VII. GUIDELINES FOR SUBMISSION OF RESEARCH PROPOSAL:

Applicants for evaluation of research projects:
ISBEC will consider the applications from the following:
Principal Investigators
Sponsors
Clinical Research Organisation (CRO)

1. A recognized institution/center wanting to conduct any prospective, retrospective studies (on drugs, investigational techniques, behavioral or dietary interventions, surgical techniques or use of biomedical devices) involving human subjects or patients can submit the proposed research protocol (RP) along with the case record form (CRF) drawn as per the GCP / ICMR guidelines.

2. The protocol should be typed in English. It should have the names, designations and dated signatures of the principal investigator (PI) and Co- investigators (CI). It should be submitted through the head of the institution or appropriate authority. If the study involves collaboration with another department or outside center, the collaborators' signatures should also be included. The proforma should include details of the clinical phase of drug trial, type of patients, place of study, duration of study, investigations to be carried out, the names of the sponsoring agencies, the cost of the trial to the sponsors and the cost to each of the participating centers in terms of manpower, man hours and actual costs, the permissions from Drugs Controller General of India (DCGI), ICMR or any other appropriate authorities,import permissions if the drug is imported and theexisting facilities and infrastructure of the institutes / centers conducting the studies.

3. All studies on drugs not marketed in India or a new combination or ingredients marketed separately, or plan to use any drug (from India or from outside) require permission from DCGI. A copy of the permissions should be submitted. If the DCGI permission is not available, the copy of the application to the DCGI can be submitted to ISBEC which may give a provisional approval subject to DCGI PERMISSION. The study cannot begin until copy of the DCGI approval is received, by ISBEC.

For drugs investigated or marketed internationally the investigational status and marketing status in all different countries should be mentioned. For multicentric studies the names of all centres and investigators should be made available to the Ethics Committee and appropriate permissions from DCGI (when required), ICMR , Health Ministry and HMSC should be submitted to ISBEC.
For Ayurvedic, Homeopathic, Unani or herbal drugs, a copy of the manufacturing license issued by FDA, to the company or institute concerned, will facilitate clearance from the Committee.

Alternatively data of the ingredients as mentioned in Standard Reference Text of the Alternative Systems of Medicine will be required.

In addition, the product under investigation should have identifiable biological markers (Passport data) as well as SOP for its manufacture, to ensure Standardization.

For Ayurvedic, Homeopathic, Unani or herbal drugs, a copy of the manufacturing license issued by FDA, to the company or institute concerned, will facilitate clearance from the Committee.

Good Ayurvedic Research Practices (GARP): Testing of Ayurvedic products will be consistent with Modern Standard of Ethics in Medicine,as per the practices mentioned in Good Ayurvedic Research Practices (as per Appendix C)

In a study involving Traditional Systems of Medicine , an investigator, who is a specialist in that system, has to be included as a co-investigator.

(Later- Similarly, an expert member from that system should be present in all the proceedings of the ISBEC related to that study.

VIII . DOCUMENTS REQUIRED FOR SUBMISSION:

ISBEC will require the following documents to be submitted by the applicant for evaluation of projects:(All documents including the covering letter should be in the form of word file or PDF attachments)

i) Prescribed form of ISBEC- Appendix No---

ii) Covering letter indicating the title of the study, number of subjects, and names

of centers (sites) to be involved- details provided later.

iii) Investigator's brochure with data on preclinical and clinical studies carried out till date and complete safety data

iv) Study protocol and amendments if any

v) Case Record Form

vi) Patient information sheet along with the translations in regional languages

vii) Copy of the Informed Consent Form along with the translations in regional languages

viii) Subject recruitment procedures and advertisements if any

ix) Details of study sites

x) Copies of permission from DCGI or any appropriate regulatory authorities/

or copy of application to regulatory authority.

xi) Study monitoring procedures if any including Data Safety Monitoring Board (DSMB) if applicable

xi) Monitoring procedures if any

xii) Copy of permission from any other Ethics Committee for the same study at another centre, copy of Health Ministry Screening Committee (HMSC) for International Collaboration

xiii) CTRI registration number

xiv) Copy of registration certificate or Quality Control certificate of the laboratories which will participate in laboratory procedures

xv) Biodata and copy of recent GCP certificate of the Principal Investigatorand Co-Investigator

xvi) Package insert and label of the IP

xvii) Publication Policy

All protocols/projects dealing with human subjects are to be preceded by the following check list irrespective of whether they are for undergraduate or postgraduate study , interventional or non-interventional study or behavioural study, and the Principal Investigator is answerable for any lapses in clinical applications.

