Research Ethics Committee Assessment Toolkit (RECAT)

2017

Evaluating the needs of research ethics committees to improve operational quality and efficiency

The **Research Ethics Committee Assessment Toolkit (RECAT)** is designed to facilitate evaluation of the operational needs of Research Ethics Committees (RECs) globally to inform local quality assurance and quality improvement efforts. The toolkit is published open-access for non-commercial use.

The RECAT was developed by the African Bioethics Consortium (ABC) whose members include the Johns Hopkins University-Fogarty African Bioethics Training Program, the University of Zambia School of Medicine, the University of Botswana Office of Research & Development, and the Makerere University College of Health Sciences. Financial support to develop the RECAT was provided to Johns Hopkins University Bloomberg School of Public Health and Berman Institute of Bioethics though a US National Institutes of Health, Fogarty International Center and National Institute of Allergy and Infectious Diseases supplemental grant under Award No. R25TW001604. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

While we make this freely available, we ask that you please reference the following citation when using or adapting the RECAT:

> African Bioethics Consortium. (2017) *Research Ethics Committee Assessment Toolkit (RECAT).* Johns Hopkins University. Version 1.0. Baltimore Maryland USA.

We also kindly request that you share your experiences with using the RECAT with us so we can better understand its potential application and continue to make future improvements as necessary.

Feedback can be sent via email to: jali@jhu.edu

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Abbreviations

ABC – African Bioethics Consortium
CIOMS – Council for International Organizations of Medical Sciences
FABTP – Fogarty African Bioethics Training Program
FIC – Fogarty International Center
IRB – Institutional Review Board
JHU – Johns Hopkins University
NIAID – National Institute of Allergy and Infectious Diseases
NIH – US National Institutes of Health
REC – Research Ethics Committee
RECAT – Research Ethics Committee Assessment Toolkit
SOP – Standard Operating Procedures
WHO – World Health Organization

Research Ethics Committee Assessment Toolkit (RECAT)
Instructional Guide

Purpose of the RECAT

The Research Ethics Committee Assessment Toolkit (RECAT) was created for the purpose of evaluating the needs of Research Ethics Committees (RECs) – also known as Institutional Review Boards (IRBs) – in order to support efficient, high quality ethics review of research protocols globally. The RECAT can be used by institutions and RECs to identify:

1. baseline operational conditions of a REC,
2. areas for the development of targeted interventions to improve REC functioning, and,
3. change in REC quality and efficiency over time across multiple domains

Key Features

- **Consistent with international REC standards**: The tool was informed by the 2011 *WHO Standards and Operational Guidance for the Ethics Review of Health Related Research with Human Participants,* which reflects the most current global guidance for RECs.
- **Mixed methods approach**: The tool triangulates data gathered through various methods, including interviews, focus groups, document review, and direct observation. This mixed methods approach allows the assessment to capture both written policies and procedures of the REC as well as the actual day-to-day practices of the REC, and incorporates perspectives from multiple key stakeholders including: institutional leadership, REC chairpersons, REC administrators, REC members, and researchers who submit applications to the REC.
- **Internal or external assessment:** The assessment can be administered by members of the assessed institution (self-assessment) or by independent external assessors.
- **Pilot tested:** Components of the tool and implementation process were piloted in the United States and the full toolkit was tested in two RECs within institutions in Zambia and Botswana.

Toolkit Components

1. **Implementation Checklist**

   The *Implementation Checklist* provides a brief overview of all key activities that should be completed by the assessment team. Additional details about each step are provided in this Instructional Guide.

2. **Institutional Briefing Memo**

   The *Institutional Briefing Memo* provides a short description of the assessment process and the time and resources commitment needed from the institution and REC being assessed. Prior to the assessment, this memo should be sent to institutional leadership responsible for overseeing the REC.

3. Assessment Tool

The *Assessment Tool* is comprised of five parts that collect information from different sources:

Part A: REC Context – *Interview with REC Administrator/Chair*

This section provides the assessor with key contextual information about national and institutional policies and background of the REC itself. The information in this section is intended to help the assessor understand the working environment of the REC.

Part B: REC Policies – *Document review*

This section assesses the written policies and standard operating procedures of the REC to determine the degree to which they include information suggested by international standards.

Part C: REC Operations – *Site visit to REC office*

This section assesses the regular practices of the REC office. Part C is completed through observation of REC office activities and infrastructure, capturing information relevant to the actual administrative practices of the REC.

Part D: REC Meeting – *Structured observation of REC meeting*

This section of the tool supports assessment of the nature of committee deliberations, the application of ethics considerations, and the extent to which meeting decisions are fully captured in meeting minutes and communicated to investigators.

Part E: REC Perceptions – *Interviews and focus groups with REC stakeholders*

Part E allows the assessor to further verify and explore the REC's challenges as perceived by key stakeholders in the research ethics review process through interviews and focus group discussions. Guides are provided for a) a focus group discussion with REC members; b) a focus group discussion with researchers; and c) an in-depth interview with the institutional official responsible for oversight of the REC (such as the Dean or Director of Research). The open-ended nature of questions in this Part allows key REC stakeholders to voice issues that may not have been captured through other parts of the assessment, and additionally to contextualize the nature of these challenges and their relative priority.

4. Reporting Template

A *Reporting Template* is provided to help assessors synthesize information gathered through the assessment. The template should help generate a comprehensive summary of findings organized by key domains which can be provided to the assessed REC and institution. The reporting template is not meant to be exhaustive and should not restrict the assessment team in its identification of relevant domains, issues and recommendations.

5. Sample Report

The *Sample Report* provides an example of the types of observations and recommendations that one might convey using the reporting template. The sample is meant to serve an illustrative purpose only.

Procedures

This section describes recommended procedures to guide assessors through the three main phases of assessment: preparation, data collection, and analysis and reporting. Please refer to the separate *Implementation Checklist* for a summary of core procedures.

A. Preparation

Institutional consultation and permission

Prior to initiating assessment activities, relevant institutional officials should be consulted about their desires and preferences regarding the REC assessment. The *Institutional Briefing Memo* can be adapted and used to help inform relevant leadership about the nature of the activity.

While each institution may have differing requirements, as a general matter, receipt of formal permission to conduct the assessment from relevant institutional leadership should suffice. Ethics committee review and approval should be considered for the assessment if assessors intend to make information collected available outside the institution including for publication purposes. In such cases, where possible, a REC other than the one being assessed should review the proposed assessment activity.

In addition to obtaining formal approval to conduct the assessment, assessors should determine if the institution would like the team to follow any particular confidentiality practices and/or would like to have a confidentiality agreement signed by members of the assessment team.

Assessment team

It is recommended that the assessment team include 1-3 individuals (more than 1 is preferable). Inclusion of individuals experienced with qualitative data collection and with basic knowledge of research ethics committees is recommended.

The composition of the assessment team should be informed by an understanding of the institutional setting and the ways in which a participatory approach may shape the information collected during the assessment. Where including a member from the REC office on the assessment team is anticipated to bias the results such that the most important barriers to REC capacity are not identified, a completely external approach may be appropriate. Where there is strong institutional commitment to the process and an openness to quality assurance and improvement, an approach that includes an REC member or administrator on the assessment team may facilitate not only the identification of the most important needs, but commitment to investing in solutions.

For *externally* conducted assessment, external assessors should identify a Point of Contact (POC) at the institution, preferably someone with knowledge of REC and/or institutional administration, to facilitate local coordination and to serve generally as a resource person.

Scheduling/Timing

The assessment is likely to require approximately 1-2 days of advance preparation, 3 days on site to collect information, and 3-5 days for initial analysis. Data collection on site should be scheduled to overlap with a REC meeting. The components of the assessment can be completed in any order, though it is preferable to begin with an interview with the institutional official and review background

documentation before observing a committee meeting. Effort should be made to avoid conducting the assessment at a time of year where many REC members or administrators are likely to be unavailable.

All activities (office observation, meeting observation, focus groups, interviews) should be scheduled in advance with appropriate invitations provided. Focus groups and interviews should be conducted in a private space and using the provided interview guides. Schedule the following sessions well in advance:

- An interview (approximately 1 hour) with an **institutional official** who is responsible for overseeing research activities and/or the REC (e.g., Director/Dean or Assistant Director/Dean of Research).
- Two separate focus group discussions (approximately 1 hour each):
    - One focus group with 6-8 **REC members**, if possible, including members with 6+ months experience serving on the REC; either current member or recently former member.
    - One focus group with 6-8 **researchers** at the institution who submitted protocols to the REC within the past 2 years and who represent different departments in the institution.

Document collection and preparation

Available documents relevant to the REC should be collected and reviewed in advance to prepare the assessment team and support completion of Parts A & B of the assessment tool. At least 2 weeks prior to assessment, obtain the following documents from the institution, if available:

- Relevant institutional policies/procedures, national laws, policies, or guidelines related to research with human participants:
    - Relevant institutional policies or procedures related to research with human participants
    - A copy of REC's Standard Operation Procedures (SOPs) and any other relevant REC policy/procedure documents
    - Relevant national laws, policies, or guidelines related to research with human participants
- Templates, forms, and checklists used by the REC office:
    - Protocol submission forms and templates used by researchers
    - Consent form templates
    - Checklist for submission documents/screening applications for completeness
    - Checklist for REC protocol review
    - Meeting minute templates
    - Approval letter templates
    - Progress reporting form
    - Adverse event reporting form
    - Amendment form
    - Continuing review form
    - Study close-out form
    - Material Transfer Agreement (MTA) template
    - Other key forms: _____

Prepare hard copies of the *Assessment Tool* for each member of the assessment team and determine who will have responsibility for collecting different data components. It is recommended that at least 2 assessors participate in the REC meeting observation and focus groups/interviews to allow for easier note-taking and reliability of findings. If permitted by respondents, assessors should consider using audio recording devices during focus groups and interviews to support data collection and analysis.

