INSTITUTIONAL ETHICAL COMMITTIE,

Office of Member Secretary, Shri Vinoba Bhave Civil Hospital, Silvassa

Format for submission of proposal to Institute Ethics Committee in studies

INVOLVING Human Participants

- Proposal Title
- Principal Investigator Details
- co-PI (if any)
- Project Personnel Details
- Please provide a brief description of the research project including scientific rationale (with the results of previous animal and human studies), hypothesis, study design and statistical basis for the structure of the investigation
- State the role of human subjects, including what will happen to the participants and what they will be told about the research.
- Describe the population to be studied, inclusion and exclusion criteria, and numbers to be recruited.
- Describe recruitment procedures, what information will be shared with potential participants, any compensation or incentives that will be provided for participation.
- Attach a copy of the informed consent form (ICF) to be shared with the participants. Please include copies of the forma with translations in regional language forms.
- Describe any features that would not be disclosed to the participants and provide a justification for the same.
- State the type of data to be collected as interviews, face to face interviews, questionnaires, education tests, physical measurements, physiological measurements, physiological sample collections including blood samples, etc.

- Describe data collection procedures. Please attach questionnaires, interview protocols.

- Describe procedures for maintaining confidentiality of participants

- Please list the expected study sites.

- Describe real and potential risks to the participants.

- Please classify the risk category as one of the following based on definitions provided in the Guidelines for Institute Ethics Committee.

  Less than minimal risk

  Minimal risk

  Greater than minimal risk

- Please list potentially harmful effects that can be adequately detected, prevented, or treated

- Describe definite and potential benefits to the participants.

- Describe ethical issues in the study and plans to address these.

- List any regulatory clearances required / obtained and attach application and approval copies of the same.

- List the sources of funding and financial requirements for the project.
- State of conflicts of interest, if any.

- A statement describing any

  compensation for study participation (including expenses and access to medical care) to be given to research participants;

  a description of the arrangements for indemnity, if applicable (in study-related injuries);

  a description of the arrangements for insurance coverage for research participants, if applicable; all significant previous decisions (e.g., those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided.

- Are the results to be published? Please note that confidentiality of the participants must be maintained while publishing.

- Provide any other information relevant to the study

- Start Date of the study

- End Date of the study

- **Please note** that all studies that involve **biological samples** must be sent to **the Institutional Infection control Committee and Bio-Medical Waste Management Committee**, **SVBCH, Silvassa.** Please state if this proposal has been submitted to the aforesaid committee. Yes / No

Undertaking by the PI

I have read the Ethical Guidelines for Biomedical Research on Human Participants, 2006 issued by ICMR and the Guidelines for Institute Ethics Committee, Shri Vinoba Bhave Civil Hospital, Silvassa.

The proposal being submitted is complete in all respects as given in the Guidelines for Institute Ethics Committee, Shri Vinoba Bhave Civil Hospital, Silvassa.

I agree to comply with all guidelines for ethical research.

On IEC approval and initiation of the study, I will

- Personally monitor the study.
- Inform the IEC of all Serious Adverse Events and the interventions undertaken.
- Inform the IEC of any protocol deviation with adequate justifications, prior to the deviation.
- Submit any protocol amendment to IEC for renewed approval.
- Inform the IEC of any new information related to the study.
- Notify the IEC of any premature termination of study along with reasons and summary of the data obtained until the termination.
- Inform the IEC of any change of investigators / sites.
- Submit a final report at the end of study to the IEC.

PI Signature:

Date:

Place:

PI Name:

Department:

Tel No:

Email:

INSTITUTIONAL ETHICAL COMMITTIE,

Office of Member Secretary, Shri Vinoba Bhave Civil Hospital, Silvassa

Format for submission of proposal to Institute Ethics Committee in studies

NOT INVOLVING Human Participation

- Proposal Title

- Principal Investigator Details
- co-PI (if any)

- Project Personnel Details
- Start Date of the study

- End Date of the study

- **Please check the sample(s) to be used in the study.**

	Blood
	Tissues (specify)
	Spinal fluid
	Urine
	Secretions (Saliva, Tears)
	Hair
	Others (specify)

- Please provide a brief description of the research project including scientific rationale (with the results of previous animal and human studies), hypothesis, study design and statistical basis for the structure of the investigation

- State the purpose of the biological samples.

- Please note that the biological samples received from institutes outside SVBCH, SILVASSA should also be accompanied with relevant ethical clearance documents.

- Provide a description of how the samples will be obtained.

- Describe the plan for coding and decoding the samples.

- State if the samples be put stored for further use and the period for which it will be stored. **Please note that this period cannot be beyond the end date of the study.**

- If yes, describe the plan for storing the samples for future use.
  Please note that the consent form should include information about storing samples for future use.

- Will the samples be shared with individuals outside of this proposal or sent to individuals outside SVBCH, SILVASSA.

- If yes, include the plan on sharing or sending outside SVBCH, SILVASSA.
  Please note that the consent form should have information on sending the samples out.

- **Please note** that all studies that involve **biological samples** must be sent to **the Institutional Infection control Committee and Bio-Medical Waste Management Committee**, **SVBCH, Silvassa.** Please state if this proposal has been submitted to the aforesaid committee. Yes / No

Undertaking by the PI

I have read the Ethical Guidelines for Biomedical Research on Human Participants, 2006 issued by ICMR and the Guidelines for Institute Ethics Committee, Shri Vinoba Bhave Civil Hospital, Silvassa.

The proposal being submitted is complete in all respects as given in the Guidelines for Institute Ethics Committee, Shri Vinoba Bhave Civil Hospital, Silvassa.

I agree to comply with all guidelines for ethical research.

On IEC approval and initiation of the study, I will

- Personally monitor the study.
- Inform the IEC of any protocol deviation with adequate justifications, prior to the deviation.
- Submit any amended protocol to IEC for renewed approval.
- Inform the IEC of any new information related to the study.
- Notify the IEC of any premature termination of study with reasons, along with summary of the data obtained until the termination.
- Inform IEC of any change of investigators / sites.
- Submit a final report at the end of study.

PI Signature:

Date:

Place:

PI Name:

Department:

Tel No:

Email: