การตรวจเยี่ยมและประเมินคณะกรรมการจริยธรรมการวิจัยในมนุษย์
Survey and Audit of the REC

วันที่เริ่มใช้
แทนที่ฉบับที่ 2.1 ลงวันที่ 25 สิงหาคม 2563

ผู้จัดทำ คณะกรรมการจริยธรรมการวิจัยในมนุษย์ มหาวิทยาลัยนครพนม
วันที่ 29 มีนาคม 2565

ผู้อนุมัติ

(ดร.พรหมสวัสดิ์ ทิพย์คงคา)
รักษาราชการแทน
อธิการบดีมหาวิทยาลัยนครพนม
วันที่ 27 พฤษภาคม 2565

สารบัญ

1. วัตถุประสงค์

1.1 เพื่อเป็นแนวทางในการพัฒนาคุณภาพของคณะกรรมการจริยธรรมการวิจัยในมนุษย์

1.2 เพื่อเป็นแนวทางในการเตรียมรับการตรวจเยี่ยมเพื่อพัฒนาคุณภาพหรือรับรองมาตรฐานการทำงานของคณะกรรมการจริยธรรมการวิจัยในมนุษย์

2. ขอบเขต

วิธีดำเนินการมาตรฐานครอบคลุมการเตรียมตัวของคณะกรรมการฯ และเจ้าหน้าที่ฯ เพื่อรับการตรวจเยี่ยมเพื่อพัฒนาคุณภาพหรือรับรองมาตรฐานการดำเนินงานของคณะกรรมการฯ

3. ความรับผิดชอบ

ประธานคณะกรรมการฯ แจ้งเรื่องต่อที่ประชุมคณะกรรมการฯ ถึงการขอรับการตรวจเยี่ยมเพื่อพัฒนาคุณภาพหรือรับรองมาตรฐานจากวช.หรือผู้ทรงคุณวุฒิจากภายนอก/หน่วยงานหรือองค์กรที่ให้การรับรองคุณภาพการทำงานของคณะกรรมการจริยธรรมฯโดยที่คณะกรรมการจริยธรรม เจ้าหน้าที่ฯ และผู้เกี่ยวข้องทุกภาคส่วน ต้องปฏิบัติงานตามแนวทางที่ระบุในวิธีดำเนินการมาตรฐาน และเตรียมพร้อมในการขอรับการตรวจเยี่ยม

4. ขั้นตอนการปฏิบัติและผู้รับผิดชอบ

ขั้นตอน	การปฏิบัติ	ผู้รับผิดชอบ
1	ขอรับการตรวจเยี่ยม	ประธานคณะกรรมการฯ เลขานุการคณะกรรมการฯ และกรรมการฯ
2	รับแจ้งเรื่องการตรวจเยี่ยม	ประธานคณะกรรมการฯ
3	เตรียมรับการตรวจเยี่ยม	คณะกรรมการฯ และ เจ้าหน้าที่ฯ
4	รับการตรวจเยี่ยม	คณะกรรมการฯ และเจ้าหน้าที่ฯ
5	รับทราบรายงานผลการตรวจเยี่ยมและปรับปรุงแก้ไขข้อบกพร่อง	คณะกรรมการฯ และเจ้าหน้าที่ฯ
6	การเก็บรักษารายงานสรุปผลการตรวจเยี่ยม	เลขานุการคณะกรรมการฯหรือเจ้าหน้าที่ฯ

5. หลักการปฏิบัติ

การขอรับการตรวจเยี่ยมอาจเป็นความประสงค์ของคณะกรรมการฯ หรืออาจเป็นความ ต้องการของหน่วยงานผู้สนับสนุนการวิจัย

5.1 ขอรับการตรวจเยี่ยม

5.1.1 คณะกรรมการฯ อาจขอรับการตรวจเยี่ยมจาก วช. หรือผู้ทรงคุณวุฒิจากภายนอกเพื่อพัฒนาคุณภาพก่อนการรับรองมาตรฐาน

5.1.2 คณะกรรมการฯ ลงมติเห็นชอบขอรับการตรวจเยี่ยมเพื่อรับรองมาตรฐานจากองค์กรระดับชาติ (NECAST) หรือนานาชาติ (SIDCER-NECAST/SIDCER-FERCAP RECOGNITION PROGRAMME) และขออนุมัติหัวหน้าหน่วยงานเพื่อขอรับการตรวจเยี่ยม

5.1.3 คณะกรรมการฯ กำหนดช่วงเวลาที่จะขอรับการตรวจเยี่ยม และดำเนินการติดต่อสำนักงานคณะกรรมการวิจัยแห่งชาติ (วช.) หรือผู้ทรงคุณวุฒิจากภายนอก/องค์กรระดับชาติ (NECAST) หรือนานาชาติ (SIDCER- NECAST/ SIDCER- FERCAP RECOSNITION PROGRAMME) เพื่อขอรับการตรวจเยี่ยม/การตรวจเยี่ยมเพื่อรับรองมาตรฐาน

5.2 รับแจ้งเรื่องการตรวจเยี่ยม

ประธานคณะกรรมการฯ รับทราบกำหนดการตรวจเยี่ยมจากคณะกรรมการตรวจเยี่ยมและแจ้งให้คณะกรรมการฯ ทราบ

5.3 เตรียมรับการตรวจเยี่ยม

5.3.1 ศึกษาข้อกำหนดของการเยี่ยมสำรวจเพื่อรับรองมาตรฐานการดำเนินการของคณะกรรมการฯ

5.3.2 คณะกรรมการจริยธรรมฯ ประเมินตนเองด้วยแบบฟอร์ม AF 09-01 หรือ AF 09-02

5.3.3 ดำเนินการตามข้อกำหนดเพื่อเตรียมรับการตรวจเยี่ยม

5.3.4 ทบทวนวิธีดำเนินการมาตรฐาน

5.3.5 ตรวจสอบความครบถ้วนของแฟ้มเอกสารโครงการวิจัย และการจัดเก็บ

5.3.6 เตรียมเอกสาร ห้องประชุมและโสตทัศนูปกรณ์

5.3.7 เรียนเชิญผู้บริหารสถาบันฯ เข้าร่วมในพิธีเปิด พิธีปิด และรับฟังข้อสรุปจากการเยี่ยมสำรวจ

5.4 รับการตรวจเยี่ยม

5.4.1 ประธานคณะกรรมการฯ และเลขานุการคณะกรรมการฯ ต้อนรับและนำผู้บริหารสถาบันฯ และคณะกรรมการตรวจเยี่ยมมายังห้องประชุมที่เตรียมไว้

5.4.2 คณะกรรมการฯ และเจ้าหน้าที่ฯ เข้าร่วมในการประชุม

5.4.3 เริ่มการประชุม โดยคณะกรรมการตรวจเยี่ยมแจ้งวัตถุประสงค์ และระบุสิ่งที่ต้องการตรวจเยี่ยมและทบทวน

5.4.4 คณะกรรมการฯ และเจ้าหน้าที่ฯ ให้สัมภาษณ์คณะกรรมการตรวจเยี่ยม และตอบคำถามของคณะกรรมการตรวจเยี่ยม ด้วยความสุภาพ ชัดเจน และตรงตามที่ปฏิบัติจริง

5.4.5 ค้นหาและจัดเตรียมข้อมูลหรือเอกสารที่กรรมการตรวจเยี่ยมร้องขอ

5.4.6 เลขานุการคณะกรรมการฯ หรือเจ้าหน้าที่ฯ บันทึกคำวิจารณ์และข้อเสนอแนะของคณะกรรมการตรวจเยี่ยม

5.5 รับทราบรายงานผลการตรวจเยี่ยมและปรับปรุงแก้ไขข้อบกพร่อง

5.5.1 เลขานุการคณะกรรมการฯ นำเสนอรายงานสรุปผลการตรวจเยี่ยมในที่ประชุมคณะกรรมการฯ

5.5.2 คณะกรรมการฯ อภิปรายเพื่อหาแนวทางการปรับปรุงแก้ไขข้อบกพร่อง

5.5.3 เขียนแผน ดำเนินการปรับปรุงแก้ไขข้อบกพร่อง ภายในระยะเวลาที่เหมาะสม

5.5.4 ส่งแผนดำเนินการแก้ไขเพื่อให้คณะกรรมการฯ ตรวจเยี่ยมรับรอง

5.6 การเก็บรักษารายงานสรุปผลการตรวจเยี่ยม

เลขานุการคณะกรรมการฯ หรือเจ้าหน้าที่ฯเก็บรักษาเอกสารที่เกี่ยวข้องกับการตรวจเยี่ยมของคณะกรรมการตรวจสอบในแฟ้ม “การตรวจเยี่ยม”

