

In a sponsored clinical trial the responsibilities lie with the study investigator as well as the study sponsored. The responsibilities have been clearly delineated in this policy. Broadly speaking the protection of the rights, safety and welfare of the subjects in the clinical study deserve top priority. The studies sponsored are endowed with several important responsibilities, but should refrain from promotional activities or commercialization of the investigational device.

It is a joined responsibility of the study investigator as well as the study sponsored to comply with good clinical practice (GCP). This defines the policy scope in a nutshell.

SCIENTIFIC MERIT

A clinical trial/project should be directed towards evaluation of newer therapeutic strategies including small drug molecules, biologics, medical devices as well as novel use of known drugs and devices. It may also be targeted towards addressing national health problems, priority areas as identified by the Government of India as well as the WHO.

SPONSORS OF A CLINICAL TRIAL/PROJECT

a) Government, Government Partnered and private Research & Development Organisations in India as well as abroad
b) Manufacturers of drug molecules, investigational new drugs, and medical devices
c) Contract Research Organisations (CRO)

INITIATION OF THE PROPOSAL

The agency/industry interested in a clinical trial/project at SBV, may approach the concerned department HOD/faculty with a request to conduct the trial. The concerned faculty shall be the Principal Investigator and submit the proposal to Clinical Trial Research Committee (CTRI) for permission.

RESPONSIBILITY OF PRINCIPAL INVESTIGATOR (PI)

The PI should have a Post Graduate Degree in the concerned specialty and should be a permanent employee of the Institution. If the PI is not a permanent employee of the institution then he should choose a co-investigator who is a permanent employee. The PI or the Co-Investigator as the case may be is responsible for the conduct of the clinical trial at the clinical trial site.

The PI shall be responsible for preparing and execution of Institute Sponsor Agreement, detailing any commitment of Institutional Resources and submit the proposal to the Clinical Trial Research Committee (CTRC) and Institution Human Ethics Committee (IHEC) for approval. He can be assisted by clinical trial coordinator of the Sponsor/CRO.

The PI is authorized to withdraw the funds after due permission from the Chairman of the CTRC, utilize the money as per the Agreement and submit audited statement of accounts to the GM Finance (through Clinical Trial Unit (CTU)) at the end of the clinical trial.

Once the study has been executed, the PI shall submit the final report to the sponsor as per the Institute Sponsor Agreement with copies to CTU, CTRC and the Dean (Research) through the concerned Head of the Department.

The PI shall be permitted to negotiate the terms and conditions of the clinical trial with the funding agencies on behalf of the Institute, with the approval of the CTRC and is permitted to attend "Investigator's Meet" (wherever applicable) with regard to the development of methodologies and protocol of clinical trial / project.

It shall be the responsibility of the PI to get the trial registered with Clinical Trial Registry of India. Head of the CTU should be kept informed at each stage.

CLINICAL TRIAL AGREEMENT (CTA)

The sponsor and the PI will prepare Clinical Trial Agreement for individual clinical trial. This will be approved by the CTRC, legal and finance authorities of the institution. No study should be started before generating this agreement.

CLINICAL TRIAL RESEARCH COMMITTEE (CTRC)

This Committee will be nominated by the Dean - Research, who will be the Appellate Authority in case of any disagreement between the members. The members of the Committee will consist of -

1) Medical Superintendent, MGMCRI - Chairperson
2) HOD, Pharmacology, MGMCRI – Member Secretary
3) Professor of General Surgery, MGMCRI/SSSMCRI – Member
4) Professor of General Medicine, MGMCRI - Member
5) Professor of OBGY, MGMCRI - Member
6) Legal Officer and Head- HR, SBV - Member

The Chairman of the Committee can co-opt up to two subject experts related to the project. The committee will hold office for a maximum period of **three** years. The quorum at each of the meetings will be **FOUR** and the Member Secretary would be responsible for

the maintenance of the minutes of all meetings, besides facilitating all of the endeavours concerned with the smooth functioning of CTRC.

The CTRC will meet in first week of every month to consider, discuss and approve the new proposals submitted and also to review the on-going proposals. The CTRC will have the full authority to call for documents pertaining to any aspect of the study and the decision of the CTRC shall be final regarding the sponsored clinical trial. In case of difference of opinion, the final decision will be that of the Appellate Authority.

