# MERETI Self-Assessment of Research Ethics Committees

## 1. Introduction

PURPOSE OF THE TOOL:
This self-assessment tool aims to assess the operations and functions of research ethics committees (RECs) against recognized international standards for RECs. Each question has been assigned a point value and therefore, your final score can be compared with an established average of other RECs in a similar stage of operation.

LENGTH OF SURVEY:
This survey should take about 30-60 minutes to complete.

CONFIDENTIALITY:
The responses you give on this survey will be anonymous and hence, the data will remain confidential. We will aggregate the data with data collected on other surveys. Any materials published will be in aggregate form.

Benefits: We will aggregate the data with data collected from other surveys. Any materials published will be in aggregate form and will contribute to an emerging database that will help inform other RECs

CONTACT INFORMATION: For further information about this survey , you can contact
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If you desire to continue, please click on the "next" button.

## 2. Organizational Aspects (Maximum 52 points)

1. What year was the REC established?

2. How often does the REC meet as a full committee to review research studies?

- ◯ once/week
- ◯ twice/month
- ◯ once/month
- ◯ every two months
- ◯ other
- ◯ has not yet met to review protocol

3. Is it required that the REC register with a national authority, for example, the Ministry of Health or another regulatory body?

- ◯ Yes
- ◯ No

4. Was the REC established under the authority of a high institutional official and reports to that office (e.g., President, Vice President, Dean)?

- ◯ Yes
- ◯ No

5. If yes to Q#4, what is the position of the high institutional official?

6. Does the REC have written Standard Operating Procedures?

- ◯ Yes
- ◯ No

7. Does the REC makes clear the specific ethical guidelines it uses to review research?

- ◯ Yes
- ◯ No

8. If Yes to question #6, which of the following guidelines does it use?

- ☐ Its own National Guidelines
- ☐ CIOMS (Council for International Organizations of Medical Sciences
- ☐ International Conference on Harmonization (ICH)
- ☐ Declaration of Helsinki
- ☐ Belmont Report
- ☐ U.S. 45 Code of Federal Regulations 46

Other (please specify)

9. Does the REC have a policy that outlines the process for appointing the REC Chair?

- ◯ Yes
- ◯ No

10. Which of the following criteria are used to select the Chair of the REC (check all that apply)

- ☐ prior training in ethics
- ☐ prior research experience
- ☐ no specific requirements
- ☐ Other (please describe)

11. Does the REC have a policy that describes the process for appointing the members of the REC and details the membership requirements and the terms of appointment?

- ◯ Yes
- ◯ No

12. Which of the following criteria is used to select REC members (check all that apply)

- [ ] prior training in ethics
- [ ] prior research experience
- [ ] no specific requirements
- [ ] Other (please describe)

13. Does the REC have a policy for disclosure and management of potential conflicts of interest for the members of the REC?

- ◯ Yes
- ◯ No

14. Does the REC have a policy for disclosure and management of potential conflicts of interest for members of the research team?

- ◯ Yes
- ◯ No

15. Does the REC have a quality improvement (QI) program for itself?

- ◯ Yes
- ◯ No

If yes, describe what was done in the last year and any changes that were made as a result of the QI program

16. Does the institution regularly evaluate the operations of the REC (e.g., budgetary, needs adequacy of material resources, adequacy of policies and procedures and practices, appropriateness of the membership given the research being reviewed, and documentation of the training requirements of the REC members)?

- ◯ Yes
- ◯ No

17. Does the REC have a mechanism whereby enrolled research participants can file complaints or direct questions regarding human subjects protection issues?

- ◯ Yes
- ◯ No

If yes, please describe the mechanism

18. How are records of the REC stored (please check only one)?

- ◯ Paper folders in a locked file cabinet
- ◯ Electronic in a password protected computer
- ◯ On an open shelf
- ◯ Other

19. Quorum: Does the REC require that there be a certain number of members present in order to make the meeting official?

- ◯ Yes
- ◯ No

## 3. MEMBERSHIP AND EDUCATIONAL TRAINING (Maximum 32 points)

1. How many members are there on the REC?

enter number here

2. Please indicate the gender distribution:

How many members are women?