B. Data Collection

For ease of reference, data collection procedures are summarized for each Part of the *Assessment Tool* in the following table. Brief instructions are also provided on each Part of the *Assessment Tool* itself.

Assessment Tool Part	Method	Source of Information	Expected Duration	Procedures
Part A: REC Context	Interview	REC administrator or Chair	1-2 hours total	Complete Part A of the Tool with assistance of an REC administrator and/or the REC chair.
Part B: REC Policies	Document review	REC SOPs, institutional and national research policy documents, REC templates and forms	2-4 hours total	Complete Part B of the Tool while reviewing copies of the written policies and procedures. Can be completed in advance.
Part C: REC Operations	Site visit to REC administrative office	Assessor observation, REC administrator	6 hours total (2 hour visit on 3 different days recommended)	Complete Part C of the Tool while physically present in the REC office. Questions can be answered through conversation with the REC administrator and visually verifying operational components of the office through observation. Observation will focus on verifying administrative resources, filing and tracking systems, submission practices and documentation, recording of REC meeting minutes, communications with researchers, and checklists and/or other tools that are used to enhance the consistency of administrative processes.
Part D: REC Meeting	Structured observation of REC meeting	Assessor observation, REC meeting	2-4 hours	Complete Part D of the Tool during and after the REC meeting selected for observation. This Part includes three sections: (D.1) which captures contextual information related to the REC meeting observed; (D.2) which provides a Protocol Review Checklist that should be completed by the assessor during the observed REC meeting (one hardcopy of checklist is needed for each protocol reviewed during the meeting); and (D.3) which describes procedures for reviewing the outputs of the REC meeting. It is strongly advised to attempt to observe an REC meeting which includes, on the agenda, the review of different types of protocols – new protocols, re-submissions, continuing reviews, etc….
Part E: REC Perceptions	Interviews and focus groups	Focus group with REC members, focus group with researchers, interview with institutional official responsible for REC oversight	3-4.5 hours total (1-1.5 hours for each interview/focus group)	Complete two separate focus group discussions and one interview with the listed groups/individual. Hold discussions in a private location. Identify a moderator and a note taker from within the assessment team. It is important to select a moderator who will help participants feel at ease with expressing views. Explain the purpose of the discussion and request permission to proceed. Assure participants that confidentiality will be maintained. Use the provided semi-structured focus group and interview guides for each session. Take comprehensive notes and audio record the sessions for future reference, if needed, with permission. To respect respondent privacy, do not log or write down participant names or other personal identifiers. Thank participants and reiterate the purpose of the exercise you are doing and how the views will be used.

C. Analysis and Reporting

Once data collection is complete, analysis can begin with reviewing the various Parts of the completed tool, interview, focus group and other notes. Notes should be typed (if not already) for ease of analysis and reporting. If audio recordings were collected, it may also be useful to transcribe the audio into typed text. The domains and sub-domains noted in the attached *Reporting Template* can serve as a preliminary guide for identifying themes related to REC operations across the various parts of the *Assessment Tool*. Assessor notes and interview/focus group transcripts should be reviewed to identify any additional themes. A review of the 2011 *WHO Standards and Operational Guidance for the Ethics Review of Health Related Research with Human Participants* may also help with the process of identifying themes and contextualizing findings from the evaluation.

Data should be reviewed several times and considered in light of relevant themes. When this is completed, a summary of what has been learned from the evaluation should be prepared. This summary report should cover all findings from the various sources/methods. Should data suggest conflicting views or practices, assessors may decide to report both perspectives, if the sources of information are reliable.

It is recommended that the *Reporting Template* be used to generate a summary statement and detailed report of key findings and recommendations by domain. A *Sample Report* also included with this toolkit provides a complete example of the types of observations and recommendations that one might convey using the reporting template. Assessors should not feel bound to the themes or format of the *Reporting Template*. A core set of REC needs should be identified based on the synthesis of findings. Importantly, the assessment should also attempt to identify what types of resources or inputs may be required to address the identified needs.

A draft report should be provided to the institutional point of contact and official responsible for oversight of the REC for review and feedback prior to finalization. Following correction of any major errors or omissions, the report should be finalized, signed by the assessor and institution, and delivered. It is advisable to schedule a meeting between relevant institutional/REC stakeholders and the assessor to review the findings together.

Research Ethics Committee Assessment Toolkit (RECAT)

Institutional Briefing Memo

Lead Assessor:

Insert Name, Address, Email, and Phone Number

Purpose: The Research Ethics Committee Assessment Toolkit (RECAT) is a structured instrument that provides research institutions, particularly those based in resource limited settings, with a method to rigorously and systematically assess the needs of their Research Ethics Committees (RECs) to support quality assurance, operational efficiency and benchmarking. The tool was systematically developed from 2014-2016 by researchers within the African Bioethics Consortium (ABC) whose members include the Johns Hopkins University-Fogarty African Bioethics Training Program, University of Zambia School of Medicine, the University of Botswana Office of Research & Development, and Makerere University College of Health Sciences. The tool, which can be implemented by internal or external assessors, can help institutions:

- Identify baseline functioning of RECs
- Create an organized list of recommendations for REC quality assurance/improvement
- Document change in the functioning of RECs over time

Assessment Team: The proposed assessment team will include:

Names of assessors and their institutional affiliations

Activities: The proposed assessment includes multiple modes of information collection: document review, interviews, focus groups, and observation of REC operations. The above assessment team will implement these activities using tools and procedures provided in the RECAT Toolkit.

Assessment components:

1. An interview with an institutional official who is responsible for overseeing research activities and/or the REC (e.g., Director/Dean or Assistant Director/Dean of Research),
2. An interview with a lead REC administrator,
3. A review of standard operating procedures and other operational documents of the REC,
4. A site visit to the REC office to observe administrative practices,
5. An observation of one REC meeting, and,
6. Two focus group discussions – one with researchers and one with REC members.

Many institutions have confidentiality requirements in place related to REC practices, communications and documents. The assessment team anticipates and is fully committed to complying with any confidentiality agreements that pertain to this assessment.

Output: A comprehensive summary of findings organized by key domains will be provided to the institution and REC. The institution will have an opportunity to review the report and correct any errors prior to finalization.

Indicate whether any other outputs are expected. Permission should be sought if the assessors intend t

Timeframe: The process of collecting relevant REC information will take approximately **3 working days, scheduled around an REC meeting**. We will endeavor to have a draft report for institutional review within Insert number of week

Research Ethics Committee Assessment Toolkit (RECAT)

Implementation Checklist

This checklist provides an overview of key activities that should be completed by the assessment team. Additional details about each step are provided in the *Instructional Guide*. Prior to initiating these activities, relevant institutional leadership should be consulted and should indicate a desire to complete an REC assessment.

A. Preparation

- ☐ Review the Preparation section of the RECAT *Instructional Guide.*
- ☐ Introduce assessment to institutional leadership using the RECAT *Briefing Memo.*
- ☐ Determine what formal institutional approvals are required for the needs assessment.
- ☐ Confirm dates of REC meeting(s) that the team could observe as part of the assessment.
- ☐ Schedule interview with an institutional official who is responsible for overseeing research activities and/or the REC (e.g., Director/Dean or Assistant Director/Dean of Research).
- ☐ Schedule two focus group discussions of approximately 1 hour each:
    - FGD 1: 6-8 REC members (if possible, recruit members with 6+ months experience serving on REC, could be either current member or recently former member).
    - FGD 2: 6-8 researchers at the institution who submitted protocols to the REC within the past 2 years and who represent different departments in the institution.
- ☐ Schedule 4-5 hours of time (can be segmented into two visits during the assessment, if needed) for assessment team members to visit REC office with the lead REC administrator/ coordinator to:
    - Review REC office operations, and
    - Interview the REC administrator
- ☐ Confirm that all relevant stakeholder/respondents are informed about the upcoming assessment.

At least 2 weeks prior to assessment, obtain the following documents from the institution, if available:

1. Relevant institutional policies/procedures, national laws, policies, or guidelines related to research with human participants:
    - ☐ Relevant institutional polices/procedures, national laws, policies, or guidelines related to research with human participants
    - ☐ A copy of REC's Standard Operation Procedures (SOPs) and any other relevant REC policy/procedure documents
    - ☐ Relevant national laws, policies, or guidelines related to research with human participants

2. Templates used by the REC office:

- ☐ Protocol submission forms and templates used by researchers
- ☐ Consent form templates
- ☐ Checklist for submission documents/screening applications for completeness
- ☐ Checklist for REC protocol review
- ☐ Meeting minute templates
- ☐ Approval letter templates
- ☐ Progress reporting form
- ☐ Adverse event reporting form
- ☐ Amendment form
- ☐ Continuing review form
- ☐ Study close-out form
- ☐ Material Transfer Agreement (MTA) template
- ☐ Other key forms: _____

B. Implementation

- ☐ Review the Data Collection section of the RECAT *Instructional Guide.*
- ☐ Prior to each assessment activity, re-introduce the assessment team and the purpose of the assessment to anyone being engaged.
- ☐ Utilize the *Assessment Tools* (Parts A-E) as appropriate for each scheduled activity.
- ☐ Take detailed notes during each activity.
- ☐ If an audio recording is desired, seek permission and audio-record interviews and focus group discussions.
- ☐ Be available in case further questions arise during the assessment.
- ☐ Collect any pertinent documents that were not provided in advance of the assessment.
- ☐ If institution is willing and able to share such documents, obtain a copy of meeting minutes from the meeting observed during the assessment exercise and of letters the committee sends to investigators about the protocols reviewed during the observed meeting.