INSTITUTIONAL HUMAN ETHICS COMMITTEE APPROVAL

Ethical clearance for all phases of clinical trials in humans shall be sought from the Institutional Human Ethics Committee (IHEC). The IHEC will ensure that the general ethical consideration relating to the trial has been followed and the informed consent form has been obtained from the patient or volunteers. IHEC will take up proposals approved by the Clinical Trial Research Committee (CTRC). The trial and informed consent form should be approved by the IHEC before commencing the study. The Principal Investigator and co-investigators shall submit half yearly progress report to the IHEC from the date of approval. The PI should also report any Serious Adverse Event (SAE) to the IHEC within 24 hours of occurrence. In case of mortality, the Principal Investigator must inform all the members of the CTRC immediately.

CLINICAL TRIAL APPLICATION (CTA)

The Sponsor or CRO may approach the concerned department HOD / qualified faculty with a request to conduct the trial. The concerned faculty shall be the Principal Investigator and will submit Clinical Trial Application (Given in Annexure 1) to the Member Secretary, CTRC. After initial scrutiny, the Member Secretary will submit the CTA to CTRC for evaluation and permission.

The Clinical Trial Application shall consist of the following:

- Covering letter
- Prescribed Clinical Trial Application Form
- Non-refundable application fees
- Clinical trial protocol
- Proof of registration with a clinical trials registry as approved

- Investigator's brochures
- Copy of IHEC Application
- Insurance cover
- Financial declaration
- Informed consent information and form(s)

The clinical trial documents shall be submitted in 6 hardcopies and one softcopy.

Explanation

a) The covering letter should be addressed to Member Secretary - CTRC
b) The application fees shall be non-refundable
c) The application form should be submitted in 6 copies signed by all participating investigators. It should contain the Name of the Trial, Sponsor details, Clinical Trial registration number, CV of Investigators, Investigators current work load, signed declaration by the Sponsor or authorized person.
d) The Clinical Trial Protocol shall include the (i) protocol title, (ii) Protocol identifying number and date and in case of any amendment, should bear the amendment number and date, (iii) Name and address of the sponsor and monitor, name and title of person authorized to sign the protocol and protocol amendment for the sponsor, (iv) Name, title, address and telephone number of the sponsors medical expert for the trial, (v) Name and title of the Principal Investigator who is responsible for conducting the trial and the address and telephone number of the trial site, (vi) Name and address of the study trial site, (vi) Name and address of the Clinical Laboratory and other medical and / or technical departments and / or Institutions involved in the trial, and (viii) Clinical Trial Agreement between the Investigator and Sponsor.

DRUG CONTROLLER GENERAL OF INDIA (DCGI) PERMISSION

The sponsor shall submit Drug Controller General's permission along with their proposal, whenever deemed necessary.

HEALTH MINISTRY SCREENING COMMITTEE (HMSC) PERMISSION

The approval from the HMSC, Government of India shall be obtained for multinational studies, whenever deemed necessary.

FUNDING

The details of funding including head-wise expenditure proposed, overhead charges of the institute, and subject compensation shall be submitted on time to the CTRC. All payment shall be sent in the name of "SBV-CLINICAL TRIAL" as per agreed schedule.

INSTITUTE OVERHEAD CHARGES

It shall be 20 % of the total cost of the project to be done at the Institute, however it does not include the PI and Co-PI consultation fees, all hospital charges including bed charges, investigations, IHEC Fees and other charges if any.

APPOINTMENT OF PROJECT STAFF

The Principal Investigator shall appoint project staff as per the norms of MGMCRI.

THE CLINICAL TRIAL UNIT (CTU)

It is recommended that the CTU be consulted for queries in conduct of clinical trials. The CTU shall be principal resource centre for all Clinical Trials related information, Adverse Drug Reaction (ADR) reporting, informed consent documents (both written and audio visual). The Head of CTU can appoint anyone under the Unit to act as study auditors and they will report their findings directly to the Head CTU, who will in turn use his/her discretion to scale up/ escalate to CTRC.

INSURANCE

The Insurance Premium Amount shall be borne by the Sponsor / CRO. Clinical Trial Agreement (CTA) shall clearly state the liabilities of the Sponsor and also insurance details of all study participants against any anticipated or unforeseen fatality, injuries, and illness related to the study.

PROTOCOL AMENDMENTS

(i) Any amendment to the trial protocol, trial arrangements and investigational products shall be submitted to the IHEC and CTRC for approval before such amendments are carried out (ii) If such amendments are necessary to protect the life of subjects, an urgent amendment may be carried out but Prinicipal Investigator shall inform the IHEC and CTRC

about such amendments with an immediate phone call, followed by a written report within 48 hours (iii) Reports of all amendments shall include, but not limited to (a) Reasons for the amendments (b) Possible consequences for subjects already included in the trial (c) Possible consequences for the evaluation of the study outcome.