7. นิยาม

การตรวจเยี่ยม (Audit)	การประเมินการทำงานของคณะกรรมการจริยธรรมการวิจัยอย่างเป็นระบบ เพื่อตรวจสอบว่าการพิจารณารับรองโครงร่างการวิจัยเป็นไปอย่างถูกต้องตรงตามวิธีดำเนินการมาตรฐานที่กำหนดและเป็นไปตามหลักจริยธรรม ได้แก่ การปฏิบัติการวิจัยทางคลินิกที่ดีของ International Conference on Harmonization (ICH) Good Clinical Practice หรือ ICH GCP
คณะกรรมการตรวจเยี่ยม	คณะกรรมการที่มีสิทธิและอำนาจหน้าที่ในการตรวจสอบการพิจารณาด้านจริยธรรมเกี่ยวกับโครงการวิจัย ได้แก่ คณะกรรมการผู้ให้ทุนวิจัย องค์กรที่รับทำวิจัยตามสัญญา (Contract Research Organization: CRO) หรือ องค์กรทั้งในประเทศและองค์กรนานาชาติที่มีหน้าที่กำกับดูแลการปฏิบัติหน้าที่ของคณะกรรมการจริยธรรมการวิจัย

7. ประวัติการแก้ไขเอกสาร

ผู้จัดทำ	**ฉบับที่**	**วันที่**	**แสดงการแก้ไขหลัก**
ดร.รุ้งลาวัลย์ เอี่ยมกุศลกิจ	01.0	5 กันยายน 2560	ฉบับแรก
ดร.รุ้งลาวัลย์ เอี่ยมกุศลกิจ	02.0	25 สิงหาคม 2563	ทบทวนประจำปี เพิ่มเติมเอกสารประกอบการขอรับการพิจารณาครั้งแรกสำหรับนักศึกษาเพิ่มเติมเอกสารคำชี้แจงสำหรับอาสาสมัครและใบยินยอมอาสาสมัคร
ผศ.ดร.สมสมร เรืองวรบูรณ์	03.0	มีนาคม 2565	ปรับปรุงแก้ไขครั้งใหญ่

8. เอกสารอ้างอิง

(1) ICH Good Clinical Practice Guideline 2016 และฉบับแปลภาษาไทยของ สำนักงานคณะกรรมการอาหารและยา กระทรวงสาธารณสุข พ.ศ. 2552

(2) แนวทางจริยธรรมการทำวิจัยในคนในประเทศไทย ชมรมจริยธรรมการวิจัยในคนในประเทศไทย พ.ศ. 2550

(3) http://www.fercap-sidcer.org/SIDCER_EC_SelfAssessmentTool_V3%5B2%5D.2.doc

9. ภาคผนวก

ภาคผนวก 1 AF/01-09/03.0 NECAST Self-Assessment Tool

ภาคผนวก 2 AF/02-09/03.0 SIDCER-NECAST Self-Assessment Tool

SELF-ASSESSMENT FORM

This tool is intended for use by Independent Ethics Committees or Institutional Review boards or Research Ethics Committee (IEC/IRB/REC) associated with a NECAST, NRCT. This is part of the process of NECAST Accreditation program, an IEC/IRB/REC will complete this form as an initial step of accreditation by NECAST.

The person completing this introduction form should have extensive knowledge of the IEC/IRB/REC being visited or assessed (usually the secretariat) and be able to answer questions or provide documentation regarding the following topics:

NAME OF THE IEC/IRB/REC:

ADDRESS OF IEC/IRB/REC:

MAIN CONTACT (NAME) FOR IEC/IRB/REC: :

BRIEF INTRODUCTION OF THE IEC/IRB/REC:

Year established: .....
Frequency of meetings: .....per month or per year

Type (e.g. Biomedical, product development etc.)

- ☐ **Clinical Research**
- ☐ **Biomedical Research**
- ☐ **Social and Behavioral Sciences Research**
- ☐ **Others,** please specify.....

Number of protocols reviewed/ 3years or per year: **.....**

Initial Review

Full board	..... /3 years or per year
Expedited	..... /3 years or per year

After Approval Review

Amendment	..... /3 years or per year
Continuing Report	..... /3 years or per year
Final Report	..... /3 years or per year
SAE Report	..... /3 years or per year
Violation/Deviation/Non-compliance	..... /3 years or per year

BRIEF INTRODUCTION OF IEC/IRB/REC STAFF AND MEMBERS

IEC/IRB/REC Composition							
No.	Name	Position	Profession/ Expertise	Gender		Affiliation(s)	
				M	F	Yes	No
1		Chair		☐	☐	☐	☐
2		Vice-chair		☐	☐	☐	☐
3		Member		☐	☐	☐	☐
4		Member		☐	☐	☐	☐
5		Member		☐	☐	☐	☐
6		Member		☐	☐	☐	☐
7		Member		☐	☐	☐	☐
8		Member		☐	☐	☐	☐
9		Member		☐	☐	☐	☐
10		Member		☐	☐	☐	☐
11		Member		☐	☐	☐	☐
12		Secretary Member		☐	☐	☐	☐
13		Assistant Secretary Member		☐	☐	☐	☐
14		Alternate member		☐	☐	☐	☐
15		Alternate member		☐	☐	☐	☐
16		Alternate member		☐	☐	☐	☐
17		Alternate member		☐	☐	☐	☐
18		Alternate member		☐	☐	☐	☐
19		Alternate member		☐	☐	☐	☐
20		Alternate member		☐	☐	☐	☐
21		Alternate member		☐	☐	☐	☐
22		Alternate member		☐	☐	☐	☐
23		Alternate member		☐	☐	☐	☐
24		Alternate member		☐	☐	☐	☐
25		Alternate member		☐	☐	☐	☐
....		Alternate member		☐	☐	☐	☐
....		Alternate member		☐	☐	☐	☐

SECTION	ITEM	A	B	C	D	COMMENTS
A	STRUCTURE AND COMPOSITION OF EC (structure, composition and skills of the EC and staff are appropriate to the amount and nature of research reviewed)					
A1	**MEMBERSHIP REQUIREMENTS** (at least 5 members, gender balance, experience, non scientific and affiliated members and terms and conditions of appointment)					
A 1.1	Does the EC have at least 5 members? *(ICH 3.2.1)*	☐	☐	☐	☐	
A1.2	Do the members contain a diversity of gender? *(WHO 4)*	☐	☐	☐	☐	
A1.3	Does EC have at least one non affiliated member? *(ICH 3.2.1, WHO 4)*	☐	☐	☐	☐	
A1.4	Does the EC membership contain non scientific member or lay person? *(ICH 3.2.1, WHO 4)*	☐	☐	☐	☐	
A1.5	Does EC membership consist of members with appropriate expertise for the research reviewed? *(ICH 3.2.1, WHO 4)*	☐	☐	☐	☐	
A1.6	Does the EC describe the party responsible for appointing members? *(WHO 4.1.1)*	☐	☐	☐	☐	
A1.7	Does the EC members posses the required experience, knowledge, skill and relevant abilities to perform their duties? *(WHO 4)*	☐	☐	☐	☐	
A1.8	Does the EC policy and procedures describe the selection process of its members? *(WHO 4.1.2, ICH 3.3.1)*	☐	☐	☐	☐	
A1.9	Do the EC terms describe the duration of appointment for its members? *(WHO 4.2.1)*	☐	☐	☐	☐	
A1.10	Do the EC terms describe the policy for the renewal of appointment for its members? *(WHO 4.2.2)*	☐	☐	☐	☐	

A1.11	Do the EC terms describe the disqualification procedure of its members? *(WHO 4.2.3)*	☐	☐	☐	☐	
A1.12	Do the EC terms describe the resignation procedure for its members? *(WHO 4.2.4)*	☐	☐	☐	☐	
A1.13	Do the EC terms describe the replacement procedures for its members? *(WHO 4.2.5)*	☐	☐	☐	☐	
A1.14	Does the EC maintain a list of all its members with their current CV.? *(ICH 3.2.1)*	☐	☐	☐	☐	
A1.15	Does EC member sign a confidentiality agreement? *(WHO 4.3.3)*	☐	☐	☐	☐	
A1.16	Are EC members willing to publicize full name, profession and affiliation? *(ICH 3.4. WHO 4.3.1)*	☐	☐	☐	☐	
A2	**ADMINISTRATIVE REQUIREMENTS.** (Adequate number of administrators to oversee the EC activities, have documentation of the functions and activities of staff and their terms and conditions of appointment)					
A2.1	Does the EC have sufficient staff (full-time or part-time) to meet its functions and responsibilities? *(WHO 4.4)*	☐	☐	☐	☐	
A2.2	Does the EC have a description of requirements for holding offices? *(WHO 4.4)*	☐	☐	☐	☐	
A2.3	Does the EC policy describe duration, disqualification, resignation and replacement procedures for its offices? *(WHO 4.4)*	☐	☐	☐	☐	
A2.4	Does the EC have documentation explaining the duties, obligations and responsibilities of its offices? *(WHO 4.4)*	☐	☐	☐	☐	
A2.5	Does the EC have an office space? *(WHO 4.4)*	☐	☐	☐	☐	