C. Analysis and Reporting

- ☐ Review the Analysis and Reporting section of the RECAT *Instructional Guide.*
- ☐ Review notes, audio-recordings (if collected) and completed *Assessment Tools*.
- ☐ As necessary, request any clarification or verification of the assessment team's findings via follow-up calls and or emails.
- ☐ Synthesize findings into a summary report using the *Reporting Template*. Report in a way that does not identify individuals, wherever possible.
- ☐ Share draft summary report with REC Chair and/or senior REC Administrator for comments and feedback.
- ☐ Incorporate feedback, finalize summary report and complete signature page. Make sure the institution receives a final copy of the summary report.

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Assessment Tool

Name of REC:		
Institution:		
Country:		
Dates of Assessment:		
Type of REC:	☐ Regional ☐ National ☐ Multiple Institution ☐ Single Institution	
Name of Assessor (s):		
	Interviews:	
Participants in Assessment:	Institutional Official:	
	REC Chair:	
	REC Administrator:	
	Focus Groups:	**Number of Participants (N)**
	REC Members:	
	Researchers:	

Part A

REC Context

Method: Interview with REC Chair or Administrator

The questions in this section provide background information on the national and institutional context in which the REC functions, as well as the history and current work portfolio of the REC. This section should be completed through an interview with the REC chair or administrator. Information can be supplemented if needed through document review.

A.1 National Context

1. Are there national policies[1] in your country about health research and/or human subjects research?
   - ☐ Yes: *(List policy names and ask for a copy and/or link if posted on a website)*
   - ☐ No
   - ☐ Don't know
   - ☐ Other: _____

   a**) If yes**, do national policies require ethics review of all or some human subjects research protocols?

   - ☐ *Yes, for ALL human subjects research*
   - ☐ *Yes, for SOME human subjects research (describe which types)* _____
   - ☐ No
   - ☐ Don't know
   - ☐ Other: _____

   b) **If yes**, do national policies require that all or some human subjects research protocols be reviewed by a national ethics committee, regardless of prior approval from an institutional REC?

   - ☐ Yes*, ALL human subjects research must be reviewed by the national ethics committee*
   - ☐ *Yes, SOME human subjects research must be reviewed by the national ethics committee (describe):*

     _____
   - ☐ No, there is no requirement for any research to be reviewed by a national ethics committee
   - ☐ Don't know
   - ☐ Other:

   c) **If yes,** is there a national institution/agency that monitors Human Subjects Research Activities in your country to ensure compliance with national policies regarding ethics review?

   - ☐ Yes (describe):_____
   - ☐ No
   - ☐ Don't know
   - ☐ Other: _____

[1] Note that for all parts of Question 1, "national policies" can be interpreted as inclusive of laws, regulation, guidelines, executive orders, etc. The relevant feature is that they are applicable at a national level.

2. Is there a national entity through which RECs are registered in your country?
   - ☐ Yes (name of entity):
   - ☐ No
   - ☐ Don't know
   - ☐ Other: _____

A.2 Institutional Context

3. Does the institution have a written policy that requires that human subjects research protocols be reviewed by an ethics committee?
   - ☐ Yes (*ask for a copy*)
   - ☐ No
   - ☐ Don't know
   - ☐ Other: _____

4. Does the institution audit approved human subjects research activities after they are approved?
   - ☐ Yes (describe for what purpose, e.g., compliance with institutional policies?):_____
   - ☐ No
   - ☐ Don't know
   - ☐ Other: _____

5. Is there an individual (Dean, Associate Dean, Director, etc.) who serves as the "Institutional Official" responsible for the formation, conduct, and oversight of human research at the institution?
   - ☐ Yes (title of individual):_____
   - ☐ No
   - ☐ Don't know
   - ☐ Other: _____

6. Does the institution have a policy or other mechanisms that require RECs to register through some formal registration system, such as national, regional, or international?
   - ☐ Yes: (describe) _____
   - ☐ No
   - ☐ Don't know
   - ☐ Other: _____

7. List all active registrations currently held by the REC, including national, regional, or international:

Name of Agency/Registering Body	**Registration Number**	**Date of registration** (mm/yyyy)
_____	_____	_____
_____	_____	_____
_____	_____	_____

A.3 REC Background

8. When was this REC established? year_____

9. Has the REC been operating continuously since it began?
   - ☐ Yes
   - ☐ No (Explain any periods of inactivity):
   - ☐ Don't know
   - ☐ Other: _____

10. Who appoints members of the REC?
    - ☐ Dean of Research or equivalent
    - ☐ Chair of REC
    - ☐ Members volunteer
    - ☐ Don't know
    - ☐ Other *(describe):*_____

11. Does the REC conduct scientific review as well as ethics review of research protocols?
    - ☐ Yes
    - ☐ No
    - ☐ Other:_____
    - ☐ Don't know

Research Portfolio

12. How many new research proposals were reviewed by the REC in the most recent year for which you have data?
    - ☐ 10 or Less
    - ☐ 11-25
    - ☐ 26-50
    - ☐ 51-100
    - ☐ 101-150
    - ☐ More than 150

    Year: _____

13. Of the protocols submitted to the REC in the most recent year, approximately what percentage of protocols submitted to the REC were:

    Student protocols from within the institution: _____
    Faculty/staff protocols originating from within the institution: _____
    Research collaborations with other institutions within country: _____
    Research collaborations with international institutions: _____
    Other: _____

14. Of the protocols submitted to the REC in the most recent year, approximately what percentage were funded by:

Funding Source	% of Protocols Submitted
The local or national government (of country where the REC is located)	
Non-governmental Organizations (local or international)	
International funders *(e.g. Wellcome Trust, NIH, EDCTP, UNAIDs)*	
Private, for profit company *(e.g. Multi-national Pharmaceutical Company)*	
No funding/self-funded *(e.g. self-funded student protocols or faculty use of discretionary funds)*	

15. Does the REC review clinical trials involving investigational drugs and/or medical devices?
    - ☐ Yes
    - ☐ No
    - ☐ Don't know
    - ☐ Other: _____

16. Does this REC review social science and behavioral research studies?
    - ☐ Yes
    - ☐ No
    - ☐ Don't know
    - ☐ Other: _____

17. How frequently is REC scheduled to meet to review research protocols?
    - ☐ Weekly
    - ☐ Bi-weekly
    - ☐ Monthly
    - ☐ Don't know
    - ☐ Other (specify): _____

18. How frequently are meeting cancelled or otherwise not held?
    - ☐ Almost never
    - ☐ About 25% of meetings
    - ☐ About 50% of meetings
    - ☐ About 75% of meetings
    - ☐ Almost always
    - ☐ Other: _____
    - ☐ Don't know

19. Does the REC allow for expedited review (by a single REC member) of certain types of research protocols?
    - ☐ Yes (*describe which types of protocols*):
    - ☐ No
    - ☐ Don't know
    - ☐ Other: _____

20. Of the protocols submitted to the REC in the most recent year, approximately what % were:

    Reviewed by a single member of the committee:_____
    Required to have a full committee review:_____
    Determined to require no review by committee:_____

21. Of the protocols submitted to the REC in the most recent year, approximately what proportion of protocols received the following decisions after first review:

    Full approval: _____
    Returned with questions (e.g. "tabled"):_____
    Disapproval (e.g. rejection):_____
    Other *(describe):* _____

22. Is there anything else about the background of this REC or the institutional context that would be important to know?

Part B

REC Policies

Method: Document review

Please use the following tables to document whether the REC has written policies or written standard operating procedures regarding each of the following:

B.1 Does the REC have written policies or standard operating procedures regarding the following aspects of committee membership?	**Yes**	**No**	**Comments**
1. The selection process of the chair and committee members			
2. The **term of appointment** of REC members			
3. The diversity of **professional backgrounds that should be represented on the committee**			
4. The diversity of gender that should be represented on the committee			
5. The required membership of someone with a non-scientific background			
6. The required membership of someone with **no affiliation to the organization that sponsors, funds, or conducts research** reviewed by the REC?			
7. The required quorum size for the committee to take actions and/or make decisions			
B.2 Does the REC have written policies or standard operating procedures regarding the following aspects of committee independence?	Yes	No	Comments
8. The required attendance of someone not affiliated with the institution during committee deliberations			
9. The extent to which investigators may participate in committee deliberations about **their own** research			
10. The definition of a conflict of interest for members of the committee			
11. The procedures through which **conflicts of interest will be addressed** when they arise			

B.3 Does the REC have written policies or standard operating procedures regarding the following aspects of <u>training for committee members?</u>	Yes	No	Comments
12. The required research ethics training for committee members			
13. The required refresher trainings for committee members during their term of service			
B.4 Does the REC have written policies or standard operating procedures regarding the following aspects of <u>committee decision-making?</u>	Yes	No	Comments
14. The types of studies for which expedited review mechanisms are allowed (if any)			
15. The process through which decisions are made (e.g. vote or consensus)			
16. The existing ethical guidelines (e.g. Declaration of Helsinki, The Belmont Report, CIOMS, etc.) that inform the ethical decision-making of the committee			
B.5 Does the REC have written policies or standard operating procedures regarding the following aspects of <u>administrative operations?</u>	Yes	No	Comments
17. The **confidentiality requirements** of REC members			
18. The **documents that are required for submissions** for ethical review			
19. The **documents that must be circulated prior to the meeting**			
20. The procedures for recording **meeting minutes**			
21. The **approval process for meeting minutes**			
22. The process for communicating **committee decisions** to researchers			
23. The process for post-approval **monitoring of protocols** (e.g. annual reviews)			
24. The **safety monitoring requirements** required for protocols involving more than minimal risk			
25. The procedures for **archiving committee documents** and communications			

Part C
REC Operations
Method: Site Visit to REC Administrative Office

*The questions in this section provide information on the **actual practices** of the REC (in contrast to written policies or standard operating procedures). They include both questions asked to the REC Administrator as well as, when possible, visual verification of the documents/systems in question. Visual verification should be noted where indicated on this form.*

C.1 REC Governance, Membership, and Participation

1. What is the typical length of time someone serves as an REC member?

   ☐ Less than 1 year
   ☐ 1-3 years
   ☐ 3-5 years
   ☐ More than 5 years
   ☐ Don't know
   ☐ Other: _____

2. Is there a maximum number of years a member can serve?

   ☐ Yes *(describe):*_____
   ☐ No
   ☐ Don't know
   ☐ Other: _____

3. Do all members rotate at the same time?

   ☐ Yes
   ☐ No (*describe):*_____
   ☐ Don't know
   ☐ Other:_____

4. What backgrounds are represented by current members of the REC?

Member Background	**Number of members**
Physicians	_____
Pharmacists	_____
Nurses	_____
Biomedical Scientists	_____
Social & Behavioral Scientists	_____
Lawyers	_____
Bioethicists	_____
Religious representatives/Theologians	_____
Community/Lay Representatives	_____
Biostatisticians	_____
Other (describe)_____	_____
Other (describe)_____	_____

5. How many members of the REC are:

   Male _____
   Female _____

6. At full review meetings, are REC actions ever taken during meetings in the **absence of** community/lay representative?

