Title: Selection and Responsibilities of Independent Consultants

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe procedures for selecting and engaging expertise of medical professionals as 'Independent Consultants' (IC) to the Sri Manakula Vinayagar Medical College and Hospital Ethics Committee (SMVMCH-EC).

2. Scope

This SOP covers the procedures for selecting, appointing ICs and getting their expert opinion during the EC review process. It also defines the responsibilities of IC.

3. Responsibility

It is the responsibility of the Chairman/ Member Secretary/ EC member/s to nominate the name of one or more IC/s. The Chairman is responsible for endorsing the choice of IC nominated by EC Member Secretary/EC member/s. The administrative procedures regarding selection, confidentiality agreement and maintenance of roster of ICs will be carried out by EC secretariat.

4. Detailed instructions

4.1 Recommendation of names of ICs and making a roster of ICs for the EC

- Chairman/ Member Secretary/ EC members will nominate the names of ICs from different specialties of Medicine.
- Member Secretary in consultation with Chairman will select a panel of IC(s) for the EC.
- Member Secretary will issue an appointment letter to the IC(s) after confirming their willingness through telephonic/ electronic communication.
- After receiving written approval from ICs, a list of specialty wise ICs will be maintained by the secretariat in the EC records. The details of each IC (Name, designation, Affiliation, contact details and updated curriculum vitae) will be maintained in the EC records.

4.2 Consulting an IC during EC review process

- An EC member/ Member Secretary/ Chairman may suggest that the opinion be sought from one or more IC(s) and may suggest the name of a particular IC(s) from the roster of ICs maintained by the EC or from outside the roster; if during the review process of any given research study if it is felt that the study involves procedures or information that is not within the area of collective expertise of the EC members.
- The Member Secretary in consultation with Chairman (or at full board meeting; as deemed necessary) will decide identify and select the IC(s) outside the roster to be invited based on area of expertise, independence and availability.
- Member Secretary on behalf of the EC will invite IC(s) in writing to assist in the review of the research study and provide his/ her independent opinion in writing. This may be done after seeking concurrence and confirming availability of the IC through telephonic/ electronic communication.

4.3 Communication with ICs

- The Secretariat may request a copy of the updated curriculum vitae of the IC (those outside roster) for EC records and future reference.
- The Member Secretary will request IC to declare conflict of interest, if any, in writing and sign confidentiality and conflict of interest agreements.
- The Secretariat will forward copies of the Confidentiality Agreement (*AX 01-A/SOP 04/V3)* and Conflict of Interest Agreement (AX 01-B/SOP 04/V3) for careful reading, understanding and signing.
- The Member Secretary will provide explanations/ clarifications (telephonically or in writing) to the IC(s) if any doubts or questions are raised. Any further explanations can be provided by the Chairman/ Legal expert/ EC members.

4.4 Reading, understanding and signing the Conflict of Interest document and Confidentiality Agreement

- The IC(s) will sign and date the Confidentiality and Conflict of Interest Agreement.
- The Secretariat will obtain the signed Confidentiality Agreement and Conflict of Interest Agreement and forward it to Chairman.

- The Chairman will sign and date the Confidentiality and Conflict of Interest Agreements. The original copies of these agreements will be retained by the Secretariat and photocopies will be sent to IC(s).

4.5 Review of research study proposal

- The Secretariat will provide study protocol documents along with the Study Assessment Form for IC(s) *AX 02/SOP 04/V3* to the IC(s). The IC(s) may be provided with a copy of 'Guidelines for Reviewers'.
- The IC(s) will be requested to complete and provide the Assessment Form (duly signed and dated) to the Secretariat within a stipulated period or by a stipulated date.
- The assessment report provided by the IC(s) becomes a permanent part of the study file.
- The assessment report will be reviewed by Member Secretary in the EC meeting when the concerned study is being discussed.
- If deemed necessary, the Chairman or Member-secretary may seek additional information or clarifications from the IC in writing. Additional Information provided by the IC will be considered as a part of the Assessment Report.
- If deemed necessary, the Chairman or Member-secretary may invite the IC(s) to attend an EC meeting for providing additional information or clarifications that may be sought by EC members or Chairman. However, the IC will not participate in the decision making process on the research study.
- If deemed necessary, IC may be reimbursed for expenses on travel, time spent, documents referred to in library/ internet or any other incidental expenses, etc.