A2.6	Does the EC have the necessary equipments to run the office? *(WHO 4.4)*	☐	☐	☐	☐	
A2.7	Does the EC have available budget to meet its functions and responsibilities?	☐	☐	☐	☐	
A2.8	Does EC document reimbursement for work and expenses and is this made available to the public upon request? *(WHO 4.3.2)*	☐	☐	☐	☐	
A3	**TRAINING OF EC MEMBERS** (EC needs to state and observe the provisions available for its members to receive introductory and continuous education)					
A3.1	Does the members' condition of appointment state the provisions for them to receive introductory and ongoing training? *(WHO 4.7)*	☐	☐	☐	☐	
A3.2	Did members of the EC receive an introductory training? *(WHO 4.7)*	☐	☐	☐	☐	
A3.3	Are EC members continually being trained to enhance their capacity for ethical review? *(WHO 4.7)*	☐	☐	☐	☐	
A3.4	Does the EC review and document trainings obtained by its members and staff? *(WHO 4.7)*	☐	☐	☐	☐	
A4	**MANAGEMENT OF CONFLICTS** (EC should have a policy to address conflicts of interests)					
A4.1	Does the EC have a process of managing, minimizing or eliminating conflicts of interest? *(WHO 4.1.3)*	☐	☐	☐	☐	

B	ADHERENCE TO SPECIFIC POLICIES (EC to have appropriate management and operational procedures for optimal and systematic conduct of ethical review)					
B1	**EC MANAGEMENT** (EC to have terms of reference)					
B1.1	Does the EC have terms of reference which includes its scope, objectives, activities, organization and management? *(WHO 4)*	☐	☐	☐	☐	
B2	**AVAILABILITY OF SOP** (EC should have an SOP that covers its function and activities which they comply with)					
B2.1	Does the EC have written SOP? *(ICH 3.2.2. WHO 4)*	☐	☐	☐	☐	
B2.2	Does the SOP cover all functions and reviews undertaken by the EC? *(ICH 3.2.2. WHO 4)*	☐	☐	☐	☐	
B2.3	Does the EC comply with the written SOP? *(ICH 3.2.2. WHO 4)*	☐	☐	☐	☐	
B2.4	Is the SOP reviewed and revised as necessary?	☐	☐	☐	☐	
B2.5	Does EC make their SOP publicly available? *(ICH 3.2.2.)*	☐	☐	☐	☐	
B3	**SUBMISSION GUIDELINES AND PROCESS** (EC should have a submission guideline including its requirements and forms)					
B3.1	Does the EC have any guidance on how to submit protocols? *(WHO 5.1)*	☐	☐	☐	☐	
B3.2	Does the EC have an application form? *(WHO 5.2.2)*	☐	☐	☐	☐	
B3.3	Does the EC indicate the format for submission? *(WHO 5.2.3)*	☐	☐	☐	☐	
B3.4	Does the EC indicate the number of copies of application to be submitted? *(WHO 5.2.6)*	☐	☐	☐	☐	

B3.5	Does the EC indicate the application procedures for protocol amendments and continuing review? *(WHO 5.2.2)*	☐	☐	☐	☐	
B3.6	Does the EC have an informed consent guidance/template which it made available to investigators to help with the preparation of the document?	☐	☐	☐	☐	
B3.7	Does the EC have a registration procedure (tracking system) for the applications made for review?	☐	☐	☐	☐	
B3.8	Does the EC specify the name and address of the EC secretariat to whom the application should be submitted? *(WHO 5.2.1)*	☐	☐	☐	☐	
B3.9	Does the EC have means of acknowledging applications made to them? *(WHO 5.2.8)*	☐	☐	☐	☐	
B3.10	Does the EC communicate the incompleteness of an application?	☐	☐	☐	☐	
B3.11	Does the EC indicate fee structure, if any, for reviewing an application? *(WHO 5.2.11)*	☐	☐	☐	☐	
B3.12	Does the EC indicate that application forms should be signed and dated? *(WHO 5.3.1)*	☐	☐	☐	☐	
B3.13	Does the EC request that protocol be submitted together with supporting documents and annexes? *(ICH 3.1.2, WHO 5.3.2)*	☐	☐	☐	☐	
B3.14	Does EC request submission of the project summary and diagrammatic representative (flow chart) of the protocol? *(WHO 5.3.3)*	☐	☐	☐	☐	
B3.15	Does EC request submission of a description of the ethical considerations involved in the research? *(WHO 5.3.4)*	☐	☐	☐	☐	

B3.16	Does EC request submission of case report forms, diary cards and other questionnaires intended for research participants? *(WHO 5.3.5)*	☐	☐	☐	☐	
B3.17	When a research involves a study product does the EC request submission an adequate summary of the study product? *(ICH 3.1.2 WHO 5.36)*	☐	☐	☐	☐	
B3.18	Does EC request submission of the investigators CV? *(ICH 3.1.2 WHO 5.3.7)*	☐	☐	☐	☐	
B3.19	Does EC request submission of the materials to be used for the recruitment of potential research participants? *(ICH 3.1.2 WHO 5.3.8)*	☐	☐	☐	☐	
B3.20	Does EC request submission of the informed consent form? *(ICH 3.1.2 WHO 5.3.10)*	☐	☐	☐	☐	
B3.21	Does EC request submission of a statement describing any compensation for study participants? *(ICH 3.1.2 WHO 5.3.12)*	☐	☐	☐	☐	
B3.22	Does EC request submission of a description of the arrangements for indemnity if applicable? *(WHO 5.3.13)*	☐	☐	☐	☐	
B3.23	Does EC request submission of a description of the arrangements for insurance coverage if applicable? *(WHO 5.3.14)*	☐	☐	☐	☐	
B3.24	Does EC request submission of a statement of agreement to comply with ethical principles set out in relevant guidelines? *(WHO 5.3.15)*	☐	☐	☐	☐	

B3.25	Does EC request submission of all significant previous decisions by the EC or regulatory authorities for the proposed study? *(WHO 5.3.16)*	☐	☐	☐	☐	
B4	**MEETING REQUIREMENTS** (EC should have documented meeting requirements which they comply with, quorum and professional requirements)					
B4.1	Does the EC meet regularly on scheduled date announced in advance? *(ICH 3.2.2 WHO 6.1.1)*	☐	☐	☐	☐	
B4.2	Does the EC form a quorum before holding its meeting? *(WHO 4.5)*	☐	☐	☐	☐	
B4.3	Does the EC require that at least one non affiliated member and a non scientist be part of a quorum for each of its meeting? *(WHO 4.5.2)*	☐	☐	☐	☐	
B4.4	Does the EC require that meetings should be minuted and there should be an approval procedure for the minutes? *(WHO 4.5.2)*	☐	☐	☐	☐	

C	COMPLETENESS OF ITS REVIEW PROCESS (EC review protocols and its supporting documents in a timely fashion according to an established procedure to protect the interest of research participants)					
C1	**REVIEW PROCESS** (enough time for protocol review, EC to have documented and detailed review process which is complied with)					
C1.1	Does the EC follow the operating procedure for review? *(ICH 3.3, WHO 6)*	☐	☐	☐	☐	
C1.2	Does the EC review protocols and all relevant documents within a reasonable time frame? *(ICH 3.1.2, WHO 6.1.2)*	☐	☐	☐	☐	
C1.3	Does the EC have an established procedure for expedited review? *(ICH 3.3.5, WHO 6)*	☐	☐	☐	☐	
C1.4	Does the EC indicate the nature of the application, amendments, continuing review and other considerations that will be eligible for expedited review? *(ICH 3.3.5, WHO 6.3.1)*	☐	☐	☐	☐	
C1.5	Does the EC have policies and procedures that describe the process used to evaluate whether research reviewed by the expedited procedures meets the criteria for review? *(ICH 3.3.5, WHO 6.3.3)*	☐	☐	☐	☐	
C1.6	Does the EC have an established procedure for full board review? *(WHO 6.2)*	☐	☐	☐	☐	
C1.7	Does the EC have an established process for obtaining additional expertise when reviewing specific protocols? *(ICH 3.3.6, WHO 4.6)*	☐	☐	☐	☐	
C1.8	Does the EC have terms of reference for independent consultants? *(WHO 4.6)*	☐	☐	☐	☐	