   ☐ Yes *(explain)*:_____
   ☐ No
   ☐ Don't know
   ☐ Other: _____

7. At full review meetings, are REC actions ever taken **when less than half of** REC members are present at a meeting?

   ☐ Yes *(explain)*:_____
   ☐ No
   ☐ Don't know
   ☐ Other: _____

C.2 REC resources

8. How are the operational costs of the REC funded? *(tick all that apply)*

   ☐ Institutional funding (allocated from the regular budget)
   ☐ Application fees and other charges
   ☐ Research Sponsor
   ☐ Other grants awarded to the institution
   ☐ Don't know
   ☐ Other: (describe)_____

9. Approximately how much of REC operational costs are supported by the institution's regular budget?

   ☐ Less than 50%
   ☐ More than 50%
   ☐ N/A (no regular budget funds allocated to REC operation)
   ☐ Don't know
   ☐ Other: _____

10. How many administrative staff does the REC Office have?

Number of full-time staff	Number of part-time staff

C.3 Training of REC members and investigators

11. Are **REC members** provided with any sort of training **BEFORE** their service?

☐ Yes
☐ No
☐ Don't know
☐ Other: _____

*a. **If yes**,* what type(s) of training opportunities have been provided to REC members before their service?

☐ Workshop/Seminar
☐ Online course (*please specify)*: _____
☐ Formal academic course
☐ Don't know
☐ Other (describe): _____

b. **If yes,** what does the training typically cover?

☐ REC operating procedures
☐ Research ethics principles and concepts
☐ Both operating procedures and research ethics principles and concepts
☐ Don't know
☐ Other:_____

c. **If yes,** how long is the average training activity?

☐ Less than one hour
☐ More than an hour, but less than one full work day
☐ One full work day
☐ More than one full work day, but less than one work week
☐ One work week
☐ More than one week
☐ Other (describe): _____

12. Are **REC members** provided with any sort of training **DURING** their service?

*a. **If yes**,* what type(s) of training opportunities have been provided to REC members during their service?

☐ Workshop/Seminar
☐ Online course *(please specify):*_____
☐ Formal academic course
☐ Don't know
☐ Other (describe): _____

b**. If yes,** what does the training typically cover?

☐ REC operating procedures
☐ Research ethics principles and concepts
☐ Both operating procedures and research ethics principles and concepts
☐ Don't know
☐ Other: _____

c. **If yes,** how long is the average training activity?

☐ Less than one hour
☐ More than an hour, but less than one full work day
☐ One full work day
☐ More than one full work day, but less than one work week
☐ One work week
☐ More than one week
☐ Other (describe): _____

d. **If yes,** how often are trainings offered to REC members?

☐ Several times a year
☐ Once every year
☐ Once every two years
☐ Less than once every two years

13. Approximately what % of the current REC members have had any training in research ethics, from any source, in the past 2 years? _____

☐ Less than 50% of members
☐ More than 50% of members
☐ Don't know
☐ Other: _____

14. Are ***investigators*** provided with any research ethics training?

☐ Yes
☐ No
☐ Don't know
☐ Other: _____

a. If yes, what type(s) of training opportunities are provided to investigators at your institution?

☐ Workshop/Seminar
☐ Online course *(please specify):*_____
☐ Formal academic course
☐ Don't know
☐ Other (describe): _____

b. If yes, what does the training typically cover?

☐ IRB operating procedures
☐ Research ethics principles and concepts
☐ Both operating procedures and research ethics principles and concepts
☐ Don't know:
☐ Other: _____

c. **If yes,** how long is the average training activity?

☐ Less than one hour
☐ More than an hour, but less than one full work day
☐ One full work day
☐ More than one full work day, but less than one work week
☐ One work week
☐ More than one week
☐ Other (describe): _____

d. If yes, how often are trainings offered to investigators?

☐ Only once, at time of appointment
☐ Once every 5 or more years
☐ Once every two years
☐ Once every year
☐ Several times a year

C.4 REC Transparency and Accountability.

15. Does your REC have a dedicated website?
    ☐ Yes *(provide web address)*: _____
    ☐ No
    ☐ Don't know
    ☐ Other: _____

16. Are REC annual reports publicly available?
    ☐ Yes
    ☐ No
    ☐ Don't know
    ☐ Other: _____

17. Are REC policies and procedures made readily available to researchers?
    ☐ Yes *(describe, e.g., website, provided hard copies, etc.)*:_____
    ☐ No
    ☐ Don't know
    ☐ Other: _____

18. Has the REC ever conducted a formal or informal performance/capacity/needs assessment in the past?
    ☐ Yes *(request copy of report if available)*
    ☐ No
    ☐ Don't know
    ☐ Other: _____

C.5 Description of REC Administrative Resources

Note: this section includes questions to be answered through interview with the REC administrator as well as opportunities to visually verify responses through observation during a site visit to the REC Office. Check the "observation" box where information is collected through observation. Check the "interview" if response is made through interview only and not visually verified. Check both if both "observation" and "interview" apply.

19. Does the REC have regular access to a confidential meeting space for committee meetings?

Response	Method
☐ Yes	☐ Observation
☐ No	☐ Interview
☐ Other: _____	

20. Does the REC have dedicated office space for its administrative staff?

Response	Method
☐ Yes	☐ Observation
☐ No	☐ Interview
☐ Other: _____	

21. Does the REC have a secure place for its research files (e.g. a lockable file cabinet)?

Response	Method
☐ Yes	☐ Observation
☐ No	☐ Interview
☐ Other: _____	

22. Which of the following resources does the REC Office have available (tick all that apply)?

	Observation	**Interview**			
Item	✓ If present day of assessment	Always available when needed	Sometimes not available	Never available	Not needed
Computer					
Internet access					
Printer					
Email address					
Telephones					
Photocopier					
Basic office supplies (stationery, ink, paper, files, etc.)					

C.6 Filing System

23. Does the REC have a filing system for all applications received?

Response	Method
☐ Yes	☐ Observation
☐ No	☐ Interview
☐ Other:	

a **. If yes,** is the filing system:

Sufficiently sized (can accommodate all files)	Yes No Other:	Observation Interview
Consistently used	Yes No Other:	Observation Interview
Easily searchable	Yes No Other:	Observation Interview

b**. If yes, LOOK AT FILES and note** what information is kept in the folder for each protocol?

☐ Original application form
☐ Original protocol documents
☐ Most recent/approved protocol documents (e.g. consent forms, recruitment scripts)
☐ Amendments
☐ Progress reports
☐ Ancillary reviews (e.g. scientific reviews, biosafety, pharmacy & therapeutics)
☐ Relevant Grants/contracts documenting funding source of the research
☐ Minutes of meetings when protocol reviewed
☐ Safety monitoring reports, if relevant to the protocol
☐ Problem events
☐ Research ethics training certificates of research team
☐ Other:_____
☐ Other:_____

C.7 Tracking System

24. Is there a tracking system available for office staff to track submissions to the REC as they move through the approval process?

Response	Method
☐ Yes	☐ Observation
☐ No	☐ Interview
☐ Other: _____	

a. **If yes,** what format is the tracking document?

☐ Paper-based
☐ Electronic
☐ Other: _____

b. **If yes**, how consistently is the tracking system used?

☐ Tracking system is up-to-date and consistently used
☐ Tracking system is regularly used, but with large gaps of time between updates
☐ Tracking system is available but is not routinely used
☐ Other: _____

c. **If yes, *LOOK AT TRACKING SYSTEM*** and note which of the following data fields are recorded:

☐ Date of submission
☐ Unique application number
☐ PI name
☐ Study title
☐ Initials of person recording the submission
☐ Submission type (e.g. new, amendment, progress report)
☐ Staff person assigned
☐ Reviewer assignment
☐ Process notes
☐ Date sent to reviewer
☐ Date received back
☐ Date of meeting where it was reviewed
☐ Final decision
☐ Correspondence dates with investigator
☐ Other: _____

C.8 Submission and Review Practices

25. Does the REC require investigators to submit a research plan or protocol with their application?

☐ Yes
☐ No
☐ Other: _____

a. If yes, what information is the investigator explicitly required to describe in the research plan? *(tick all that apply)*

☐ Aims of study
☐ Rationale for research
☐ Study design
☐ Participant sample
☐ Recruitment procedures
☐ Consent procedures
☐ Study implementation
☐ Storage of data collected
☐ Risks of the study
☐ Benefits of the study
☐ Payment to participants, if any
☐ Other:_____

b. If yes, does the REC have a template or checklist for investigators to use listing the required components of the research plan for their application?