How many members are men?

3. Are high ranking officials not allowed to act as chair or as a member of the REC, thus ensuring that the REC can make independent decisions?

- ◯ Yes
- ◯ No

4. Are any of the members not affiliated with the institution?
(A person is not affiliated if he/she is not employed by the institution and is not related to a person who is employed)?

- ◯ Yes
- ◯ No

5. Are any of the members considered to be a non-scientist?
(A Non-Scientific Member is any member who does not have a terminal degree in a medical or scientific field).

Please note that one member may fulfill both criteria of a non-scientist and a non-affiliated person. If this is the case, please check "Yes" for this question and for #3 above.

- ◯ Yes
- ◯ No

6. Are any lay people (members of the community) a member of the REC?

- ◯ Yes
- ◯ No

7. Is there a requirement that the REC chair (or the designee who is in charge of running the committee) has any prior formal training in research ethics?

- ◯ yes
- ◯ no

8. If yes, what type of training is required (check all that applies)?

- ☐ web-based training
- ☐ workshop in research ethics
- ☐ course

Other (please describe)

9. Does the institution require that REC members have training in research ethics in order to be a member of the REC?

- ◯ yes
- ◯ no

10. If yes, what type of training is required (check all that applies)?

- ☐ web-based training
- ☐ workshop in research ethics
- ☐ course

Other (please describe)

11. Does the institution require that investigators have training in research ethics in order to submit protocols for review by the REC?

- ◯ Yes
- ◯ No

12. If yes, what type of training is required (check all that applies)?

- [ ] web-based training
- [ ] workshop in research ethics
- [ ] lecture
- [ ] course

Other (please describe)

13. Does the REC conduct continuing education in research ethics for its members on a regular basis?

- ( ) yes
- ( ) no

14. Does the REC document in writing the training that its members have received in research ethics?

- ( ) yes
- ( ) no

## 4. SUBMISSION ARRANGEMENTS (Max 12 points)

**Does the REC have a policy on any of the following items?**

1. Written guidelines for the submission of protocols to the REC?

- ◯ Yes
- ◯ No

2. A requirement for investigators to use a specific application form for them to submit their protocols to the REC?

- ◯ yes
- ◯ no

3. A requirement that investigators follow an informed consent template that helps guide investigators in the writing of informed consent forms?

- ◯ yes
- ◯ no

4. A requirement that the department chair (or another individual) approve and sign off on the research protocol prior to submission to the REC?

- ◯ Yes
- ◯ No

5. A deadline by which investigators need to submit protocols (e.g., two weeks prior to the next REC meeting)?

- ◯ Yes
- ◯ No

6. SUBMISSION MATERIALS

Which of the following items are requested from the Principal Investigators when they submit their research protocols to the REC?

| | Yes | No |
|---|---|---|
| Full protocol | ○ | ○ |
| Informed consent form | ○ | ○ |
| Investigator's qualifications [e.g., CV, medical license, etc.] | ○ | ○ |
| Conflict of interests disclosure forms for members of the research team | ○ | ○ |
| Recruitment material (e.g., advertisements, signs, posters, etc), when applicable | ○ | ○ |
| Questionnaires/surveys that will be used in the research, when applicable | ○ | ○ |
| Investigator Drug Brochure or materials describing the nature of the drug being used in a clinical trial, when applicable | ○ | ○ |

## 5. MINUTES (Maximum 13 points)

1. Does the REC maintain minutes of each meeting?

- ◯ yes
- ◯ no

**If minutes are kept, please indicate which of the following are documented in the "minutes"**

2. Members were asked whether they had a conflict of interest regarding any of the protocols that will be reviewed and that such members did not participate in the decision on the relevant protocols?

- ◯ Yes
- ◯ No

3. A quorum was present for all actions requiring a decision?

- ◯ Yes
- ◯ No

4. All actions requiring a decision included at least one scientist (i.e., participated in the review and voted on the action)?

- ◯ Yes
- ◯ No

5. All actions requiring a decision included at least one non-scientist?

- ◯ Yes
- ◯ No

6. All actions requiring a decision included at least one person who is not affiliated with the institution?

- ◯ Yes
- ◯ No

7. The names of REC members who abstained from a vote and a reason abstaining?

- ◯ Yes
- ◯ No

8. The names of REC members who were excused from any action requiring a decision due to a conflict of interest?

- ◯ Yes
- ◯ No

9. A discussion of the controversial aspects of the research protocol, when applicable?

- ◯ Yes
- ◯ No

## 6. **POLICIES: Is there a policy regarding each of the following items** (11 points)

1. How protocols will be reviewed?

- ◯ Yes
- ◯ No

2. Obtaining the services of a consultant when necessary to provide specific expertise for review of a particular protocol?

- ◯ Yes
- ◯ No

3. A requirement that REC members receive the protocol and other materials at a specified time prior to the meeting?

- ◯ Yes
- ◯ No

4. A requirement that the reviewers use a checklist to document their ethical assessment of the research submission?

- ◯ Yes
- ◯ No

5. The conditions for expedited REC review?

- ◯ Yes
- ◯ No

6. The conditions for when studies may qualify for exempt status?

- ◯ Yes
- ◯ No

7. That the interval of continuing review is based on the risk of the study?

- ◯ Yes
- ◯ No

8. How decisions are made (e.g., consensus or a vote)?

- ◯ Yes
- ◯ No

9. Whether REC members are asked at the beginning of each meeting if they have a conflict of interest regarding any of the protocols to be discussed?

- ◯ Yes
- ◯ No

10. A process regarding communicating REC decisions to principal investigators?

- ◯ Yes
- ◯ No

11. Does the REC have a policy that details the process for early termination and suspension of protocols?

- ◯ Yes
- ◯ No

## 7. Scientific Design and Conduct of the Study (Maximum 3 points)

**Which of the following items regarding Scientific Design and Study Conduct are reviewed by the REC?**

1. The suitability of the investigators' qualifications to conduct the study?

- ◯ Yes
- ◯ No

2. The adequacy of the clinical site, including the supporting staff, available facilities, and emergency procedures?

- ◯ Yes
- ◯ No

3. Prior scientific reviews performed by another committee; or, if such reviews are not available, does the REC determine whether the study design is adequate to address the objectives of the study, the appropriateness of the statistical methodology, and the potential for addressing the objectives with the smallest number of research participants?

- ◯ Yes
- ◯ No

## 8. Considerations of Risks and Benefits (Maximum 6 points)

**Which of the following items does the REC review or evaluate?**

1. The different risks of the research protocol?

- ◯ Yes
- ◯ No

2. Whether risks have been minimized?

- ◯ Yes
- ◯ No

3. Whether the risks are greater than minimal risk based on a written definition of minimal risk?

- ◯ Yes
- ◯ No

4. The potential benefits of the research to the participants?

- ◯ Yes
- ◯ No

5. The importance of the knowledge to society that may reasonably be expected to result from the research?

- ◯ Yes
- ◯ No

6. Whether the risks to research participants are reasonable in relation to any anticipated benefits to participants and the importance of the knowledge to be gained to society?

- ◯ Yes
- ◯ No

## 9. Selection of Research Participants (Maximum 6 points)

**Which of the following items does the REC review or evaluate?**

1. The investigators' plans to identify and recruit potential participants?

- ◯ Yes
- ◯ No

2. Whether the recruitment plans ensure that the selection of subjects will be equitable with regards to gender, religion, and ethnicity?

- ◯ Yes
- ◯ No

3. Whether any of the potential participants are from vulnerable groups, (such as, children, prisoners, persons with mental disabilities, or persons who are economically or educationally disadvantaged)?

- ◯ Yes
- ◯ No

4. The justification for including vulnerable populations in the research?

- ◯ Yes
- ◯ No

5. Whether additional safeguards are needed for vulnerable persons that will further protect their rights and welfare?

- ◯ Yes
- ◯ No

6. The appropriateness of any financial or other incentives offered to participants for their participation in the research?