C1.9	Does the EC have an established process for inviting applicants/investigators to elaborate on specific issues when applicable? *(ICH 3.2.5)*	☐	☐	☐	☐	
C2	**ELEMENTS OF REVIEW** (EC to have a policy and procedure for review, elements reviewed should include the scientific design and conduct and ethics)					
C2.1	Does the EC have a policy and procedure for reviewing protocols? *(WHO 6.2)*	☐	☐	☐	☐	
C2.2	Does the EC review the scientific design and conduct of the study? *(WHO 6.2.1)*	☐	☐	☐	☐	
C2.3	Does the EC review the justification for the use of control arms? *(WHO 6.2.1.3)*	☐	☐	☐	☐	
C2.4	Does the EC review the criteria for prematurely withdrawing research participants? *(WHO 6.2.1.4)*	☐	☐	☐	☐	
C2.5	Does the EC review the criteria for suspending or terminating the research? *(WHO 6.2.1.5)*	☐	☐	☐	☐	
C2.6	Does the EC have justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and concerned communities? *(WHO 6.2.1.2)*	☐	☐	☐	☐	
C2.7	Does the EC review the adequacy of provisions made for monitoring and auditing the conduct of the research, including the constitution of a data safety and monitoring board (DSMB)? *(WHO 6.2.1.6)*	☐	☐	☐	☐	

C2.8	Does the EC review the manner in which the results of the research will be reported and published? *(WHO 6.2.1.8)*	☐	☐	☐	☐	
C2.9	Does the EC review whether the risk posed to research subjects is reasonable in relation to its anticipated benefits? *(WHO 6.2.1.2)*	☐	☐	☐	☐	
C2.10	Does the EC follow the established procedure for determining if potential risks posed to the vulnerable population are acceptable? *(ICH 3.1.6)*	☐	☐	☐	☐	
C2.11	Does the EC review the description of the informed consent process and the identification of those responsible for obtaining it? *(WHO 6.2.5.1)*	☐	☐	☐	☐	
C2.12	Does the EC review the informed consent focusing on measures to improve participant understanding and voluntary decision making? *(WHO 6.2.5.2)*	☐	☐	☐	☐	
C2.13	Does the EC review justification to include research individual that cannot consent and account of the arrangements for obtaining consent? *(ICH 3.1.6, WHO 6.2.5.3)*	☐	☐	☐	☐	
C2.14	Does the EC have and follow the established procedure to determine if the vulnerable subjects are protected in the consent process? *(ICH 3.1.5)*	☐	☐	☐	☐	
C2.15	Does the EC have and follow the established procedure in reviewing the consent process in emergency situation in research protocol? *(ICH 3.1.2)*	☐	☐	☐	☐	

C2.16	Does the EC review the information assuring research participants that they will receive available information during the course of the research relevant to their participation? *(WHO 6.2.5.4)*	☐	☐	☐	☐	
C2.17	Does the EC review the provisions made by researchers for receiving and responding to queries and complaints from participants or representatives during the course of the research? *(WHO 6.2.5.5)*	☐	☐	☐	☐	
C2.18	Does the EC review the suitability of the investigators qualifications and experience for the proposed study? *(ICH 3.1.3, WHO 6.2.3.1)*	☐	☐	☐	☐	
C2.19	Does the EC review any plans to withdraw or withhold standard therapies for the purpose of the research and the justification for such action? *(WHO 6.2.3.2)*	☐	☐	☐	☐	
C2.20	Does the EC review the steps to be taken if research participants voluntarily withdraw during the course of the research? *(WHO 6.2.3.5)*	☐	☐	☐	☐	
C2.21	Does EC have and follow an established procedure in evaluating the protection of privacy and confidentiality of the research participants during and after the completion of the research? *(WHO 6.4)*	☐	☐	☐	☐	
C2.22	Does the EC have and follow established procedure to determine if the vulnerable subjects are properly protected? *(ICH 3.1.6)*	☐	☐	☐	☐	

C2.23	Does EC have and follow procedures of determining whether the method used to recruit the research subjects is acceptable or not? *(WHO 6.2.2)*	☐	☐	☐	☐	
C2.24	Does the EC review the description of the plan to make the study product available to research participants following the research if applicable? *(WHO 6.2.3.8)*	☐	☐	☐	☐	
C2.25	Does the EC have and follow established procedure for evaluating the inclusion and exclusion criteria? *(WHO 6.2.2.4, 6.2.2.5)*	☐	☐	☐	☐	
C2.26	Does the EC have and follow established procedure for evaluating the characteristics of the population from which participants are drawn? *(WHO 6.2.2.1)*	☐	☐	☐	☐	
C2.27	Does EC have methods of ensuring that additional safe guards are included to protect the rights and welfare in research involving vulnerable populations? *(ICH 3.1.6, 3.1.7)*	☐	☐	☐	☐	
C2.28	Does the EC review payment for research participants to determine if it will unduly influence them to participate in research? *(ICH 3.1.8, WHO 6.3.2.10)*	☐	☐	☐	☐	
C2.29	Does the EC review compensation for research participants to determine if it they adequately compensated for injury? *(ICH 3.1.9, WHO 6.3.2.11)*	☐	☐	☐	☐	
C2.30	Does EC review the standard of care and other post trial benefits offered to participants? *(WHO 6.3.2.3)*	☐	☐	☐	☐	

C2.31	Does the EC review the impact and relevance of research on the local community from which the research participants are drawn? *(WHO 6.3.6.1)*	☐	☐	☐	☐	
C2.32	Does the EC review the steps taken to consult with the concerned communities during the course of the designing of the research? *(WHO 6.3.6.2)*	☐	☐	☐	☐	
C2.33	Does the EC review the influence of the community on the consent of individuals? *(WHO 6.3.6.3)*	☐	☐	☐	☐	
C2.34	Does the EC review proposed community consultation during the course of the research? *(WHO 6.3.6.4)*	☐	☐	☐	☐	
C2.35	Does the EC review the extent to which research contributes to capacity building within the community? *(WHO 6.3.6.5)*	☐	☐	☐	☐	
C2.36	Does the EC review a description of the availability and affordability of any successful study product to the concerned communities following the research? *(WHO 6.3.6.6)*	☐	☐	☐	☐	
C2.37	Does the EC review the rights to give subjects additional information when the additional information would add meaningfully to the protection of the rights, safety and/or well-being of the subjects? *(WHO 6.2.5.4)*	☐	☐	☐	☐	

C3	**AFTER PROTOCOL APPROVAL** (EC to document and follow procedures of reviews of amendments, continuing, SAE reports)					
C3.1	Does the EC have continuing review? *(ICH 3.1.4, 3.3.3, WHO 9)*	☐	☐	☐	☐	
C3.2	Does the EC have and follow an established procedure for determining the frequency of continuing review? *(ICH 3.1.4, WHO 9.2)*	☐	☐	☐	☐	
C3.3	Does the EC have and follow an established procedure for handling modification (amendments) of research protocol? *(ICH 3.2.7, WHO 9.3)*	☐	☐	☐	☐	
C3.4	Does the EC have documents required for continuous review and is this list made available to investigators?	☐	☐	☐	☐	
C3.5	Does the EC consider the submitted relevant information and documents in its continuing review? *(WHO 9.3)*	☐	☐	☐	☐	
C3.6	Does the EC have and follow an established procedure to notify investigators when it will conduct a continuing review? *(ICH 3.1.4, WHO 9.4)*	☐	☐	☐	☐	
C3.7	Does ERC have and follows policies and procedures for suspending or terminating previously approved research if need be based on findings in monitoring or continuing review? *(WHO 9.4)*	☐	☐	☐	☐	

C3.8	Does the EC require the investigator to notify the EC in writing of the reasons and a summary of the research results when applicant prematurely suspend or terminate the study? *(WHO 9.5)*	☐	☐	☐	☐	
C3.9	Does EC do a follow up review when serious and unexpected adverse events occur as a result of the conduct of the study or study (test) product and necessary steps need to be instituted to protect participants? *(WHO 9.3b)*	☐	☐	☐	☐	
C3.10	Does the EC specify that no deviations from, or changes of, the protocol should be initiated without prior written IRB/IEC approval/favorable opinion of an appropriate amendment? *(ICH 3.3.7)*	☐	☐	☐	☐	
C3.11	Does the EC specify that the investigator should promptly report to the IRB/IEC any deviations from, or changes of, the protocol to eliminate immediate hazards to the trial subjects? *(ICH 3.3.8, WHO 9.3c)*	☐	☐	☐	☐	
C3.12	Does the EC specify that the investigator should promptly report to the IRB/IEC changes increasing the risk to subjects and/or affecting significantly the conduct of the trial? *(ICH 3.3.8, WHO 9.3c)*	☐	☐	☐	☐	
C3.13	Does the EC specify that the investigator should promptly report to the IRB/IEC all adverse drug reactions (ADRs) that are both serious and unexpected? *(ICH 3.3.8)*	☐	☐	☐	☐	

C3.14	Does the EC specify that the investigator should promptly report to the IRB/IEC any new information that may affect adversely the safety of the subjects or the conduct of the trial? *(ICH 3.3.8)*	☐	☐	☐	☐	
C3.15	Does the EC require the applicant to notify the EC the time of completion of a study? *(WHO 9.6)*	☐	☐	☐	☐	
C3.16	Does the EC require the applicant to submit in writing at the completion of the study a final report describing how the study was conducted and a summary of the study results? *(WHO 9.7)*	☐	☐	☐	☐	
C4	**COMPLETENESS OF IEC/IRB MEETING MINUTES** (minutes should be a complete record and reflect actions taken during the meeting)					
C4.1	Does the EC record and keep minutes of its meeting? *(ICH 3.2.2, WHO 6.1.3)*	☐	☐	☐	☐	
C4.2	Does the EC record in its minute members present for each meeting, members voted and all the actions that took place during the meeting? *(ICH 3.1.2)*	☐	☐	☐	☐	
C4.3	Does the minutes record protocols and documents reviewed, the dates of approval, modifications required prior to its approval or disapproval and termination/suspension of any prior approval? *(ICH 3.1.2)*	☐	☐	☐	☐	
C4.4	Does the EC have an approval procedure for its minutes? *(WHO 6.1.3)*	☐	☐	☐	☐	

C5	**DECISION MAKING PROCESS** (EC should have a procedure for decision making and members should participate in the process)					
C5.1	Are decisions only made in meetings where a quorum is present? *(ICH 3.2.3, WHO 7.3)*	☐	☐	☐	☐	
C5.2	Does EC ensure that only members who participate in the review should participate in the decision? *(ICH 3.2.4, WHO 7.5)*	☐	☐	☐	☐	
C5.3	Are all relevant documents required for full review available and considered before a decision is made? *(WHO 7.4)*	☐	☐	☐	☐	
C5.4	Does the EC have a predefined method of arriving at a decision e.g. by consensus or vote? *(WHO 7.6)*	☐	☐	☐	☐	
C5.5	Does the EC ensure that members with conflicts of interest are not part of the decision? (WHO 7.1)	☐	☐	☐	☐	
C5.6	Do the EC members have sufficient time to review and discuss before a decision is made? *(WHO 7.2)*	☐	☐	☐	☐	
C5.7	When a decision is made to re-review a protocol, does the EC clearly document the areas needed to be revised? *(WHO 7.8)*	☐	☐	☐	☐	
C5.8	Are negative decisions supported with clearly stated reasons? *(WHO 7.9)*	☐	☐	☐	☐	

D	AFTER REVIEW PROCESS (EC should adequately and effectively communicates its decision to investigators)					
D1	**COMMUNICATING A DECISION** (EC have an effective and timely way of communicating a decision with clearly stated reasons)					
D1.1	Are the conclusions of a decision communicated in writing to the applicant within 14 days? *(WHO 8)*	☐	☐	☐	☐	
D1.2	Does the EC clearly specify areas that need to be revised when communicating a provisional approval decision to investigators? *(ICH 3.3.9, WHO 7.4)*	☐	☐	☐	☐	
D1.3	Does the decision letter include the exact title of the protocol reviewed? *(WHO 8.1)*	☐	☐	☐	☐	
D1.4	Does the decision letter include the specific identification number of the documents reviewed including the informed consent form? *(WHO 8.2)*	☐	☐	☐	☐	
D1.5	Does the decision letter include the name and title of the applicant(s)? *(WHO 8.4)*	☐	☐	☐	☐	
D1.6	Does the decision letter include the date and place of the decision? *(WHO 8.6)*	☐	☐	☐	☐	
D1.7	Does the decision letter include the name of the EC taking the decision? *(WHO 8.7)*	☐	☐	☐	☐	
D1.8	Does the decision letter include a statement of the responsibilities of the applicant? *(ICH 3.3.6, 3.3.7, WHO 8.11)*	☐	☐	☐	☐	

D1.9	Does the decision letter include the signature of the chairperson (or other authorized person) and date? *(WHO 8.14)*	☐	☐	☐	☐	
D1.10	Does the EC inform investigators of its re-review procedure, schedule/plan of ongoing review? *(WHO 8.12)*	☐	☐	☐	☐	
D1.11	Does the EC issue suspension or termination letters with reasons for suspension or termination (or the conditions of lifting suspension or termination) clearly stated? *(ICH 3.3.9, WHO 9.5)*	☐	☐	☐	☐	
D1.12	Does the decision documentation clearly explain how the applicant can communicate with the EC? *(WHO 8.11)*	☐	☐	☐	☐	
E	DOCUMENTATION AND ARCHIVING (EC systematically document and archive its activities for a good time period)					
E1.1	Does the EC have and follow operating procedures for record keeping and archiving of all records and communication documents? *(ICH 3.4, WHO 10)*	☐	☐	☐	☐	
E1.2	Does EC have and follow operation procedure for the access or retrieve of various documents, files or archives? *(ICH 3.4, WHO 10)*	☐	☐	☐	☐	
E1.3	Does the filing, archiving, accessing and retrieving of the documents meet the established procedures? *(ICH 3.4, WHO 10)*	☐	☐	☐	☐	
E1.4	Does the EC maintain a complete file or database of all the relevant materials in each research protocol? *(WHO 10.7)*	☐	☐	☐	☐	

E1.5	Does the EC follow the requirement to retain all the records for at least 3 years after the completion of investigation? *(ICH 3.4, WHO 10)*	☐	☐	☐	☐	
E1.6	Could all the relevant records be inspected by the appropriate authority? *(ICH 3.4, WHO 10)*	☐	☐	☐	☐	
E1.7	Does the EC document its SOPs and terms of reference? *(WHO 10.1)*	☐	☐	☐	☐	
E1.8	Does the EC document the CV of all its members? *(WHO 10.2)*	☐	☐	☐	☐	
E1.9	Does the EC document its published guideline for submission of protocols? *(WHO 10.4)*	☐	☐	☐	☐	
E1.10	Does the EC document the agenda and minutes of its meetings? *(WHO 10.5, 10.6)*	☐	☐	☐	☐	
E1.11	Does the EC document copies of its decision and any advice or requirements sent to the applicants? *(WHO 10.9)*	☐	☐	☐	☐	
E1.12	Does the EC document all the written documentations received during the follow-up? *(WHO 10.10)*	☐	☐	☐	☐	
E1.13	Does the EC document the notification of completion, premature suspension or termination of study? *(WHO 10.11)*	☐	☐	☐	☐	
E1.14	Does the EC document the final report of the study? *(WHO 10.12)*	☐	☐	☐	☐	

SELF-ASSESSMENT FORM

This tool is intended for use by research ethics committees or Institutional Review boards (IEC/IRB) associated with a SIDCER member Regional Forum. This is part of the process of SIDCER-NECAST recognition programme, an IEC/IRB will complete this form as an initial step of surveying and evaluation to be recognized by SIDCER-NECAST

The person completing the assessment should have extensive knowledge of the IEC/IRB being assessed (usually the secretariat) and be able to answer questions or provide documentation regarding the following topics:

NAME OF THE EC:

ADDRESS OF EC:

MAIN CONTACT (NAME) FOR EC:

BRIEF INTRODUCTION OF THE EC:

Year established:

Frequency of meetings:

Type (e.g. Biomedical, product development etc.) and number of protocols reviewed/year:

BRIEF INTRODUCTION OF IEC/IRB STAFF AND MEMBERS

IEC/IRB Composition					
Name	Profession & Credentials	Gender		Affiliation(s)	
		M	F	Yes	No
		☐		☐	
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SECTION	ITEM	A	B	C	D	COMMENTS
A	STRUCTURE AND COMPOSITION OF EC (structure, composition and skills of the EC and staff are appropriate to the amount and nature of research reviewed)					
A1	**MEMBERSHIP REQUIREMENTS** (at least 5 members, gender balance, experience, non scientific and affiliated members and terms and conditions of appointment)					
A 1.1	Does the EC have at least 5 members? (ICH 3.2.1)	☐	☐	☐	☐	
A1.2	Do the members contain a diversity of gender? *(WHO 4)*	☐	☐	☐	☐	
A1.3	Does EC have at least one non affiliated member? *(ICH 3.2.1, WHO 4)*	☐	☐	☐	☐	
A1.4	Does the EC membership contain non scientific member or lay person? *(ICH 3.2.1, WHO 4)*	☐	☐	☐	☐	
A1.5	Does EC membership consist of members with appropriate expertise for the research reviewed? *(ICH 3.2.1, WHO 4)*	☐	☐	☐	☐	
A1.6	Does the EC describe the party responsible for appointing members? *(WHO 4.1.1)*	☐	☐	☐	☐	
A1.7	Does the EC members posses the required experience, knowledge, skill and relevant abilities to perform their duties? *(WHO 4)*	☐	☐	☐	☐	
A1.8	Does the EC policy and procedures describe the selection process of its members? *(WHO 4.1.2, ICH 3.3.1)*	☐	☐	☐	☐	
A1.9	Do the EC terms describe the duration of appointment for its members? *(WHO 4.2.1)*	☐	☐	☐	☐	
A1.10	Do the EC terms describe the policy for the renewal of appointment for its members? *(WHO 4.2.2)*	☐	☐	☐	☐	