Response

☐ Yes
☐ No
☐ Other: _____

Method

☐ Observation
☐ Interview

26. What are all of the documents that are required to be submitted with each new application? *(tick all that apply)*

☐ Full study protocol
☐ Protocol summary or research plan
☐ Consent materials
☐ Recruitment materials
☐ Research instruments (e.g. questionnaires, interview guides)
☐ Investigators' certificate of research ethics training
☐ Curriculum Vitae of Principal Investigator
☐ Detailed budget for study
☐ For drug/device studies, product information for investigational product
☐ Other (describe):_____

27. In the last 12 months, approximately what % of applications included all required documentation on the *first submission* of the application?

☐ More than 75%
☐ About 50% - 75%
☐ Less than 50%

28. Does any staff member of the REC office conduct a pre-review of submitted applications to see if the application is complete prior to scheduling an application for review?
    - ☐ Yes *(describe who does the review)*:_____
    - ☐ No

29. Does any staff member of the REC office conduct pre-review of the submitted applications prior to scheduling an application for review for **any other purpose**?
    - ☐ Yes, to determine eligibility for expedited review or exempt status
    - ☐ Yes, to determine whether applications qualify as Human Subjects Research
    - ☐ Other *(describe purpose):* _____
    - ☐ No, pre-review is not conducted for any other purpose.

30. Is each application assigned one or more primary reviewer(s)?
    - ☐ Yes
    - ☐ No
    - ☐ Other: _____

31. Is each application additionally assigned one or more secondary reviewers?
    - ☐ Yes
    - ☐ No
    - ☐ Other: _____

32. How regularly are agenda items made available to REC members **in advance** of REC meeting?
    - ☐ Always
    - ☐ Often
    - ☐ Rarely
    - ☐ Never

    a) **If yes,** how long in advance of each meeting are agenda items made available?
    - ☐ Less than 1 week
    - ☐ 1-week or more

    b) **If no**, are materials made available at the meeting itself?
    - ☐ Yes
    - ☐ No

33. How long, on average, do REC meetings run?
    - ☐ Less than 1 hour
    - ☐ 1- 2 hours
    - ☐ More than 2 hour but less than 3 hours
    - ☐ 3 hours
    - ☐ More than 3 hours

34. On average, how many **NEW** protocols are reviewed during each meeting?
    - ☐ 0-2 protocols
    - ☐ 3-5 protocols
    - ☐ 6-10 protocols
    - ☐ More than 10 protocols

35. Approximately how many **CONTINUING** protocols are reviewed during each meeting?

    ☐ 0-2 protocols
    ☐ 3-5 protocols
    ☐ 6-10 protocols
    ☐ More than 10 protocols

36. What is the approximate length of time between submission of a protocol to the REC and the completion of the first/initial review by the committee?

    ☐ Less than 1 month
    ☐ 1-2 months
    ☐ 3-4 months
    ☐ More than 4 months

C.9 Meeting Minutes

37. Are meeting minutes recorded for each meeting, either during the meeting itself or typed up from notes soon after the meeting?

    ☐ Yes *(describe who takes minutes and when*):_____
    ☐ No
    ☐ Other: _____

38. Is there a template for meeting minutes?

    ☐ Yes
    ☐ No
    ☐ Other: _____

    a. **If yes, *LOOK AT A SAMPLE of 3 meeting minutes*** and note what information is consistently recorded in meeting minutes:

	Meeting 1	Meeting 2	Meeting 3
Meeting date and time			
Attendance			
List of applications reviewed			
Issues of concern or deliberation			
Regulatory determinations (e.g. for devices or experimental drugs)			
Study product status (investigational, approved, etc.)?			
Review by consultants			
Review by pharmacologist, for drug studies			
Mention of consent procedures			
Actions taken for each protocol reviewed (*e.g. approval, conditional approval, table*)			

39. Does the REC require members to sign in on an attendance sheet?

    ☐ Yes
    ☐ No
    ☐ Other: _____

a. **If yes,** does anyone verify that the attendance recorded in the minutes matches the attendance sheet?

☐ Yes
☐ No
☐ Other: _____

b. **If yes,** does anyone verify that the votes recorded in the minutes reflect those in attendance during the vote?

☐ Yes
☐ No
☐ Other: _____

C.10 Communication Practices

40. Are letters/emails regularly sent to investigators following the meeting in which their protocol was reviewed?

☐ Yes
☐ No

a**. If yes,** how soon following meetings are letters sent to investigators?

☐ Less than 1 week later
☐ Within 1-2 weeks
☐ More than 2 weeks

b. **If yes**, is there a template for the approval letters sent to applicants following the review of a research protocol?

Response

☐ Yes
☐ No
☐ Other: _____

Method

☐ Observation
☐ Interview

c. ***If yes, LOOK AT A SAMPLE OF APPROVAL LETTERS SENT FROM THE REC OFFICE.*** What information is consistently present in the approval letter sent to applicants?

	Letter 1	Letter 2	Letter 3
Approval decision from REC			
Expiration date of approval, if granted			
Requirement that **any changes** to the approved research plan must **be submitted for review as an amendment**			
Requirement for the **prompt reporting of any adverse events** or unanticipated problems			
Requirement for the **prompt reporting of protocol deviations**			
Requirement for investigators to **use approved consent and data collection forms**			
Requirement for investigators to **use stamped consent and data collection forms**			
Requirement to **submit close out report** upon study completion			

41. Are investigators required to submit progress reports about approved research?

☐ Yes
☐ No
☐ Other: _____
☐ Don't know

a. **If yes,** how often are investigators required to submit progress reports about approved research?

☐ More than once per year
☐ Once per year
☐ Once, at the end of the study
☐ N/A (progress reports not required)
☐ Other:_____

b. **If yes**, what are the consequences for failing to submit progress reports? *(tick all that apply)*

☐ Investigator will receive reminder letters
☐ Ethics committee or designee will conduct a site visit
☐ Research may be stopped or interrupted
☐ Other:_____

42. Does the ethics committee or its designee conduct site visits to provide continuing oversight of approved research protocols?

☐ Yes, for all approved studies
☐ Yes, but only for some studies (*describe):*_____
☐ Not for any studies
☐ Other: _____

a. **If yes**, how frequently do site visits occur?

☐ More than once a year
☐ Once a year
☐ At least once during period of study
☐ Other: _____

C.11 Protocol Review Structure

43. Does the REC have a checklist of relevant ethical considerations to guide reviewers of research protocols?

Response	Method
☐ Yes	☐ Observation
☐ No	☐ Interview
☑ Other: _____	

a. **If yes, look at the template** and identify which of the following ethics review criteria are on the checklist? *(tick all that apply)*

☐ Scientific Validity
☐ Balanced Risks and Potential Benefits to Participants
☐ Appropriate consideration for stigma and social risks to participants
☐ Fair Selection and Recruitment of Subjects
☐ Justifiable Compensation of Subjects
☐ Adequate Privacy and Confidentiality Protections
☐ Adequate Informed Consent Process
☐ Adequate approaches to communicating with participants and communities during and after research
☐ Consideration for Community Interests (e.g., inclusion of community harms in risk assessments, respect for community structures during informed consent process, etc.)
☐ Responsiveness of research to local priorities
☐ Identified procedures for handling adverse events
☐ Appropriate qualification of researchers
☐ Other:_____
☐ Other:_____

Part D
REC Meeting
Method: Structured observation of REC Meeting

This Part includes three sections: (D.1) which captures contextual information related to the REC meeting observed; (D.2) which provides a Protocol Review Checklist that should be completed by the assessor during the observed REC meeting (one hardcopy of checklist is needed for each protocol reviewed during the meeting); and (D.3) which describes procedures for reviewing the outputs of the REC meeting. It is strongly advised to attempt to observe an REC meeting which includes, on the agenda, the review of different types of protocols – new protocols, re-submissions, continuing reviews, etc….

D.1 Meeting Context

Date:
Start Time:
Stop Time:
Number of New Protocols Reviewed:
Number of Continuing Review Protocols:

1. Did you (observer) receive a copy of agenda items?

☐ Yes
☐ No

Notes

2. Did you sign a confidentiality agreement as a guest?

☐ Yes
☐ No

Notes

3. Is your name on the agenda OR were you asked to sign in?

☐ Yes
☐ No

Notes

4. Did the meeting occur in a confidential room?

☐ Yes
☐ No

Notes

5. Members:

Member *(note names during meeting –consult meeting register/attendance sheet to confirm)*	Background *(clarify after meeting if necessary)*	M/F

6. Was there a non-scientific member present?

☐ Yes

☐ No

Notes

7. Was there a committee member unaffiliated with the institution present?

☐ Yes

☐ No

Notes

8. Was there a quorum present (were at least half of the members present)?

☐ Yes

☐ No

Notes

9. Were any non-members present (e.g., investigators whose protocols are under review, consultants, etc.)

☐ Yes

☐ No

Notes

10. Were conflicts of interest declared?

☐ Yes

☐ No

Notes

11. Did member who declared conflicts of interest participate in discussions of the items for which they had declared conflicts?

☐ Yes
☐ No
☐ N/A

Notes *(i.e., how were conflicts of interest addressed)*:

12. Were notes or minutes taken during the meeting?

☐ Yes
☐ No

Notes:

13. Was a checklist used to ensure consideration of relevant ethical decisions?

☐ Yes
☐ No

Notes:

14. How was a decision reached?

☐ Vote
☐ Consensus
☐ Other: _____

15. Other notes about the meeting:

D.2 Protocol Review Checklist

Complete one checklist for each protocol reviewed during meeting. Print out as many copies of the checklist as the number of protocols being reviewed on the agenda.

REC:		
Meeting Date:		
Protocol:		
START TIME:		**END TIME:**

1. **Type of Protocol:**

☐ New Protocol, 1st review ☐ New Protocol, 2nd or later review ☐ Continuing review ☐ Administrative changes ☐ Other: ____

2. Presenter *(tick all that apply)*:

☐ Primary reviewer ☐ Secondary reviewer ☐ Invited researcher ☐ Invited consultant ☐ Chair ☐ Other: _____

Were the following ethics considerations mentioned and/or discussed in the review?
(M=Mentioned by one person, D=Discussed by at least two people, N= Neither)

Consideration	**M**	**D**	**N**	**Notes**
Scientific design and conduct of study				
Risks and potential benefits				
Selection of study population				
Recruitment of research participants				
Inducements, financial benefits, and financial costs				
Protection of participants' privacy or confidentiality of data				
Informed consent process or wording				
Community considerations *(e.g. stigma, draining community capacity, or promotion of positive effects on communities)*				
Other				

D.3 Post Meeting Follow-up

The following questions pertain to REC practices that occur AFTER the conclusion of a meeting. It requires looking at copies of **meeting minutes** as well as decision **letters sent to investigators** describing the outcome of the review. The meeting minutes and letters reviewed should correspond to the same meeting. This section may be completed in one of two ways, depending on the feasibility for the assessor in the context of the evaluation:

OPTION 1: Prospective Assessment

For this option, the assessor should review the meeting minutes and letters sent to investigators pertaining to the same meeting that the assessor observed. Use this option if the assessor will remain in contact with the REC administrator and will be able to obtain copies of meeting minutes and communications to investigators when they are sent by the REC Office.

OPTION 2: Retrospective Assessment

*For this option, the assessor should review meeting minutes and letters sent to investigators pertaining to a previous meeting that the assessor did **not** observe. Use this option if it will not be feasible for the assessor to obtain copies of the minutes and REC communications to investigators that are generated from the meeting observed by the assessor.*

Note which option is used below:

☐ *Option 1: Prospective Assessment*
☐ *Option 2: Retrospective Assessment*

Date of Reference Meeting: _____

Meeting Minutes

16. How soon after the meeting were minutes approved?
    ☐ No minutes approved
    ☐ Within 1 week after the meeting
    ☐ Within 2 weeks after the meeting
    ☐ Within 1 month after the meeting
    ☐ More than 1 month after the meeting

17. Do the minutes seem to reflect an adequate record of the concerns, questions, and decisions voiced at the REC meeting?
    (Note: for prospective follow-up, the assessor can compare minutes generated against his/her own notes for the meeting. For retrospective assessment, the assessor should determine whether the minutes contain information about both the concerns and questions and well as decisions made, whether the concerns and questions reflect appropriate ethical considerations, and whether the decisions seem aligned with the nature of questions and concerns described.)

    ☐ Yes
    ☐ Partially
    ☐ No
    ☐ N/A (meeting minutes never produced)

    Notes:

Communications to Investigators:

18. How soon after the meeting were letters sent to the investigators whose applications were reviewed during the meeting?

☐ Within one week after the meeting
☐ Within two weeks after the meeting
☐ Within one month after the meeting
☐ More than one month after the meeting

LOOK AT A LETTER SENT REGARDING AN UNCONDITIONALLY APPROVED PROTOCOL reviewed during the meeting. If no protocol was approved during the meeting, check the box below and skip to question 21.

☐ No protocol was unconditionally approved during the meeting

19. Does the study approval decision match what was recorded in meeting minutes?

☐ Yes
☐ No
☐ N/A (no meeting minutes produced for meeting of reference)

20. What information is present in the letter?

☐ Approval decision from REC
☐ Expiration Date of approval
☐ Requirement that any changes to the approved research plan must be submitted for review as an amendment
☐ Requirement for the prompt reporting of any adverse events or unanticipated problems
☐ Requirement for the prompt reporting of protocol deviations
☐ Requirement for investigators to use approved, stamped consent forms

21. **LOOK AT A LETTER SENT REGARDING A PROTOCOL THAT WAS "APPROVED WITH CHANGES" or "TABLED". Mark which decision was made below. If no study was "Approved with Changes" or "Tabled" during the meeting, check the box below.**

☐ Approved with Changes
☐ Tabled
☐ No protocol was "Approved with Changes" or "Tabled" during the meeting

22. Do the concerns and requested changes described in the letter reflect what was recorded in the minutes?

☐ Yes
☐ Partially
☐ No
☐ N/A (no meeting minutes produced)

Notes:

Part E
REC Perceptions
Method: Interviews and Focus Groups with Key Stakeholders

This section is intended to be open-ended and provide an opportunity for additional stakeholders to comment on the needs and priorities of the REC. We recommend engaging three stakeholder groups in this part of the assessment: 1) the Dean of research or equivalent individual who is responsible for REC oversight, 2) REC members, and 3) investigators who submit applications to the REC. The following sets of questions are suggested interview/focus group guides that the assessor may use to facilitate discussion among different stakeholder groups.

E.1 Interview Guide - Dean/Institutional Leadership

Thank you for taking time to talk with me today. As you know, I am here as part of a needs assessment exercise to help strengthen your REC. I am interested in your perspective about the REC, its role in the institution, and the top issues you perceive as important for strengthening the REC in the future.

1. What is the history of the REC at this institution?
    a. What considerations went into the formation of the REC?
    b. How important do you view the role of the REC within the institution now?

2. What kinds of resources does the institution make available to the REC?
    a. In your view, are these resources adequate? Why or why not?

3. What do you think the REC is doing really well?

4. What do you think are some of the challenges REC members experience in fulfilling the work of the committee?

5. What do you think are some of the challenges REC administrative staff experience in fulfilling the work of the office?

6. What do you think are some of the challenges researchers experience in their interactions with the REC?

7. What are some things you think the institution could do to improve the quality and efficiency of the REC?
    a. First, what do you think you could do to improve the QUALITY of the REC?
    b. Now, what are some things you think the institution could do to improve the EFFICIENCY of the REC?

8. What changes would you like to see happen with respect to the REC?
    a. What would the REC need to make these changes happen?

9. Is there anything else that I haven't asked about that you would like say about research ethics committee review at your institution?

E.2 Focus Group Guide - REC Members

Thank you for taking time to talk with me today. As you know, I am here in as part of a needs assessment exercise to help strengthen your REC. I am interested in your perspective about the REC, its strengths and weaknesses, and the top issues you perceive as important for strengthening the REC in the future.

Background/Context

1. First, what do you feel are the roles of the REC? Do you think it serves its function(s)? Why/why not?
2. Do you think the written REC policies and procedures (e.g. Standard Operating Procedures) are adequate? Are there any that you would change?
3. What is your committee's relationship with other committee(s), if any others exist? Does anyone sit on more than one of the committees?
4. What major changes has the REC seen in the past two years? What caused those changes?
5. How independent do you think the committee's decisions are from the influence of outsiders (e.g. high-ranking institutional officials, well-known researchers, etc.)?

REC Composition

6. Is the REC capable of reviewing any type of research proposal? E.g., clinical drug trial, psycho-social study, interventional study, etc…. Do you think REC membership is adequately diverse?
    a. Where, if anywhere, is content-area expertise lacking in the committees?
7. Is community representation on the REC valuable? Do you think the REC has appropriate community representation? How does the REC recruit community representatives?
8. Do you think the REC has enough members? Too many?
9. How is REC membership 'turnover'?

Quality and Efficiency of REC Review

10. I'd like to hear any thoughts you might have on the quality of REC review. Do you feel like the review process adds something to the research being conducted? If yes, what does it add? If no, what is missing?
11. How would you describe the deliberations of the committee? Do you think everyone has an opportunity to contribute? Are interactions generally thoughtful and respectful?
12. During an average protocol review, what does the REC spend most of its time reviewing? (e.g. science, ethics, budget, researcher qualifications, etc…) Why are certain things emphasized over others?
13. How efficient do you feel the REC's administrative processes are? What are some obstacles to administrative efficiency?

REC Resources

14. Do you think the REC has adequate resources to do its work? What does it need and why?
    a. Material resources?
    b. Support staff?
    c. Compensation for time?

Researchers

15. How would you describe the REC's relationship with researchers?

16. How do you think researchers understand the role of the REC or what it does?

17. How well or poorly do you think that researchers know what they need to submit to the REC, how to submit it and when to submit it? How would a researcher learn this information?

18. Do you think that most research proposals that should be submitted to the REC are indeed submitted to the REC? Are there any reasons why you think researchers might be hesitant to submit proposals to the REC?

19. Could you tell me a little about the quality of the materials that are submitted by researchers to the REC? Are there parts of the submissions that are typically of lower quality (e.g., informed consent documents), and parts that are typically of higher quality (e.g., research methods)? Does the quality differ by the type/area of research?

Ethics Training

20. What sort of experiences have you had in the past with ethics training? Did those training experiences focus on things that facilitated your ability to conduct ethics review?

21. What additional training might help increase your ability to conduct REC review?

22. Does the REC help train researchers in research ethics? If so, how?

Perception of Strengths/Challenges

23. If you could ask the University administration to do one thing to improve the REC's ability to operate, what would that be?

24. What do you see as the committee's greatest strength?

25. What do you see as the committee's greatest challenges moving forward?

26. Is there anything else that you would like to say about the REC or research at your institution that I haven't asked about?

E.3 Focus Group Guide - Researchers who Submit Protocols to the REC

Thank you for taking time to talk with me today. I am here in as part of a needs assessment exercise to help strengthen your REC. As researchers who rely on the REC to conduct your work, I am interested in your experiences working with the REC, your perception of what is going well and what isn't, and your suggestions for strengthening the REC in the future.

1. Tell me about your interaction with the REC?
    a. Why do you submit protocols to this REC (e.g. institutional requirement, funder requirement, personal motivation)?
    b. Are there times when you don't submit? If so, why not?
    c. Do you ever consult the REC about a study before submitting an application?
    d. How frequently do you submit research protocols to the REC?
    e. What kinds of protocols do you submit?

2. How do you know whether it is required to submit an REC application for your research projects?
    a. What kinds of research ethics training have you received?
    b. Are you familiar with institutional policies and/or guidelines about research with human participants?
    c. Have you ever asked the REC whether you should submit a protocol for review?
    d. What do you do if you're not sure whether you should submit a protocol to the REC?