4.6 Tenure of Services of IC

- The roster of ICs maintained at the EC office will be updated every 3 years
- For IC appointed for a particular study, the services of IC get automatically terminated once the final decision regarding the study is taken by the EC. The EC will document the termination of the services of IC by providing a letter thanking the IC for the services rendered.

4.7 ***Responsibilities of IC***

- If IC agrees to review a research proposal, he/she will comply with EC requirements of signing confidentiality and conflict of interest agreements.
- IC will review the research study and complete the Assessment Form (duly signed and dated) within a stipulated period or by a stipulated date.
- IC will attend an EC meeting for providing additional information or clarifications, if invited by Member Secretary/ Chairman. However, the IC will not participate in the decision making process on the research study.
- IC will remain available for telephonic and email communication till the review process of the given research proposal is complete.

Independent Consultant: An independent consultant is a subject expert in a specified field who gives advice, comments and suggestions upon review of the study protocols. He/she has no affiliation to the investigators proposing the research protocols.

5. Reference to other applicable SOPs - Nil

6. Annexures

Annexure 1 *AX 01-A/SOP 04/V3* - Confidentiality Agreement for an IC

AX 01-B/SOP 04/V3 - Conflict of Interest Agreement for an IC

Annexure 2 *AX 02/SOP 04/V3* - Study Assessment Form for an IC

Annexure 01-A: AX 01-A/SOP 04/V3

Confidentiality Agreement Form for an Independent Consultant

I,_____

_____ (Name and Designation) as a non-member of Sri Manakula Vinayagar Medical College and Hospital Ethics Committee (SMVMCH-EC) understand that the copy / copies given to me by the EC is/are confidential. I shall use the information only for the indicated purpose as described by the EC and shall not duplicate, give or distribute these documents to any person(s) without prior permission from the EC. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

Signature of the Consultant with Date Chairman of EC with Date

Annexure 01-B: AX 01-B/SOP 04/V3

Conflict of Interest Agreement Form for Independent Consultants

- I understand that it is the policy of the EC that no reviewer may participate in the review, comment or approve of any activity in which he/she has a conflict of interest except to provide information as requested by the EC.
- I do not have any actual or potential conflict of interest in relation to the particular proposal submitted for review by the EC to me.
- In the event that I develop any conflict of interest in relation to the particular proposal during the review process, I will declare it to EC and refrain from reviewing it.

I, _____ (name) have read and accept the aforementioned terms and conditions as explained in this Agreement.

Signature of IC with Date Chairman's Signature with Date

I acknowledge that I have received a copy of this Agreement signed by the EC Chairman and me.

Signature with Date

[The original (signed and dated Agreement) will be kept on file in the custody of the EC. A copy will be given to you for your records]

Annexure 2: AX 02/SOP 04/V3

Study Assessment Form for an Independent Consultant

EC Protocol Number:	
Protocol Title:	
Comments on the protocol:	
Comments on the Informed Consent Document:	
Comments on any other issues/ aspects:	

Remarks:	Recommend approval Recommend approval after incorporation of changes Suggested Recommend disapproval (Please state Reasons) Any other (Please specify with reasons)
Name of the Consultant:_____ Reviewing the project: Signature with Date:	

7. Flow Chart

No.	Activity	Responsibility
1	Recommendation of a name of one or more IC(s)	EC Member, Member Secretary or Chairman
2	Selection and Appointment of IC(s)	Member Secretary in consultation with Chairman
3	Invitation to IC(s) on behalf of EC	Chairman/ Member-Secretary
4	Co-ordination with IC(s) for fulfilling administrative requirements	EC Secretariat

5	Reading, understanding and signing the Conflict of Interest document and Confidentiality agreement	IC, Chairman
6	Maintenance of a specialty-wise list/ roster of ICs	EC Secretariat
7	Reviewing documents pertaining to research project	IC

8. References

1. Forum for Ethics review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 22nd October 2018). Available from: http:// www.ferci.org/sops/
2. Indian Council of Medical Research (ICMR). National Ethical guidelines for biomedical and health research involving human participants, October 2017. (cited 23rd October 2018) available from: http: //www.icmr.nic.in.
3. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf

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