DATA SAFETY MONITORING BOARD (DSMB)

(i) An independent Data Safety Monitoring Board to be established by the Sponsor to assess at intervals the progress of a clinical trial, the safety data and the critical efficacy endpoints and to recommend to the Sponsor whether to continue, modify or stop a trial. (ii) The Sponsor shall include the charter of work, membership and curriculum vitae of the DSMB when applicable and share the same with the PI.

UTILIZATION OF UNSPENT BALANCE

The Principal Investigator may refund the unspent balance to the funding agency. In case he/she desires to utilize the unspent balance for a pilot study of another research project, he/she shall obtain approval from the Sponsor and Dean (Research). However, in no case the unspent fund shall be utilized for any personal benefit. The unspent money may also be donated to SBV for research if a written letter of permission from the funding firm/industry is received.

CLOSURE OF A CLINICAL TRIAL/PROJECT

At the time of closure of study, the Principal Investigator should submit project completion report and also audited statement of accounts to the Dean (Research) office through Clinical Trial Research Committee, within 2 months of completion of the study.

PUBLICATION CLINICAL TRIAL REPORT

A publication policy of the clinical trial report must be in place if not addressed in a Clinical Trial Agreement.

DECISION ON DISPUTES

In case of any dispute related to clinical trial, decision of the Dean (Research), SBV shall be final.

LEGAL ASPECTS

The CTA (as approved by the legal Head of the Institute)shall be governed by and interpreted in accordance with the laws of India and both parties consent to the exclusive Jurisdiction of the Courts at Pondicherry/Chennai, India.

RESPONSIBILITIES OF THE SPONSOR / CONTRACT RESEARCH ORGANIZATION / CLINICAL TRIAL UNIT AND PRINCIPAL INVESTIGATOR					
S No	Activities	Sponsor's Responsibilities	CRO's Responsibilities	CTU, MGMCRI Responsibilities	PI's Responsibilities
1	Patient recruitment	No	No	Yes	Yes
2	Organizing site initiations	Yes (just to be in knowledge)	Yes	Yes	No
3	3.1. Study medications Accountability: receipt from Sponsor at the site 3.2. Maintenance, Storage, managing, dispensing, reconcile used / unused supplies	Yes No	Yes No	Yes Yes	No Yes
4	Designing SOPs for the Institution on Clinical Research	No	No	Yes	No
5	Updating of SOPs	No	No	Yes	No
6	Organizing Sponsor visits	Yes	Yes	No	Yes
7	Negotiating budgets	Yes	No	Yes	Yes

8	Bidding new studies	Yes	Yes	No	Yes
9	Pooling in patients as per each protocol	Yes (subject to special conditions wherein usual recruitment within Institute is not sufficient)	Yes (subject to special conditions wherein usual recruitment within Institute is not sufficient)	Yes	Yes
10	Assisting investigators to collate patients for a protocol	Yes	Yes	Yes	No
11	Following up of clinical study patient visits	No	No	Yes	Yes
12	Maintaining source documents as per clinical research norms	Yes	Yes	Yes	Yes
13	Completing case record forms	No	No	No	Yes
14	Resolving queries of data management	Yes	Yes	Yes	Yes
15	Drafting serious Adverse event reports	Yes	Yes	No	Yes
16	Coordinating with Ethics Committee	Yes	Yes	Yes	yes

17	Communicating with Stakeholders	Yes	Yes	Yes	Yes
18	Cooperating with Sponsors during their routine monitoring visits	Yes	Yes	Yes	Yes
19	Handling queries of Sponsors	No	Yes	Yes	Yes
20	Coordination of Sponsor Audits	No	Yes	Yes	Yes
21	Coordination of Regulatory Inspections	No	Yes	Yes	Yes
22	Collating patient data of each visit of a particular study	Yes	Yes	Yes	Yes
23	Providing status updates to Sponsors	No	Yes	Yes	Yes
24	Ensuring adherence to the Regulatory norms of Clinical Research	Yes	Yes	Yes	Yes

ANNEXURE 1

SRI BALAJI VIDYAPEETH

Puducherry – 607 402

CLINICAL TRIAL APPLICATION FORM

(Six copies to be submitted to the Member Secretary, Clinical Trial Research Committee)

CTRC NO:_____

(to be filled by the Office)

1. Title of the Clinical Trial:

2. Name of Principal Investigator:

3. Designation :

4. Department :

5. Sponsor's Name and Address:

6. Proposed date of start of Clinical Trial:

7. Proposed date of termination of Clinical Trial :

8. Duration of Clinical Trial :

9. IHEC approval received : Yes ☐ No ☐

If Yes, approval number and date :