3. How clear are REC submission instructions?
    a. How did you find out what you needed to submit?
    b. Where do you look for guidance when preparing your application?
    c. What kinds of challenges, if any, did you experience in the submission process?

4. What kind of comments and requested changes have you received on your protocols?
    a. Did you understand them?
    b. Did they seem well justified?
    c. Did you think they were helpful and/or enhanced the quality of the study?

5. In your experience, approximately how long has it taken from the time you submit an application to the time you receive a decision from the REC?

6. What changes to the REC guidelines or operations would you recommend to improve the quality and efficiency of ethics review at your institution?
    a. First, what recommendations do you have to improve the **QUALITY** of ethics review?
    b. Now, what recommendations do you have to improve the **EFFICIENCY** of ethics review?

7. Is there anything else that you would like to say about the REC or research at your institution that I haven't asked about?

Research Ethics Committee Assessment Toolkit (RECAT)

Reporting Template

***

[Name of REC] **Needs Assessment**

REPORT

DATES OF ASSESSMENT _____

ASSESSORS _____

PARTICIPANTS _____

ASSESSMENT METHODS _____

INTRODUCTION

SUMMARY OF FINDINGS

1. **Quality of ethics review**

   Summary

   Recommendations

2. **Operational efficiency**

   Summary

   Recommendations

	DOMAIN	SUB-DOMAIN	EXPECTATIONS	OBSERVATIONS	RECOMMENDATIONS
1	**ESTABLISHMENT OF REC**	National Context	A national environment that promotes, supports and requires ethical review and continued oversight.		
2		Institutional Context	An institutional environment that supports and requires ethical review.		
3	**RESOURCES**	Human	Adequate resources to support operations.		
4		Other	Adequate resources to support operations.		
5	**TOOLS**	SOPs	SOPs available covering all essential operations.		
6		Application forms	REC should have comprehensive application forms to ensure that submissions are uniform and meet REC requirements.		

7		Review Form	REC should have a review checklist to ensure consistency and thoroughness of review.		
8		Other forms	REC should have forms for ensuring consistency in handling requests or reports.		
9		Approval letters	Comprehensive letter templates for various review outcomes.		
10	**MEMBERSHIP**	Professional backgrounds	Varied backgrounds.		
11		Training on review	Members trained in ethical review and other relevant topics.		
12	**DOCUMENTATION**	Filing system	An efficient filing system to ensure easy retrieval.		
13			Good document maintenance practices for each study/proposal.		
14		Document Storage	Adequate space for storage.		

15	**SERVICE TO CLIENTS**	Client Satisfaction	REC should ensure that researchers are generally satisfied by the service that it provides.		
16		Guidance to clients	Adequate guidance should be provided to researchers.		
17		Communication	Communications to researchers should be timely and responsive.		
18		Training in Research Ethics	Training in research ethics should be provided to research community.		
19	**RESEARCH MONITORING**	Active Monitoring	REC should actively monitor approved studies.		
20		Passive Monitoring	REC should have a system that allows for passive monitoring of studies.		
21		Tracking system	REC should have a tracking system for tracking all studies.		

22	**REC MEETING ISSUES**	Review procedures	REC review procedures should ensure thoroughness of review.		
23		Expedited processing	REC should have efficient and transparent expedited processing procedures.		
24		Preparation for meeting	Meeting should be planned ahead of time including invitations and availing of agenda.		
25		Meeting agenda	Agenda should cover all essential items that reflect on the operations of the REC.		
26		Confidentiality	REC should have measures to ensure confidentiality of meeting deliberations.		
27		Managing COI	REC should have measures for managing COI by its own members.		
28		Meeting space and atmosphere	Meeting space should be available and conducive.		

29		Content/ Discussion	REC members should be knowledgeable and conversant about ethical and scientific issues; meetings should provide for adequate time to deliberate on these issues.		
30		Decision making	REC should have a democratic way of reaching decisions.		
31		Proceedings	REC meetings need to be conducted in an orderly manner following the adopted agenda.		
32		Meeting minutes	Minutes should be prepared timely and should be detailed enough to reflect on deliberations.		

SIGNATURES:

Institutional Representatives *We the undersigned, confirm receipt of this report and accept the observations.*

	Official 1	**Official 2**
Full name	_____	_____
Capacity	_____	_____
Signature	_____	_____

Assessment Team Representatives *We the undersigned confirm that this report is based on our observations including documents that were made available during the assessment exercise.*

	Assessor 1	**Assessor 2**
Full Name	_____	_____
Signature	_____	_____
Date	_____	_____

Research Ethics Committee Assessment Toolkit (RECAT)
Sample Report

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XYZ Research Ethics Committee (XYZ REC) Needs Assessment

REPORT

DATES OF ASSESSMENT	4th – 7th March 2017
ASSESSORS	Dr. Nashwa Beatty (External Institution) and Mr. James Thompson (Independent Consultant/Offsite)
PARTICIPANTS	Prof. Apple (Dean, School of Health Sciences), Dr. Button (Deputy Dean, School of Medicine), Prof. Cello (Director, Office of Research), Dr. Delta (Asst. Director, Office of Research), Dr. Eagle (Biomedical REC Chair), Ms. Fiddle (REC Administrator), Ms. Ginger (REC Administrator), Mr. Hamper (REC Administrator)
ASSESSMENT METHODS	Interviews with institutional leadership (Dean, Deputy Dean, Director of Research, Assistant Director of Research, REC Chair); FGDs with 6 researchers and 9 REC members; REC meeting observation; document review; REC office observation

INTRODUCTION

Below is a report based on the assessors' findings from carrying out an REC Needs Assessment exercise focused on the XYZ University Research Ethics Committee (XYZ REC). We acknowledge and thank XYZ REC members and administrators, XYZ leaderships and researchers for their time, engagement and honest feedback. This exercise is intended as a benchmarking activity, providing a baseline that will allow stakeholders to evaluate the strengths and challenges faced by the XYZ REC at this point in time and later to revisit this process to measure progress and any persistent challenges. This evaluation was part of a pilot test of an REC Needs Assessment Tool that provides a systematic approach to assess and guide REC capacity building across a variety of institutional settings in low and middle-income countries. These results can serve as a baseline for future work with XYZ REC. The assessors note that these findings are the result of a rapid assessment and may not fully capture all relevant institutional factors. Thus, interpretation and subsequent action planning should involve local expertise at the institutional level. Further, the recommendations listed below are not triaged according to importance. Decisions about the ease of implementation and urgency of each recommendation may vary based on institutional context.

We first offer a summary of our findings within three domains of interest and recommendations for strengthening XYZ REC capacity based on a full report provided in the table following the domains. The table organizes observations documented during the assessment under key domains and describes recommendations for addressing current gaps.

SUMMARY OF FINDINGS

1. **Quality of ethics review**

Summary

Overall, the ethical review process runs smoothly and XYZ REC meetings involve substantive and nuanced discussions about scientific merit and ethical considerations of submitted research proposals. Assessors felt that members had adequate training in research ethics and work in an atmosphere conducive to thoughtful reviews. Ensuring that Research Ethics Committee (REC) Chair and Vice Chair have protected time to carry out expedited reviews as well as standardized templates and forms for all types of review and reporting are a few suggestions for improvement, with further suggestions listed below.

Recommendations

a. Need for XYZ to consider some protected time for the REC Chair and Vice Chair since they deal with a vast amount of expedited requests (see Row 2).
b. There is need for the REC to adopt additional tools such as continuing review forms, amendment request forms, Serious Adverse Event (SAE) reporting forms (see Row 8).
c. Approval letters need to clearly state reporting requirements/expectations (see Row 9)
d. Need to consider adding more female members to REC to ensure some gender balance (see Row 10)
e. Need to ensure that Research Ethics Training is provided to all staff (see Row 18)
f. REC needs to schedule more and regular study inspections (see Row 19).
g. REC needs to consider imposing penalties for late or non-renewals (see Row 20).
h. Agenda template needs updating to cover all REC activities (see Row 25).

2. **Operational efficiency**

Summary

XYZ REC receives and processes over 150 proposal submissions a year. Researchers and REC members reported being generally satisfied with how the REC functions. However, researchers, REC members and the assessors did note opportunities to improve the efficiency and organization of the administration office.

XYZ REC has Standard Operating Procedures (SOPs) that cover most of the areas that are covered by international standards for REC's. SOPs are however too brief in some areas to ensure consistency in their application. Review checklists and approval letters are also largely aligned with international standards, though some modification is recommended.

Recommendations

a. Need to strengthen relations with national REC at Ministry of Health to ensure national oversight (see Row 1).
b. REC reviewer checklist needs to be updated so it becomes more comprehensive (see Row 7).
c. Need to create permanent institutional REC positions (see Row 3)
d. REC support staff need to undergo training that addresses REC administration (see Row 3).
e. REC requires a dedicated webpage for uploading guidance information and forms (see Row 4).
f. REC SOPs need streamlining as well as to be more detailed. Guidance for researchers should be separated from SOPs (see Row 5).
g. Filing system requires improvement so that it becomes easy to locate files (see Row 12).

h. All documents in study files need to be numbered consecutively (folio numbering) to ensure document order and security (see Row 13).
i. Extra copies of study documents should be disposed appropriately after approval (see Row 14).
j. REC should ensure that comments to researchers are sent in a single batch so as to avoid inconveniencing researchers (see Row 15).
k. REC should make arrangements to facilitate pre-submission consultations (see Row 16).
l. Detailed guidance should be made available to researchers (see Row 16).
m. REC needs to create an electronic tracking system for tracking studies and submissions (see Row 21).

All expedited issues should be formally ratified during REC meeting and this should be documented in REC meeting minutes (see Rows 23 and 31).