A1.11	Do the EC terms describe the disqualification procedure of its members? *(WHO 4.2.3)*	☐	☐	☐	☐	
A1.12	Do the EC terms describe the resignation procedure for its members? *(WHO 4.2.4)*	☐	☐	☐	☐	
A1.13	Do the EC terms describe the replacement procedures for its members? *(WHO 4.2.5)*	☐	☐	☐	☐	
A1.14	Does the EC maintain a list of all its members with their current CV.? *(ICH 3.2.1)*	☐	☐	☐	☐	
A1.15	Does EC member sign a confidentiality agreement? *(WHO 4.3.3)*	☐	☐	☐	☐	
A1.16	Are EC members willing to publicize full name, profession and affiliation? *(ICH 3.4. WHO 4.3.1)*	☐	☐	☐	☐	
A2	**ADMINISTRATIVE REQUIREMENTS.** (Adequate number of administrators to oversee the EC activities, have documentation of the functions and activities of staff and their terms and conditions of appointment)					
A2.1	Does the EC have sufficient staff (full-time or part-time) to meet its functions and responsibilities? *(WHO 4.4)*	☐	☐	☐	☐	
A2.2	Does the EC have a description of requirements for holding office *(WHO 4.4)*	☐	☐	☐	☐	
A2.3	Does the EC policy describe duration, disqualification, resignation and replacement procedures for its offices? *(WHO 4.4)*	☐	☐	☐	☐	
A2.4	Does the EC have documentation explaining the duties, obligations and responsibilities of its offices? *(WHO 4.4)*	☐	☐	☐	☐	
A2.5	Does the EC have an office space? *(WHO 4.4)*	☐	☐	☐	☐	
A2.6	Does the EC have the necessary equipments to run the office? *(WHO 4.4)*	☐	☐	☐	☐	

A2.7	Does the EC have available budget to meet its functions and responsibilities?	☐	☐	☐	☐	
A2.8	Does EC document reimbursement for work and expenses and is this made available to the public upon request? *(WHO 4.3.2)*	☐	☐	☐	☐	
A3	**TRAINING OF EC MEMBERS** (EC needs to state and observe the provisions available for its members to receive introductory and continuous education)					
A3.1	Does the members' condition of appointment state the provisions for them to receive introductory and ongoing training? *(WHO 4.7)*	☐	☐	☐	☐	
A3.2	Did members of the EC receive an introductory training? *(WHO 4.7)*	☐	☐	☐	☐	
A3.3	Are EC members continually being trained to enhance their capacity for ethical review? *(WHO 4.7)*	☐	☐	☐	☐	
A3.4	Does the EC review and document trainings obtained by its members and staff? *(WHO 4.7)*	☐	☐	☐	☐	
A4	**MANAGEMENT OF CONFLICTS** (EC should have a policy to address conflicts of interests)					
A4.1	Does the EC have a process of managing, minimizing or eliminating conflicts of interest? *(WHO 4.1.3)*	☐	☐	☐	☐	

B	**ADHERENCE TO SPECIFIC POLICIES** (EC to have appropriate management and operational procedures for optimal and systematic conduct of ethical review)					
B1	**EC MANAGEMENT** (EC to have terms of reference)					
B1.1	Does the EC have terms of reference which includes its scope, objectives, activities, organization and management? *(WHO 4)*	☐	☐	☐	☐	
B2	**AVAILABILITY OF SOP** (EC should have an SOP that covers its function and activities which they comply with)					
B2.1	Does the EC have written SOP? *(ICH 3.2.2. WHO 4)*	☐	☐	☐	☐	
B2.2	Does the SOP cover all functions and reviews undertaken by the EC? *(ICH 3.2.2. WHO 4)*	☐	☐	☐	☐	
B2.3	Does the EC comply with the written SOP? *(ICH 3.2.2. WHO 4)*	☐	☐	☐	☐	
B2.4	Is the SOP reviewed and revised as necessary?	☐	☐	☐	☐	
B2.5	Does EC make their SOP publicly available? *(ICH 3.2.2.)*	☐	☐	☐	☐	
B3	**SUBMISSION GUIDELINES AND PROCESS** (EC should have a submission guideline including its requirements and forms)					
B3.1	Does the EC have any guidance on how to submit protocols? *(WHO 5.1)*	☐	☐	☐	☐	
B3.2	Does the EC have an application form? *(WHO 5.2.2)*	☐	☐	☐	☐	
B3.3	Does the EC indicate the format for submission? *(WHO 5.2.3)*	☐	☐	☐	☐	
B3.4	Does the EC indicate the number of copies of application to be submitted? *(WHO 5.2.6)*	☐	☐	☐	☐	

B3.5	Does the EC indicate the application procedures for protocol amendments and continuing review? *(WHO 5.2.2)*	☐	☐	☐	☐	
B3.6	Does the EC have an informed consent guidance/template which it made available to investigators to help with the preparation of the document?	☐	☐	☐	☐	
B3.7	Does the EC have a registration procedure (tracking system) for the applications made for review?	☐	☐	☐	☐	
B3.8	Does the EC specify the name and address of the EC secretariat to whom the application should be submitted? *(WHO 5.2.1)*	☐	☐	☐	☐	
B3.9	Does the EC have means of acknowledging applications made to them? *(WHO 5.2.8)*	☐	☐	☐	☐	
B3.10	Does the EC communicate the incompleteness of an application?	☐	☐	☐	☐	
B3.11	Does the EC indicate fee structure, if any, for reviewing an application? *(WHO 5.2.11)*	☐	☐	☐	☐	
B3.12	Does the EC indicate that application forms should be signed and dated? *(WHO 5.3.1)*	☐	☐	☐	☐	
B3.13	Does the EC request that protocol be submitted together with supporting documents and annexes? *(ICH 3.1.2, WHO 5.3.2)*	☐	☐	☐	☐	
B3.14	Does EC request submission of the project summary and diagrammatic representative (flow chart) of the protocol? *(WHO 5.3.3)*	☐	☐	☐	☐	
B3.15	Does EC request submission of a description of the ethical considerations involved in the research? *(WHO 5.3.4)*	☐	☐	☐	☐	

B3.16	Does EC request submission of case report forms, diary cards and other questionnaires intended for research participants? *(WHO 5.3.5)*	☐	☐	☐	☐	
B3.17	When a research involves a study product does the EC request submission an adequate summary of the study product? *(ICH 3.1.2 WHO 5.36)*	☐	☐	☐	☐	
B3.18	Does EC request submission of the investigators CV? *(ICH 3.1.2 WHO 5.3.7)*	☐	☐	☐	☐	
B3.19	Does EC request submission of the materials to be used for the recruitment of potential research participants? *(ICH 3.1.2 WHO 5.3.8)*	☐	☐	☐	☐	
B3.20	Does EC request submission of the informed consent form? *(ICH 3.1.2 WHO 5.3.10)*	☐	☐	☐	☐	
B3.21	Does EC request submission of a statement describing any compensation for study participants? *(ICH 3.1.2 WHO 5.3.12)*	☐	☐	☐	☐	
B3.22	Does EC request submission of a description of the arrangements for indemnity if applicable? *(WHO 5.3.13)*	☐	☐	☐	☐	
B3.23	Does EC request submission of a description of the arrangements for insurance coverage if applicable? *(WHO 5.3.14)*	☐	☐	☐	☐	
B3.24	Does EC request submission of a statement of agreement to comply with ethical principles set out in relevant guidelines? *(WHO 5.3.15)*	☐	☐	☐	☐	

B3.25	Does EC request submission of all significant previous decisions by the EC or regulatory authorities for the proposed study? *(WHO 5.3.16)*	☐	☐	☐	☐	
B4	**MEETING REQUIREMENTS** (EC should have documented meeting requirements which they comply with, quorum and professional requirements)					
B4.1	Does the EC meet regularly on scheduled date announced in advance? *(ICH 3.2.2 WHO 6.1.1)*	☐	☐	☐	☐	
B4.2	Does the EC form a quorum before holding its meeting? *(WHO 4.5)*	☐	☐	☐	☐	
B4.3	Does the EC require that at least one non affiliated member and a non scientist be part of a quorum for each of its meeting? *(WHO 4.5.2)*	☐	☐	☐	☐	
B4.4	Does the EC require that meetings should be minuted and there should be an approval procedure for the minutes? *(WHO 4.5.2)*	☐	☐	☐	☐	