10. Budget details / Plan :

Sl.No	BUDGET HEADS	Amount (Rs)

1	Equipment and Consumables	
2	Salary	
3	Investigators fee/Honororium	
4	Hospital expenses (Investigation, hospital stay charges etc.)	
5	Subject compensation (transport, lodging etc.)	
6	Travel (investigator's meet, conferences, project work etc.)	
7	Contingencies (Xerox, stationary, postage, telephone etc.)	
8	Insurance charges (for investigators, patients/volunteers)	
9	TOTAL COST OF CLINICAL TRIAL	
10	Add Institute Over Head Charges (20 %)	
11	GRAND TOTAL	

11. Signature of the investigators

Name Department Designation
Signature

Principal Investigator

1.

Co-Investigators

1. 2. 3.

CTRC NO:_____

(to be filled by the Office)

CHECK LIST FOR ENCLOSURES

a) Covering letter	Enclosed	Yes / No
b) Prescribed Clinical Trial Application Form	Enclosed	Yes / No
c) Non-refundable application fee as prescribed	Enclosed	Yes / No
d) Request letter from Sponsor (if applicable)	Enclosed	Yes / No
e) Clinical trial protocol	Enclosed	Yes / No
f) Investigator's brochures (COA, GMP)	Enclosed	Yes / No
g) DCGI approval	Enclosed	Yes / No
h) Proof of registration with Clinical Trial Registry	Enclosed	Yes / No
i) Copy of IHEC Application / Approval	Enclosed	Yes / No
j) Financial declaration	Enclosed	Yes / No
k) Insurance cover	Enclosed	Yes / No
l) Informed consent information and form(s)	Enclosed	Yes / No

m) Any other documents enclosed (give details):

Signatures of the investigators

Name Department Designation

Signature

Principal Investigator

1.

Co-Investigators

1.

2.

3.

SRI BALAJI VIDYAPEETH

Puducherry – 607 403

RECOMMENDATION OF THE CTRC

For office use

Date: CTRC NO:_____

(to be filled by the Office)

Project Title:

Principle Investigator:

Comments / Suggestions:

Decision: Approved / Not Approved

CHAIRMAN GM-Finance

CTRC SBV

Date:

GLOSSARY:

1. **Adult:** A person who is eighteen years of age or over that age.
2. **Adverse Drug Reaction (ADR):** All noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reaction. A causal relationship between a medicinal product and an adverse event is at least a reasonable possibility (i.e.) the relationship cannot be ruled out.
3. **Adverse Event (AE):** Any undesirable experience occurring to a subject during a clinical trial, whether or not considered related to the investigational product(s).
4. **Applicable Regulatory Requirement(s):** Any Law(s) and Regulation(s) by Central Drug Standard Control Organization (CDSCO), Govt. of India addressing the conduct of clinical trials of investigational products.
5. **Approval:** The affirmative decision of the appropriate bodies (CTRC, IHEC) that the clinical trial has been reviewed and may be conducted at the Institution site within the constraints set forth by appropriate institution, Good Clinical Practice (GCP) and Applicable Regulatory Requirements.
6. **Biological Specimen / Sample:**means materials derived from human sources (ranging from fluids like blood, tissues and cells).
7. **Case Report Form (CRF):** A printed, optical or electronic document designed to record all of the protocol required information. There should be assurance of accurate input and presentation and it should allow verification.
8. **Certificate of Analysis (COA):** An authenticated document issued by an appropriate authority that certifies the quality and purity of pharmaceuticals, an animal and plant products.
9. **Child / Minor:** A person who is below eighteen years of age.
10. **Contract Research Organization (CRO):** A research organization (commercial or academic) contracted by a Sponsor to perform some of the Sponsor's trial related duties and functions.

11. **Clinical Trial Site:** The Location(s) where trial – related activities are actually conducted.

12. **Clinical Trial:** means an investigation consisting of a particular description by, or under the direction of a medical practitioner or dentist to the patient where there is evidence that a medicine, medical device or procedure or herbal medicinal product of that description has effects which may be beneficial and safe to the patient, and the medicine, medical device or procedure or herbal medicine for the purpose of ascertaining beneficial or harmful effects.
13. **Clinical Trial Agreement (CTA):** The Clinical Trial Agreement will be prepared by the Sponsor/CRO and the Principal Investigator for individual Clinical Trial with the approval of the CTRC, IHEC, Legal and Financial Authority of the Institution. It should also include publication policy of the Clinical Trial outcome.
14. **Clinical Trial Research Committee (CTRC):** This Committee reviews and approves all sponsored clinical trials. The decision of the CTRC shall be final regarding the sponsored clinical trial. It will be nominated by the Dean-Research, who will be the Appellate Authority in case of any disagreement between the members.
15. **Data Safety Monitoring Board (DSMB):** An independent data monitoring committee that may be established by the Sponsor to assess at intervals the progress of a clinical trial, safety data, and critical efficacy endpoints and to recommend the Sponsor whether to continue, modify or stop a clinical trial.
16. **Date of Commencement:** For the purpose of the Clinical Trial Certificate and Quarterly Progress Report Form, this is defined as the date when the clinical trial site shall start to enroll participants in the clinical trial.
17. **Drug / devices:** All medicines / devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with CDSCO.
18. **Drug Controller General of India (DCGI):**The DCGI is the authority before whom the sponsor shall submit the proposal for permission wherever and whenever deemed necessary.