FULL REPORT

	DOMAIN/SUB DOMAIN	SUB-DOMAIN	EXPECTATIONS	OBSERVATIONS	RECOMMENDATIONS
1	**ESTABLISHMENT OF REC**	National Context	A national environment that promotes, supports and requires ethical review and continued oversight	The Health Research Act of 2011 clearly states that all health research is supposed to be reviewed and approved by a REC. XYZ REC is nationally recognized and relied upon by other institutions as the REC of record. XYZ REC is represented on National Committee at Health Research Board. MOH Committee visited REC once in past three years to conduct an inspection. Communication between national Board and XYZ REC still minimal since structures are still being established at MOH.	Establish and maintain systematic communication between XYZ REC and the National Health Research Ethics Board to help ensure adequate national oversight of research ethics review.
2		Institutional Context	An institutional environment that supports and requires ethical review	REC is recognized institutionally as a standing committee, and is supported by institutional policy. REC members are appointed by the Vice Chancellor. REC operates semi-autonomously with no interference from management. Chair and Vice Chair process many requests for expedited protocols.	Chair and Vice Chair need protected time, especially as they process many requests for expedited review.
3	**RESOURCES**	Human	Adequate resources to support operations	REC is supported by one fulltime staff member who has not received adequate training on REC administration. REC administrator is employed by a large grant. The fact that the position is supported by an external grant implies weak institutional commitment. This also implies that the position may disappear in the event of termination of the project prematurely or at end of project life.	XYZ should consider creating permanent institutional position(s) for REC staff to ensure continuity of REC activities beyond the end of the project currently funding the REC Administrator position. XYZ could consider other options while lobbying for permanent institutional positions. REC support staff members need to receive relevant training.

4		Other	Adequate resources to support operations	REC is provided with resources such as space, computers, internet, photocopier etc.	REC Office would benefit from a dedicated webpage from which clients/researchers can download all up-to-date forms needed for submission and reporting on proposals and access information.
5	**TOOLS**	SOPs	SOPs available covering all essential operations.	SOPs Version III of 2015 cover all the essential areas of REC operation as per the assessment list.	SOPs are a combination of guidance for researchers and SOPs. Need to be streamlined and detailed so as to promote consistency in operations. Guidance for researchers should be presented separately from REC SOPs.
6		Application forms	REC should have comprehensive application forms to ensure that submissions are uniform and meet REC requirements.	Application forms are available for researchers, local students and foreign students	OK, although creation of a webpage where researchers and students could access forms would be desirable
7		Review Form	REC should have a review checklist to ensure consistency and thoroughness of review.	Review form is available to guide reviewers in ethical and scientific review. Form captures a variety of ethical issues, though not all areas listed in international standards.	REC reviewer checklist should be modified to include all important scientific and ethical aspects that the reviewers need to consider during review, to ensure each proposal is thoroughly and systematically reviewed and documented. For example for scientific issues, need to cover issues such as design, methods, sample size, sampling strategy, statistical considerations, data handling etc.

8		Other forms	REC should have forms for ensuring consistency in handling requests or reports.	The REC does not have the following forms that can assist researchers: continuing review, amendment, serious adverse event, protocol deviation.	It is recommended that the committee adopt additional reporting tools that can ensure improved oversight of ongoing research projects including continuing review form, amendment form, serious adverse event reporting forms, etc.
9		Approval letters	Comprehensive letter templates for various review outcomes.	Approval letter covers essential information such as reference, approval date and expiry date. But does not cover the need for researchers to report problem events such as protocol deviations, SAEs and unexpected problems.	Approval letters need to clearly state expectations on reporting of, protocol deviations and serious adverse events. Review the international standards for approval letters and consider incorporating additional items into approval letter templates.
10	**MEMBERSHIP**	Professional backgrounds	Varied backgrounds	Members represented various backgrounds. Five female members and ten male members. Two community representatives attended meeting.	Need to consider adding more female members to ensure gender balance.
11		Training on review	Members trained in ethical review and other relevant topics	Members are trained on appointment and are also provided with continuing training during their term of office.	OK
12	**DOCUMENTATION**	Filing system	An efficient filing system to ensure easy retrieval	REC uses a filing system that orders/numbers proposal by the month submitted and year. Information on submitted proposals is kept in MS-Word word documents.	Filing system can be improved to make it easy for administrator to provide information on submitted protocols e.g. using continuous numbers. Becomes hard to find a protocol if can't remember when it was initially reviewed. Would be very beneficial to create a comprehensive and searchable

					tracking system for protocol submissions.
13			Good document Maintenance practices for each study/proposal	Each proposal is filed in a separate file. Documents do not have folio numbers to ensure order of filing.	Need to ensure that all study documents are numbered consecutively (folio numbering) in the order in which they are received. This ensures document order and security and is part of good document filing practices.
14		Document Storage	Adequate space for storage	Additional filing space available in storage container. REC Filing room is secure. No shredder and too many duplicate documents kept on file. In some study files, there were three or four sets of the same actioned documents (e.g. study protocols).	Need to appropriately dispose unnecessary duplicate documents as a way of saving space. Recommend purchase of shredder.
15	**SERVICE TO CLIENTS**	Client Satisfaction	REC should ensure that researchers are satisfied by the service that it provides.	Researchers generally expressed satisfaction regarding the quality of feedback from REC. Encourage that REC should provide feedback once and avoid sending additional comments after researcher has responded.	REC members and admin should avoid sending additional comments after researcher has responded to initial comments.

16		Guidance to clients	Adequate guidance should be provided to researchers	A brief checklist is available to guide researchers on submission expectations. No detailed guidance is available to researchers on what REC expects. Few faculty have received training in research ethics.	REC should be available for pre-submission consultations, either through office hours, appointments, or some other mechanism. REC should find a way of ensuring that info on its expectations is disseminated to postgrads and researchers. Detailed guidance for researchers should be publicly available. REC should promote/facilitate training of faculty in research ethics.
17		Communication	Communications to researchers should be timely.	Communications to researchers are issued in a timely manner	OK
18		Training in Research Ethics	Training in research ethics should be provided to research community	Training is provided to postgraduate students. No training is provided to faculty/staff.	REC should facilitate/organize provision of training in research ethics for researchers and their teams.
19	**RESEARCH MONITORING**	Active Monitoring	REC should actively monitor approved studies.	REC at times engages in site inspections for large studies.	REC could schedule more site inspections.
20		Passive Monitoring	REC should have a system that allows for passive monitoring of studies.	No penalties for late renewal or non-renewal.	REC should consider imposing penalties for late or non-renewals.
21		Tracking system	REC should have a tracking system for tracking approved studies.	The REC does not have a tracking system and it is difficult for the Admin to know to provide information on processing of proposals.	REC should consider creating an electronic proposal tracking system.

22	**REC MEETING ISSUES**	Review procedures	REC review procedures should ensure thoroughness of review	Every proposal is sent for review to three REC members selected by Chair. Reviewers are thorough in their review as confirmed by detailed comments.	OK
23		Expedited processing	REC should have efficient and transparent expedited processing procedures.	Expedited protocols are included in REC agenda items, but are not discussed and formally ratified by the REC during the meeting.	Need to ensure that all expedited approvals are formally ratified during the REC meeting for accountability. The formal ratification should also be noted in the minutes.
24		Preparation for meeting	Meeting should be planned ahead of time including invitations and availing of agenda.	Meeting invitation and agenda are sent more than 1 week ahead of meeting.	OK
25		Meeting agenda	Agenda should cover all essential items that reflect on the operations of the REC.	Agenda is developed using a template and covers some of the essential items.	The template could be improved so that it reflects all the activities of the REC. Examples of items that need to be added to agenda template include training opportunities, study inspections, correspondence, REC statistics, report back from meetings, serious adverse events, etc. This may assist the REC in assessing how it is performing across its functions/activities.
26		Confidentiality	REC should have measures to ensure confidentiality of meeting deliberations.	Assessors completed confidentiality agreements and were introduced at start of meeting. All REC members sign confidentiality agreements upon appointment.	OK
27		Managing COI	REC should have measures for managing COI by its own members.	Members declare conflict of interest and recuse themselves from the meeting room during discussion of items on which they had COI.	OK

28		Meeting space and atmosphere	Meeting space should be available and conducive.	Meeting space is convenient and members are served with refreshments during meeting	OK
29		Content/ Discussion	REC members should be knowledgeable and conversant about ethical and scientific issues; meetings should provide for adequate time to deliberate on these issues.	Reviewers provided detailed comments on ethical and scientific issues. The REC spent an average of 8 minutes discussing each new proposal (REC spent 15 minutes discussing one of the proposals). Issues raised and discussed ranged from inclusion criteria, letters of permission, confidentiality, specimen issues, use of jargon in ICF, material transfer agreements, justification of study, statistical issues, referencing, risks and benefits, assent, community benefits, provision of results, reimbursements, translation of ICF, community benefits, registration of study drug with National authority.	OK
30		Decision making	REC should have a democratic way of reaching decisions.	Decisions are reached by consensus and all members were provided with opportunity to comment before reaching decision.	OK
31		Proceedings	REC meetings need to be conducted in an orderly manner following the adopted agenda.	Expedited issues were not ratified during the meeting. Focus was mainly on new proposals.	All expedited issues handled by Chair should be formally ratified by REC during the meeting and this should be documented in the minutes.
32		Meeting minutes	Minutes should be prepared timely and should be detailed enough to reflect on deliberations.	Meeting minutes were detailed and accurate as evidenced by the few corrections. Minutes are prepared using a template.	OK

SIGNATURES:

Institutional Representatives *We the undersigned, confirm receipt of this report and accept the observations.*

	Official 1	**Official 2**
Full name	_____	_____
Capacity	_____	_____
Signature	_____	_____

Assessment Team Representatives *We the undersigned confirm that this report is based on our observations including documents that were made available during the assessment exercise.*

	Assessor 1	**Assessor 2**
Full Name	_____	_____
Signature	_____	_____
Date	_____	_____