C	**COMPLETENESS OF ITS REVIEW PROCESS** (EC review protocols and its supporting documents in a timely fashion according to an established procedure to protect the interest of research participants)					
C1	**REVIEW PROCESS** (enough time for protocol review, EC to have documented and detailed review process which is complied with)					
C1.1	Does the EC follow the operating procedure for review? *(ICH 3.3, WHO 6)*	☐	☐	☐	☐	
C1.2	Does the EC review protocols and all relevant documents within a reasonable time frame? *(ICH 3.1.2, WHO 6.1.2)*	☐	☐	☐	☐	
C1.3	Does the EC have an established procedure for expedited review? *(ICH 3.3.5, WHO 6)*	☐	☐	☐	☐	

C1.4	Does the EC indicate the nature of the application, amendments, continuing review and other considerations that will be eligible for expedited review? *(ICH 3.3.5, WHO 6.3.1)*	☐	☐	☐	☐	
C1.5	Does the EC have policies and procedures that describe the process used to evaluate whether research reviewed by the expedited procedures meets the criteria for review? *(ICH 3.3.5, WHO 6.3.3)*	☐	☐	☐	☐	
C1.6	Does the EC have an established procedure for full board review? *(WHO 6.2)*	☐	☐	☐	☐	
C1.7	Does the EC have an established process for obtaining additional expertise when reviewing specific protocols? *(ICH 3.3.6, WHO 4.6)*	☐	☐	☐	☐	
C1.8	Does the EC have terms of reference for independent consultants? *(WHO 4.6)*	☐	☐	☐	☐	
C1.9	Does the EC have an established process for inviting applicants/investigators to elaborate on specific issues when applicable? *(ICH 3.2.5)*	☐	☐	☐	☐	
C2	**ELEMENTS OF REVIEW** (EC to have a policy and procedure for review, elements reviewed should include the scientific design and conduct and ethics)					
C2.1	Does the EC have a policy and procedure for reviewing protocols? *(WHO 6.2)*	☐	☐	☐	☐	
C2.2	Does the EC review the scientific design and conduct of the study? *(WHO 6.2.1)*	☐	☐	☐	☐	
C2.3	Does the EC review the justification for the use of control arms? *(WHO 6.2.1.3)*	☐	☐	☐	☐	

C2.4	Does the EC review the criteria for prematurely withdrawing research participants? *(WHO 6.2.1.4)*	☐	☐	☐	☐	
C2.5	Does the EC review the criteria for suspending or terminating the research? *(WHO 6.2.1.5)*	☐	☐	☐	☐	
C2.6	Does the EC have justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and concerned communities? *(WHO 6.2.1.2)*	☐	☐	☐	☐	
C2.7	Does the EC review the adequacy of provisions made for monitoring and auditing the conduct of the research, including the constitution of a data safety and monitoring board (DSMB)? *(WHO 6.2.1.6)*	☐	☐	☐	☐	
C2.8	Does the EC review the manner in which the results of the research will be reported and published? *(WHO 6.2.1.8)*	☐	☐	☐	☐	
C2.9	Does the EC review whether the risk posed to research subjects is reasonable in relation to its anticipated benefits? *(WHO 6.2.1.2)*	☐	☐	☐	☐	
C2.10	Does the EC follow the established procedure for determining if potential risks posed to the vulnerable population are acceptable? *(ICH 3.1.6)*	☐	☐	☐	☐	
C2.11	Does the EC review the description of the informed consent process and the identification of those responsible for obtaining it? *(WHO 6.2.5.1)*	☐	☐	☐	☐	

C2.12	Does the EC review the informed consent focusing on measures to improve participant understanding and voluntary decision making? *(WHO 6.2.5.2)*	☐	☐	☐	☐	
C2.13	Does the EC review justification to include research individual that cannot consent and account of the arrangements for obtaining consent? *(ICH 3.1.6, WHO 6.2.5.3)*	☐	☐	☐	☐	
C2.14	Does the EC have and follow the established procedure to determine if the vulnerable subjects are protected in the consent process? *(ICH 3.1.5)*	☐	☐	☐	☐	
C2.15	Does the EC have and follow the established procedure in reviewing the consent process in emergency situation in research protocol? *(ICH 3.1.2)*	☐	☐	☐	☐	
C2.16	Does the EC review the information assuring research participants that they will receive available information during the course of the research relevant to their participation? *(WHO 6.2.5.4)*	☐	☐	☐	☐	
C2.17	Does the EC review the provisions made by researchers for receiving and responding to queries and complaints from participants or representatives during the course of the research? *(WHO 6.2.5.5)*	☐	☐	☐	☐	
C2.18	Does the EC review the suitability of the investigators qualifications and experience for the proposed study? *(ICH 3.1.3, WHO 6.2.3.1)*	☐	☐	☐	☐	

C2.19	Does the EC review any plans to withdraw or withhold standard therapies for the purpose of the research and the justification for such action? *(WHO 6.2.3.2)*	☐	☐	☐	☐	
C2.20	Does the EC review the steps to be taken if research participants voluntarily withdraw during the course of the research? *(WHO 6.2.3.5)*	☐	☐	☐	☐	
C2.21	Does EC have and follow an established procedure in evaluating the protection of privacy and confidentiality of the research participants during and after the completion of the research? *(WHO 6.4)*	☐	☐	☐	☐	
C2.22	Does the EC have and follow established procedure to determine if the vulnerable subjects are properly protected? *(ICH 3.1.6)*	☐	☐	☐	☐	
C2.23	Does EC have and follow procedures of determining whether the method used to recruit the research subjects is acceptable or not? *(WHO 6.2.2)*	☐	☐	☐	☐	
C2.24	Does the EC review the description of the plan to make the study product available to research participants following the research if applicable? *(WHO 6.2.3.8)*	☐	☐	☐	☐	
C2.25	Does the EC have and follow established procedure for evaluating the inclusion and exclusion criteria? *(WHO 6.2.2.4, 6.2.2.5)*	☐	☐	☐	☐	
C2.26	Does the EC have and follow established procedure for evaluating the characteristics of the population from which participants are drawn? *(WHO 6.2.2.1)*	☐	☐	☐	☐	

C2.27	Does EC have methods of ensuring that additional safe guards are included to protect the rights and welfare in research involving vulnerable populations? *(ICH 3.1.6, 3.1.7)*	☐	☐	☐	☐	
C2.28	Does the EC review payment for research participants to determine if it will unduly influence them to participate in research? *(ICH 3.1.8, WHO 6.3.2.10)*	☐	☐	☐	☐	
C2.29	Does the EC review compensation for research participants to determine if it they adequately compensated for injury? *(ICH 3.1.9, WHO 6.3.2.11)*	☐	☐	☐	☐	
C2.30	Does EC review the standard of care and other post trial benefits offered to participants? *(WHO 6.3.2.3)*	☐	☐	☐	☐	
C2.31	Does the EC review the impact and relevance of research on the local community from which the research participants are drawn? *(WHO 6.3.6.1)*	☐	☐	☐	☐	
C2.32	Does the EC review the steps taken to consult with the concerned communities during the course of the designing of the research? *(WHO 6.3.6.2)*	☐	☐	☐	☐	
C2.33	Does the EC review the influence of the community on the consent of individuals? *(WHO 6.3.6.3)*	☐	☐	☐	☐	
C2.34	Does the EC review proposed community consultation during the course of the research? *(WHO 6.3.6.4)*	☐	☐	☐	☐	
C2.35	Does the EC review the extent to which research contributes to capacity building within the community? *(WHO 6.3.6.5)*	☐	☐	☐	☐	

C2.36	Does the EC review a description of the availability and affordability of any successful study product to the concerned communities following the research? *(WHO 6.3.6.6)*	☐	☐	☐	☐	
C2.37	Does the EC review the rights to give subjects additional information when the additional information would add meaningfully to the protection of the rights, safety and/or well-being of the subjects? *(WHO 6.2.5.4)*	☐	☐	☐	☐	
C3	**AFTER PROTOCOL APPROVAL** (EC to document and follow procedures of reviews of amendments, continuing, SAE reports)					
C3.1	Does the EC have continuing review? *(ICH 3.1.4, 3.3.3, WHO 9)*	☐	☐	☐	☐	
C3.2	Does the EC have and follow an established procedure for determining the frequency of continuing review? *(ICH 3.1.4, WHO 9.2)*	☐	☐	☐	☐	
C3.3	Does the EC have and follow an established procedure for handling modification (amendments) of research protocol? *(ICH 3.2.7, WHO 9.3)*	☐	☐	☐	☐	
C3.4	Does the EC have documents required for continuous review and is this list made available to investigators?	☐	☐	☐	☐	
C3.5	Does the EC consider the submitted relevant information and documents in its continuing review? *(WHO 9.3)*	☐	☐	☐	☐	