Check list for protocol submission:

Serial No	Item	Yes	No	Not Applicable
1	Covering letter signed by the PI /Sponsor as an attachment giving the title and general information and a complete numbered list of all documents submitted as listed below and any additional documents when required			
2	First Page- with Title, Address, Names & Signatures of Investigators, Co-Investigators, Centres, Sponsors			
3.	Title- must include type of study, population for study, intervention or observational subject, site of study			
4	Type of Clinical study, address of centres, population to be studied, duration of study			
5	Expected cost of study			
6	Permissions from authorities like departmental or institutional head, DCGI, State authorities, marketing license, Import license when applicable, CTRI registration, HMSC permission for international collaboration			
7	Copy of EC permission from another centre if available			
8	List of project staff & Responsibilities			
9	Infrastructure facilities available, to be acquired			
10	Interventional drugs- Manufacturing batch no,			

	stock received, preservation, shelf life			
11	Instrumental intervention- Manufacturing Licence, Model No, Year of manufacture etc			
12	Nutritional products-preparation, preservation, shelf life			
13	Sample size, study & control subjects when applicable, statistical basis			
14	Period of enrollment, Total duration of study, period for Statistical analysis- Duration of follow up when required			
15	Ayurvedic, Homeopathic, Unani or herbal drugs- manufacturing license, Passport data of plants & extracts, Certificate of analysis, details of types of extracts, formulation			
16	Preclinical data when applicable			
17	Review of Literature and rationale- old as well as recent, summary tables with authors and years of publications			
18	Purpose of the study			
19	Primary Objectives			
20	Secondary Objectives			
21	Investigator's brochure- summary of preclinical and previous clinical trial data			
22	Study Protocol with Amendments if any			
23	Case Record Form, Questionnaire, Food Frequency form, Activity form , QoL Assessment forms			
24	Subject information sheet with translations			
25	Informed Consent form with statement on confidentiality, Insurance when applicable, translations, Assent forms for children aged 7 years or more, Waiver of consent			
26	Information about ISBEC and Contact information on Consent form			
27	Subject recruitment procedures, advertisements			
28	Study site details, co-investigators			
29	Subject Inclusion /Exclusion criteria			
30	Treatment or Intervention details, package insert, copy of the label			
31	Assessment criteria			
32	Investigations, amount of blood to be collected at each visit and total amount collected during the study, laboratory details, QC certificates, references for methods used			
33	Monitoring Procedures including DSMB			

	when required			
34	Criteria for discontinuation of subject or for the study, Fail Safe procedures, Details of Clinician on project for Student's project when needed, procedures for subjects excluded from study but requiring referral Eg Severe anemia, complications			
35	Adverse Event and Adverse Drug Reaction Reporting forms and procedures and plan of management, Data safety, confidentiality procedures			
36	Subject Insurance details when applicable- copy of insurance policy, subject compensation details when applicable			
37	Study site details, co-investigators			
38	Biodata of PI, Co-I, Copy of Recent GCP certificate of PI, Co-I			
39	Signed undertaking by PI			
40	Publication policy			

Principal Investigator:

Signature: Date:

Appropriate fees for the evaluation will be charged depending on the type of Institute/Company submitting the project and the nature of the project.

Applicant will be informed regarding the amount to be paid, and date for the review on receipt of the proposal

A demand draft in favour of "Inter System Biomedica Ethics Committee" should be forwarded before the meeting is scheduled

Projects on Alternative and Indian System of medicine must include an expert in the system as a co- investigator with the biodata. All collaborations must be mentioned.