DESKTOP SURVEILLANCE ASSESSMENT (ETHICS COMMITTEE)

PREFACE

For an accredited Ethics Committee (EC) to maintain its accreditation status, it is mandatory that the EC continues to comply with the requirements of Accreditation Standards for Ethics Committee (1st edition: March 2015), for which NABH conducts mid cycle surveillance. The purpose of on-site surveillance is to verify the continued compliance to the accreditation standards.

Due to pandemic COVID-19 crises and complete lock down announced by Government of India, the on-site assessments of NABH have also come to a halt.(this line can be tweaked as emergency situations or environmental conditions instead of COVID-19 as this protocol may be continued after COVID also) In view of the situation, NABH has decided to develop a methodology to verify the continued compliance of the accredited ECs to the applicable standards and the first step towards it is “Desktop Surveillance” wherein the ECs will be required to submit documents as required by NABH.

For the purpose of Desktop Surveillance, the EC shall provide the information as per this document and the same shall be considered for verifying the continued compliance. The information provided by the EC shall be evaluated at NABH secretariat and on the basis of this evaluation, decision regarding continuation of accreditation shall be taken.

The ECs are therefore advised to provide the essential information accurately as per the format. Incorrect information provided may lead to adverse decision by National Accreditation Board for Hospitals & Healthcare Providers (NABH).

Note: The format provided for Desktop surveillance is in accordance with 1st Edition of Ethics Committee Standard.

Instruction to fill the Format for Desktop surveillance

1. **General Information:**

   Provide relevant information only. **(Refer to Table no. A)**

2. **Status of Non-Conformities (NC's) of previous on-site assessment:**

   Mention non-conformities raised in previous on-site assessment along with relevant standard in column no. 2 & 3. In the column no. 4 the Ethics Committee may mention the proposed corrective action taken and in the last column Ethics Committee mention the evidence submitted for that non-conformance. For e.g. there are two documents submitted as evidence, name of the file shall be 2.1 a CAPA <brief about file> & 2.1 b CAPA <brief about file>. **(Refer to Table No. B)**

   Attach Annexures of CAPA till date to ensure continued compliance against the NCs raised previously. (Annexure 2.1 <Objective Element>)

3. **Ethics Committee Meeting Review:**

   Ethics Committee has to submit the signed minutes of the latest EC meeting. The Ethics Committee may submit the minutes as per their standard format. However, sample format of minutes of meeting has been attached in this document as (**Annexure 3).**

4. **Training Details:** Ethics Committee has to mention the training details as per the format Training record must include name of training imparted & feedback obtained. PDF scanned copies of Attendance Sheet with Post Test analysis can be submitted after highlighting the name of the trainer. **(Refer to Table-C)**

5. **Details of EC Composition:** Ethics Committee may provide the details in the Excel Sheet saved in pdf format only. The Format is enclosed as **(Annexure-4)**

6. **Details of Ongoing Trials:** Ethics Committee may provide the details in the Excel Sheet saved in pdf format only. The format is enclosed as **(Annexure-5)**

7. **Details of SAEs (Serious Adverse Events):** Ethics Committee may provide the details in the Excel Sheet saved in pdf format only. The format is enclosed as **(Annexure-6)**

8. **Updated Biography of all the EC Members:** Ethics Committee may provide a brief CVs of all the EC members with detailed experience in Pdf format. Kindly submit a separate updated of all the EC members as Annexures. (E.g. Annexure 7.1 -CV of Chairperson, Annexure 7.2 -CV of Member Secretary) **(Annexure 7)**

9. **Has there been a change in the following since last assessment? (Table No. D)**

9.a Ethics Committee SOP: Ethics Committee is required to mention the exact changes done in SOP with revision date, version number and name of the authority who has approved it.

9.b Change in the EC membership: Ethics Committee is required to mention the change of any members since the last assessment. Ethics Committee may submit the revised membership duly approved by the DCGI.

Ethics Commitee needs to provide the details for changes as annexures 8.1, 8.2, 8.3 (SOP heading) & annexures 9.1, 9.2, 9.3 (Name of the EC Members)

10. **Statutory Compliances:** Ethics Committee may provide the EC Registration Certificate approved by DCGI **(Table No. E)**

    Ethics Committee needs to attach the valid EC certificate with the name of the Ethics Committee **(Annexure-10)**

11. **Documents/Manuals**: Ethics Committee may provide the Ethics Committee SOP as per NABH Standard. If there is any amendment in the SOP since last assessment then Ethics Committee needs to mention those clearly giving reference to the old SOP.

12. **Photograph to show the compliance to NABH Standards for Ethics Committee**

    EC is required to attach the geotagged and time stamp photos as per the given table against each row. For example, If Photograph of EC registration certificate is required then then the name of the files uploaded shall be 1.1 registration of Ethics Committee. **(Table No. F)**

    - Photographs to be less than 3 MB in jpg format with good resolution
    - For Geotagged and timestamp
    - Open 'Camera' App-Head to the 'Settings' of the camera App-Look for the ‘time stamp on photos’/'Location tag'/ 'Save location' option and enable it depending on your OS version.
    - ‘GPS Map Ca’ App can be used for Geotagging (Can be downloaded and installed from android play store app)

13. **Declarations by Ethics Committee**

    All the three declarations i.e. self-declaration by the Ethics Committee, Declaration by the Ethics Committee for the Trial Sites and Declaration by the Ethics Committee for Investigator may be downloaded from the online application form. All these forms need to be filled up and signed by chairperson mentioning date & time. **(Annexure 11-for Ethics Committee; 12-for Trial site & 13-for Investigator)**

14. **Details of payment of 1st & 2nd Year Annual accreditation fee and Processing fee for Desktop surveillance assessment** are mandatory to be provided by EC without which the desktop surveillance documents will not be processed.

Information to be Furnished by HCO for Desktop Surveillance Assessment

1. General Information (Table A)

Information	Details
EC Reference Number	
EC name	
EC address	
No. of Ongoing Trials	
Accreditation Cycle – Accredited since (mention the year)	
Accreditation Validity Period:	
Previous assessment type: FA/ RA/ Verification/ Focus	
Date of Previous assessment	
Name of Owner/ CEO or equivalent	
Email of Owner/ CEO or equivalent	
Name of Accreditation Coordinator	
Email of Accreditation Coordinator	

2. Status of Non-Conformities (NCs) of previous on-site assessment:

Status of implementation and monitoring the effectiveness of corrective actions(s) taken on non-conformities raised during previous on-site assessment*: (please provide details in tabular format)*

(Table B)

Sl.	Non-conformities raised during previous on-site assessment	Ref to NABH EC Standards on Objective Element	Corrective actions taken/ Purposed by the Ethics Committee	Evidence of continued compliance of corrective actions to be attached (as on date)
1.				
2.				
3.				
4.				

3. Ethics Committee Meeting (Annexure-3)

Sl. No.	Name	Chairperson	Member Secretary	Clinician	Basic Medical Scientist	Legal expert	Lay person from community	Philosopher / ethicist / social scientist
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								

Members Absent:

1.
2.

Non-Voting Member:

Alternate Members if any:

Invitees/Subject Experts (Include Affiliation):

Total count:

Quorum:

Definition of Quorum: The quorum is defined as a majority of members, provided the members meet certain specific criteria (not less than 50% and the specific mandatory category) of the members of the total number.

Attendance Notes: movement register (EC members part of the quorum leaving the EC committee meeting in between).

Conflict of Interest:

Approval of Previous Minutes:

Previous Meeting:

Previous Minutes Comments:

Total votes for approval: (Total members voting)

Affirmative:

Negative:

Recusal:

Absent: non-voting:

Points of Discussion

1. **Discussion of Protocol, initial, amendments**
2. **Discussion on other trial related documents (Informed Consent, Contracts, Information Brochure (IB), recruitment strategies including selection of vulnerable subjects)**
3. **Discussion on Serious Adverse Events (SAEs), action taken**
4. **Discussion on Protocol Violation (PV) and Protocol Deviation (PD) and action taken**
5. **Discussion on Reporting of Adverse Drug Reactions (Format for reporting)**
6. **Training and other matters**
7. **Any other deemed appropriate**

4. Training Details: (Table C)

Sl.	Name of the Training	Date of the Training	Name & designation of the Trainer	Certificate Issued (Yes/No)	Validity of the Certificate
4.1	Good Clinical Practice (GCP)				
4.2.	NABH Ethics Committee Standards				
4.3.	New Drugs and Clinical Trial Rules (NDCT)				
4.4.	Bioethics				
4.5.	ICMR Guidelines				
4.6.	Any other				

5. Details of Ethics Committee Composition (Annexure-4)

Sr. No	Name with age & gender	Qualification	Designation in the Ethics Committee	Roles in IEC	Date of Joining	Past Affiliation with Institution	Present Affiliation with Institution

6. Details of Ongoing Trials (Annexure-5)

Sl No.	Name of the Trial	Objective of the Trial	Name of the PI and Co-I	Phase	Date of Start of Study	Date of DCGI approval	Date of EC approval	No. of patients recruited	Unicentric/Multi centric	Trial site Names	Proposed Sample Size	Proposed Study close out date	Site Sample Target	No. of SAEs/SAEs death

7. Details of SAEs (Annexure-6)

Sl No.	Protocol Name & No.	CTRI No.	SAE onset date (DD/MM/YYYY)	SAE Stop Date (DD/MM/YYYY)	SAE Term	Death if any	Details of the Cause	DCGI Decision	Compensation Paid (Y/N)	If Yes, provide the evidence	if No, then Steps taken by the Ethics Committee

8. Updated Biography of all the EC Members: Ethics Committee to submit CVs of all the EC members in pdf format (Annexure-7)

9. Has there been a change in the following aspects of the EC operations since last assessment? (Table D)

Sl.		Yes/No	(If yes, give details thereof)	Approved or not	Changes from the last Assessment (Y/N) -If yes please provide details
9.1.	Change in SOPs if any				
9.2.	Change in membership				

10. Statutory Compliances (Table E)

Sl.	Name of legal document	Certifying Authority	EC Certificate No	Valid from	Valid up to	Attach (Yes/ No/ Not applicable) pdf only	Remarks Lapsed / applied for
10.1	EC Registration						

11. EC is required to enclose geotagged photographs with timestamp of the following:

Sl.	Areas	Applicable (Y/N)	If applicable, please upload the photographs
1	Ethics Committee Secretariat at the Hospital		
2	Place where the consent is taken		
3	EC members present at the day of Audit		
4	Evidences of compensation/travel reimbursements or medical management provided to subjects in case of ADRs		

5	Minutes of the meeting and communication from Principal Investigators to DCGI and Ethics Committee in case of ADRs		
6	Archival area (inside & outside)		
7	Document storage area for ongoing studies		
8	Place where Ethics Committee meetings are Conducted		
9	Signed consent, source narratives, Subject Log, Patient charter (Only the first page or Cover Page of the documents)		

12. Checklist of Evidence based Implementation of Standard

Sl.	Standard wise requirement	Implementation (Y/N)	Remarks
1	The SOP for formation of Ethics committee, member selection and resource allocation has been reviewed periodically for making changes and others SOPs like Required amendments in SOP with updated version. The issue date, revision date & validity date of Ethics Committee.		
2	Terms of Reference (TOR) for the ethics committee. (Signed Copy)		
3	TOR for preparing, updating and amending the SOP (Any one Sample)		
4	Documented communication to invite Experts & Representatives to the meeting (Any one meeting record)		
5	Minutes of meeting: Should demonstrates the participation of all members (Latest Meeting Conducted)		
6	Training schedule/log, Records of training material, Tools used for evaluation of training (Latest Training)		
7	Signed Conflict of Interest (COI) disclosure form (Latest EC meeting)- 2 samples		
8	Source documents and files to verify Re-consent if any and new safety information being provided to the subjects.		

9	Translation & Back Translation Certificate of the Consent (Any one Consent)		
10	Causality Assessment report and evidence of payment of compensation to the trial subjects as per the informed consent, contract and applicable rules and regulations		
11	Process for grievance redressal with the CAPA taken – (one sample case)		
12	Advertisement materials to verify the source from where Investigator plans to recruit. (Any one Advertisement of recruitment)		
13	Institution policy for conduct of trials on vulnerable population. (Sample filled Checklist for undertaking trial on children & one sample Assent form)		
14	Minutes of meeting demonstrating deliberations and risk assessment of amendments. (Any MOM with changes done in SOP)-one sample		
15	DCGI Approval letter and EC Approval letter (for any one trial)		
16	EC decision regarding trial proposal is based on the benefit- risk assessment and comply to the ethical standards and norms (Sample MOM)		
17	Compensation has been calculated using Formula and communication record with DCGI for decision (Any one sample if applicable)		
18	Ongoing Monitoring of the Trials (Audit report done for any deviations, problems and non-compliance)		
19	Records of serious noncompliance in Sponsors monitoring (CAPA report with minutes of meeting)		
20	Records for evaluation for checking the self-assessment done by the EC and the number of periodic reviews done (Any checklist/Review Process/MOM)-one sample		
21	Policy for root cause analysis for a process or system failure (One sample with CAPA and timelines)		

13. Self-Declarations (to be submitted on the letter head of EC, duly signed by the EC Chairperson)

I. I hereby declare that the HCO (name) is in continued compliance of 1st Edition of NABH standards for Ethics Committee since last on-site assessment.

II. I also declare that each statement and/or contents and /or documents, certificates submitted as Desktop Surveillance documents are true, correct and authentic. I am aware that any wrong information / declaration given therein may lead to adverse actions by NABH.

14. Details of 2nd Year Annual Accreditation Fee payment by EC:

a. **Amount of Fee paid:**

b. **Date of payment;**

c. **Mode of payment along with complete details.**

15. List of Annexures

Sl. No.	Name of the Document	Annexure Number
1	Corrective Actions of the Previous Assessments	2
2	Minutes of Ethics Committee meeting	3
3	EC Membership List	4
4	List of Ongoing Trials	5
5	SAE Reporting	6
6	Biography of EC Members	7
7	Changes in SOPs	8
8	Changes in EC Composition	9
9	EC Registration Certificate	10

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