C3.6	Does the EC have and follow an established procedure to notify investigators when it will conduct a continuing review? *(ICH 3.1.4, WHO 9.4)*	☐	☐	☐	☐	
C3.7	Does ERC have and follows policies and procedures for suspending or terminating previously approved research if need be based on findings in monitoring or continuing review? *(WHO 9.4)*	☐	☐	☐	☐	
C3.8	Does the EC require the investigator to notify the EC in writing of the reasons and a summary of the research results when applicant prematurely suspend or terminate the study? *(WHO 9.5)*	☐	☐	☐	☐	
C3.9	Does EC do a follow up review when serious and unexpected adverse events occur as a result of the conduct of the study or study (test) product and necessary steps need to be instituted to protect participants? *(WHO 9.3b)*	☐	☐	☐	☐	
C3.10	Does the EC specify that no deviations from, or changes of, the protocol should be initiated without prior written IRB/IEC approval/favorable opinion of an appropriate amendment? *(ICH 3.3.7)*	☐	☐	☐	☐	
C3.11	Does the EC specify that the investigator should promptly report to the IRB/IEC any deviations from, or changes of, the protocol to eliminate immediate hazards to the trial subjects? *(ICH 3.3.8, WHO 9.3c)*	☐	☐	☐	☐	

C3.12	Does the EC specify that the investigator should promptly report to the IRB/IEC changes increasing the risk to subjects and/or affecting significantly the conduct of the trial? *(ICH 3.3.8, WHO 9.3c)*	☐	☐	☐	☐	
C3.13	Does the EC specify that the investigator should promptly report to the IRB/IEC all adverse drug reactions (ADRs) that are both serious and unexpected? *(ICH 3.3.8)*	☐	☐	☐	☐	
C3.14	Does the EC specify that the investigator should promptly report to the IRB/IEC any new information that may affect adversely the safety of the subjects or the conduct of the trial? *(ICH 3.3.8)*	☐	☐	☐	☐	
C3.15	Does the EC require the applicant to notify the EC the time of completion of a study? *(WHO 9.6)*	☐	☐	☐	☐	
C3.16	Does the EC require the applicant to submit in writing at the completion of the study a final report describing how the study was conducted and a summary of the study results? *(WHO 9.7)*	☐	☐	☐	☐	
C4	**COMPLETENESS OF IEC/IRB MEETING MINUTES** (minutes should be a complete record and reflect actions taken during the meeting)					
C4.1	Does the EC record and keep minutes of its meeting? *(ICH 3.2.2, WHO 6.1.3)*	☐	☐	☐	☐	
C4.2	Does the EC record in its minute members present for each meeting, members voted and all the actions that took place during the meeting? *(ICH 3.1.2)*	☐	☐	☐	☐	

C4.3	Does the minutes record protocols and documents reviewed, the dates of approval, modifications required prior to its approval or disapproval and termination/suspension of any prior approval? *(ICH 3.1.2)*	☐	☐	☐	☐	
C4.4	Does the EC have an approval procedure for its minutes? *(WHO 6.1.3)*	☐	☐	☐	☐	
C5	**DECISION MAKING PROCESS** (EC should have a procedure for decision making and members should participate in the process)					
C5.1	Are decisions only made in meetings where a quorum is present? *(ICH 3.2.3, WHO 7.3)*	☐	☐	☐	☐	
C5.2	Does EC ensure that only members who participate in the review should participate in the decision? *(ICH 3.2.4, WHO 7.5)*	☐	☐	☐	☐	
C5.3	Are all relevant documents required for full review available and considered before a decision is made? *(WHO 7.4)*	☐	☐	☐	☐	
C5.4	Does the EC have a predefined method of arriving at a decision e.g. by consensus or vote? *(WHO 7.6)*	☐	☐	☐	☐	
C5.5	Does the EC ensure that members with conflicts of interest are not part of the decision? (WHO 7.1)	☐	☐	☐	☐	
C5.6	Do the EC members have sufficient time to review and discuss before a decision is made? *(WHO 7.2)*	☐	☐	☐	☐	
C5.7	When a decision is made to re-review a protocol, does the EC clearly document the areas needed to be revised? *(WHO 7.8)*	☐	☐	☐	☐	

C5.8	Are negative decisions supported with clearly stated reasons? *(WHO 7.9)*	☐	☐	☐	☐	
D	**AFTER REVIEW PROCESS** (EC should adequately and effectively communicates its decision to investigators)					
D1	**COMMUNICATING A DECISION** (EC have an effective and timely way of communicating a decision with clearly stated reasons)					
D1.1	Are the conclusions of a decision communicated in writing to the applicant within 14 days? *(WHO 8)*	☐	☐	☐	☐	
D1.2	Does the EC clearly specify areas that need to be revised when communicating a provisional approval decision to investigators? *(ICH 3.3.9, WHO 7.4)*	☐	☐	☐	☐	
D1.3	Does the decision letter include the exact title of the protocol reviewed? *(WHO 8.1)*	☐	☐	☐	☐	
D1.4	Does the decision letter include the specific identification number of the documents reviewed including the informed consent form? *(WHO 8.2)*	☐	☐	☐	☐	
D1.5	Does the decision letter include the name and title of the applicant(s)? *(WHO 8.4)*	☐	☐	☐	☐	
D1.6	Does the decision letter include the date and place of the decision? *(WHO 8.6)*	☐	☐	☐	☐	
D1.7	Does the decision letter include the name of the EC taking the decision? *(WHO 8.7)*	☐	☐	☐	☐	
D1.8	Does the decision letter include a statement of the responsibilities of the applicant? *(ICH 3.3.6, 3.3.7, WHO 8.11)*	☐	☐	☐	☐	

D1.9	Does the decision letter include the signature of the chairperson (or other authorized person) and date? *(WHO 8.14)*	☐	☐	☐	☐	
D1.10	Does the EC inform investigators of its re-review procedure, schedule/plan of ongoing review? *(WHO 8.12)*	☐	☐	☐	☐	
D1.11	Does the EC issue suspension or termination letters with reasons for suspension or termination (or the conditions of lifting suspension or termination) clearly stated? *(ICH 3.3.9, WHO 9.5)*	☐	☐	☐	☐	
D1.12	Does the decision documentation clearly explain how the applicant can communicate with the EC? *(WHO 8.11)*	☐	☐	☐	☐	
E	DOCUMENTATION AND ARCHIVING (EC systematically document and archive its activities for a good time period)					
E1.1	Does the EC have and follow operating procedures for record keeping and archiving of all records and communication documents? *(ICH 3.4, WHO 10)*	☐	☐	☐	☐	
E1.2	Does EC have and follow operation procedure for the access or retrieve of various documents, files or archives? *(ICH 3.4, WHO 10)*	☐	☐	☐	☐	
E1.3	Does the filing, archiving, accessing and retrieving of the documents meet the established procedures? *(ICH 3.4, WHO 10)*	☐	☐	☐	☐	
E1.4	Does the EC maintain a complete file or database of all the relevant materials in each research protocol? *(WHO 10.7)*	☐	☐	☐	☐	

E1.5	Does the EC follow the requirement to retain all the records for at least 3 years after the completion of investigation? *(ICH 3.4, WHO 10)*	☐	☐	☐	☐	
E1.6	Could all the relevant records be inspected by the appropriate authority? *(ICH 3.4, WHO 10)*	☐	☐	☐	☐	
E1.7	Does the EC document its SOPs and terms of reference? *(WHO 10.1)*	☐	☐	☐	☐	
E1.8	Does the EC document the CV of all its members? *(WHO 10.2)*	☐	☐	☐	☐	
E1.9	Does the EC document its published guideline for submission of protocols? *(WHO 10.4)*	☐	☐	☐	☐	
E1.10	Does the EC document the agenda and minutes of its meetings? *(WHO 10.5, 10.6)*	☐	☐	☐	☐	
E1.11	Does the EC document copies of its decision and any advice or requirements sent to the applicants? *(WHO 10.9)*	☐	☐	☐	☐	
E1.12	Does the EC document all the written documentations received during the follow-up? *(WHO 10.10)*	☐	☐	☐	☐	
E1.13	Does the EC document the notification of completion, premature suspension or termination of study? *(WHO 10.11)*	☐	☐	☐	☐	
E1.14	Does the EC document the final report of the study? *(WHO 10.12)*	☐	☐	☐	☐	