19. **Health Ministry Screening Committee:** The HMSC is the authority before whom the approval shall be obtained for multi-national studies wherever and whenever deemed necessary.

20. **Good Clinical Practice (GCP):** means Good Clinical Practice with reference to guidelines published by the International Council for Harmonization (ICH).
21. **Good Manufacturing Practice (GMP):** The part of the Pharmaceutical Quality Assurance which ensures that products are consistently produced and controlled as per quality standards appropriate to their intended use and as required by the marketing authorization.
22. **Institutional Human Ethics Committee (IHEC):**An independent body constituted of medical, scientific, legal and non-scientific members, constituted as per the ICMR guidelines. Its responsibility is to ensure the protection of the rights, safety and well-being of humans involved in a clinical trial by among other things, reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of trial subjects.
23. **Institution Over Head Charges (IOHC):**It is the overhead charges to be paid to the Institute. However it does not include the PI and Co-PI consultation fees, all hospital charges including bed charges, investigations, IHEC Fees and other charges if any.
24. **Local Monitor:** A person appointed by the Sponsor or CRO to oversee the progress of a clinical trial and of ensuring that it is conducted, recorded and reported in accordance with the Standard Operating Procedures, Good Clinical Practice and the applicable regulatory requirements.
25. **Principal Investigator (PI) :**He is responsible for the conduct of the clinical trial at the clinical trial site, who is entitled to provide health care under Indian Laws. The PI shall be responsible for preparing and execution of Institute Sponsor Agreement, detailing any commitment of Institutional Resources and submitting the proposal to the CTRC and IHEC for approval. At the end of the trial, PI shall submit the final report to the sponsor as per the Institute Sponsor Agreement with copies to CTU,

CTRC and the Dean (Research) Office through the concerned Head of the Department.

26. **Research Institution:** Any public or private entity, agency, medical or dental facility where clinical trials are conducted.

27. **Serious adverse event (SAE):** means any untoward medical occurrence that at any dose results in death or is life threatening or requires in-patient hospitalization or prolongation of existing hospitalization or results in persistent or significant disability / in capacity or are a congenital anomaly / birth defects.
28. **Sponsor:** An individual, company, institution or organization which takes responsibility for the initiation, management and / or financing of a Clinical Trial. They may or may not choose to use a CRO.
29. **Vulnerable Population:** An individual whose willingness to volunteer in a clinical trial may be unduly influenced by the expectations, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate, like pregnant women, cognitively impaired subjects, children and prisoners.

RESPONSIBILITY

- Member Secretary will be responsible for monitoring the implementation, outcomes and scheduled review of this policy and its accompanying procedure.
- Head of Department of Pharmacology, MGMCRI is responsible for maintaining the content of this policy as delegated by the Chairperson.
- Senior Personnel Manager is responsible for the administration support for the maintenance of this policy as directed by the General Manager (Administration).

INVOLVEMENT OF MEDIA, IF ANY

NIL

INVOLVEMENT, IF ANY OF MAJOR FINANCIAL IMPLICATIONS CONCERNING EXTERNAL AGENCIES

NIL

EXCEPTIONS, IF ANY

NIL

ANY OTHER PERTINENT DETAILS

NIL

ENQUIRIES

All enquiries related to this policy should be addressed to the Legal Officer,sbv with a copies addressed to the Registrar and General Manager(Administration) , SBV.

Sl.No	Role	Name	Designation	Signature
1	Prepared by	Dr. Nirmal Coumare	Medical Superintendent, MGMCRI	
		Dr. Pratheba Balu	Associate Dean Research, IGIDS	
2	Reviewed by	Dr. Adithan C	Dean – Research, SBV	
		Mr. Ralph Alexander Mathews	Legal Officer & Head, HR, SBV	

Approved by: Prof. Subhash Chandra Parija, Vice Chancellor, SBV: