AN1-V1/KSSSCISOP 03/V1

Project Submission Form for Review by IEC

(5 copies (Hard) & E-mail also)

To be filled by IEC Secretariat:
Project ID:_____Date of Submission of completed form:_____

A. Identification:

Project Title:				
Principal Investigator (PI)		**Department and Designation**	**Tel. no./E-mail**	**Signature**
Co-PI/ Collaborator*/Student*				
1.				
2.				
3.				
4.				
5.				
Project funded	☐No ☐Yes	Funding Agency: ☐Intramural ☐Extramural ☐ClinicalTrial	Sponsor/CRO/Funding agency: ……. Budget: …….	
Student project	☐No ☐Yes*	DM ☐M.Ch ☐PhD ☐JRF ☐ SRF ☐Any other☐		

Collaborative	☐No ☐Yes	☐National ☐International	Name of Institute/'s:
Study duration			

*See instructions/notes

B. Project Details

I. Study Design	☐Interventional ☐Others …….. ☐Observational		☐Single Centre ☐Multicentre
II. Participants			
1. From KSSSCI* Controls Particip antss	Numbers ……..... …….....	Source …… …….	Total (if multicentre) …… …… …… ……
2. Gender	☐Both ☐Males only ☐Femalesonly		
3. Clearly defined inclusion/ exclusion criteria: ☐Yes ☐No			
4. Vulnerable Participants	☐No ☐Yes	☐Pregnancy☐Children☐Elderly☐Illiterate ☐Handicapped ☐Terminally/seriouslyill ☐Mentally challenged ☐Economically/socially backward☐Others	
5. Special group Participants:	☐No ☐Yes	☐Captives ☐Employees ☐Students☐Nurses ☐Armed Forces ☐Healthcare workers ☐Any other	
6. Advertising for recruitment of Particip ants	☐No ☐Yes	If yes, please attach copies of posters, flyers, brochures, websites etc.	
III. Specimen collection	☐No ☐Yes	If yes, complete section B.III	

<table>
<tr><td>IV. Interventional Study</td><td>☐No
☐ Yes</td><td>If yes, complete section B. IV</td></tr>
<tr><td>V. Risk and Benefits</td><td colspan="2">a. Does this study qualify for ☐ Minimal risk’*
☐More than minimumrisk
☐High risk
b. Is there benefit a) to the Participant? ☐Yes ☐No; ☐Direct
☐Indirect
b) to the society? ☐Yes ☐No
c. Is the risk commensurate to the benefits to be accrued by the Participants/ community/country? ☐Yes ☐No</td></tr>
<tr><td>VI. Privacy and Confidentiality</td><td colspan="2">Study Involves: ☐Direct Identifier (Participant identified by name/ Cr. No) ☐ Indirect identifiers (Participants identified by study ID)
☐ Completely Anonymized (Participant cannot beidentified)
Confidential handling of data by staff: ☐Yes ☐No</td></tr>
<tr><td rowspan="4">VII. Informed Consent Documents: a. Participant Information Document (PID)*
b. Informed Consent Forms (ICF’s)</td><td colspan="2">☐ None (Waiver of consentform)</td></tr>
<tr><td>☐Written
☐Verbal
☐Audiovisual</td><td>-Language: ☐Hindi ☐English ☐Others
-Study includes children: ☐Yes ☐No
If yes, Age group …….</td></tr>
<tr><td colspan="2">PID and ICF for: ☐Participants☐Controls/volunteers
☐Parents/LAR
LAR-Legally acceptable/authorized representative/guardian</td></tr>
<tr><td colspan="2">PID and Assent form (children 7-18yrs): ☐Child</td></tr>
<tr><td colspan="2">Consent will be taken by: ☐PI/Co-PI ☐Nurse ☐Counselor
☐Research Staff ☐Student ☐AnyOther</td></tr>
</table>

VIII. Archival of records by IEC Secretariat for more than 3years (5years for clinical trials) after termination/completion of study: ☐Yes☐No

If yes, for how manyyears……

Reasons for Archival……

*See instructions/notes

C. Identify the ethical Issues (if any) related with thestudy:

……

……

……

……

D. Brief proposalsummary

Aim(s) and objectives, methodology describing the potential risks and benefits, outcome measures (maximum 500 words).

Signature of PI

Name_____ **Date**_____

Section B.III (Specimen collection)

1. Type	Nature	Amount	Frequency	Total amount	Comment
Blood					
Body fluid					
Tissue					
Others					

2. Collection of fetal tissue or abortus: ☐No ☐Yes

Specify……

3. Use of pre-existing/stored/left over samples: ☐No ☐Yes

Providedetails……

……

4. Proper disposal of material: ☐Yes ☐No

5. **Storage for banking/future research:** ☐Yes ☐No

6. Will any sample collected from the Participantss be sent abroad? ☐Yes

☐No If yes, give details and address of collaborators:

_____

_____

Sample will be sent abroad because: ☐Facility not available in India

☐Facility in India isinaccessible

☐Facility available but not beingaccessed

If so, reasons_____

***Has necessary clearance been obtained*: ☐**Yes ☐No

Section B.IV (For Interventional studies only)

1. **Study involves use of: ☐**Drugs* ☐Devices* ☐Vaccines*☐Radiopharmaceutical

   ☐Recombinant DNA/Gene therapy ☐Stem cell ☐Indian/Alternate system ofMedicine

   ☐Any other…….

*(need approval from *DCGI; BARC for radioactive substances and from DBT for gene therapy. Research in alternate system of medicine in accordance to AYUSH-GCP guidelines)*

2. **Is it approved and marketed in? ☐**India ☐UK & Europe ☐USA ☐OtherCountries

   Approved Indication, specify…….

3. **Is it an Investigational New Drug?** ☐Yes☐No.

If yes:

a. Investigator's Brochure enclosed ☐Yes☐No

b. Preclinical studies data available (If yes, provide summary ☐Yes☐No

c. Clinical studies data available (If yes, provide summary ☐Yes☐No

d. Clinical study in Phase: ☐I ☐II ☐III☐IV☐NA

   If phase I-III will the drug/device provided free? ☐Yes ☐No

   If phase IV will drug/device provided at cost less than Hospital pharmacy? ☐Yes ☐No

e. DCGI's permission obtained: ☐Yes ☐No, **if yes,** copy of letter enclosed ☐Yes☐No

5. Datamonitoring

a. Is there plan for reporting of adverse events? ☐Yes☐No

If yes, reporting will be done to: ☐Sponsor ☐ IEC ☐DCGI

b. Is there a plan for interim analysis of data? ☐Yes☐No

Mention Date Monitoring Plan

……

…..……

6. **Provision for travel/treatment due to injury from study funds:** ☐Yes ☐No

If yes, by: ☐Sponsor ☐Investigator ☐Insurance Company ☐Any Other

7. Registered with Clinical Trial Registry – India: ☐Yes ☐No

If yes, copy of certificate enclosed: ☐Yes ☐No

Instructions/ Notes:

1. Submit Five copies and one C.D/ pendrive of form and all documents as perchecklist.
2. Submit detailed Study/Project Protocol (Short review of literature, justification for study, aim, methodology, inclusion, exclusion criteria, statisticalanalysis).
3. Submit case reportform (CRF)
4. Submit a page of recent, signed and dated curriculum vitae for **PI outside KSSSCI**or of the **student (MD/MS/DM/M.Ch/PhD)** who has submitted thesis/project.
5. Mention sample size calculation inprotocol
6. Mention source of controls/healthy volunteers.
7. PID should be in simple language avoiding technical terms
8. 'More than minimal risk': *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (US-FDA2014).