- ◯ Yes
- ◯ No

## 10. Privacy and Confidentiality (Maximum 2 points)

**Which of the following items does the REC review or evaluate?**

1. Whether the setting in which participants are recruited protects their privacy?

- ◯ Yes
- ◯ No

2. The methods for protecting the confidentiality of the collected research data?

- ◯ Yes
- ◯ No

## 11. Comunity Consultation (Maximum 3 points)

**Which of the following items does the REC review or evaluate?**

1. Whether the potential benefits of the research are relevant to the health needs of the local community/country and whether any successful study product will be reasonably available to the concerned communities after the research?

- ◯ Yes
- ◯ No

2. Whether any successful study product will be reasonably available to the concerned communities after the research is performed?

- ◯ Yes
- ◯ No

3. Whether the community was consulted regarding the design and implementation of the research, if applicable?

- ◯ Yes
- ◯ No

## 12. Safety Monitoring, Research Related Injury, and Pediatric Research (Maximum 3 points)

**Which of the following items does the REC review or evaluate?**

1. Whether the research plan, when applicable, includes adequate provisions for monitoring the data collected to ensure the safety of subjects?

- ◯ Yes
- ◯ No

2. Whether the sponsors of the research have adequate insurance to cover the treatments of injury related to the research?

- ◯ Yes
- ◯ No

3. The need to obtain the child's assent in pediatric research?

- ◯ Yes
- ◯ No

## 13. Informed Consent (Maximum 5 points)

**Which of the following items does the REC review or evaluate?**

1. The process by which informed consent will be obtained?
For example, how do investigators identify potential subjects, where does the informed consent process take place, are potential subjects allowed to take the consent form home and are participants given enough time to ask questions, etc.?

- ◯ Yes
- ◯ No

2. Which members of the research team will approach potential participants for their informed consent?

- ◯ Yes
- ◯ No

3. Whether the informed consent document is understandable to the subject population?

Suggested ways to assess the comprehension of the consent form include:
• evaluate the reading level of the consent document
• have a community member read the consent form
• require investigators to assess the subject's
understanding of the consent form

- ◯ Yes
- ◯ No

4. Whether the requirement to obtain informed consent can be waived that is based on written criteria?

- ◯ Yes
- ◯ No

5. Whether the requirement to have a written signature on the informed consent document can be waived that is based on written criteria?

- ◯ Yes
- ◯ No

## 14. Basic Elements of Informed Consent (Maximum 15 points)

1. Does the REC evaluate whether the informed consent form contains the following basic elements of informed consent?

| | Yes | No |
|---|---|---|
| A statement that the study involves research. | ○ | ○ |
| An explanation of the purposes of the research. | ○ | ○ |
| The expected duration of the subject's participation. | ○ | ○ |
| A description of the study's procedures to be followed. | ○ | ○ |
| Identification of any experimental procedures. | ○ | ○ |
| A description of any reasonably foreseeable risks or discomforts to the participant. | ○ | ○ |
| A description of any benefits to the participant or to society that might reasonably be expected from the research. | ○ | ○ |
| A disclosure of appropriate alternative treatments that might be available to participants if they decline to participate in the study. | ○ | ○ |
| A statement describing the extent to which the data will be kept confidential. | ○ | ○ |

| | Yes | No |
|---|---|---|
| For research involving more than minimal risk, an explanation as to whether any treatments are available if injury occurs. | ○ | ○ |
| An explanation of whom to contact for questions about the research. | ○ | ○ |
| An explanation of whom to contact for questions about research participants' rights. | ○ | ○ |
| A statement that participation is voluntary. | ○ | ○ |
| A statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled. | ○ | ○ |
| A statement that participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled. | ○ | ○ |

## 15. COMMUNICATION A DECISION (APPROVAL LETTER) Maximum 5 points

**This section involves questions regarding the approval letter that is sent to the PI. If your REC does not send an approval letter to the investigator, please skip this section.**

**Which of the following items are in the approval letter?**

1. An expiration date for the conduct of the research that is 1 year from the date of the convened REC meeting in which the study was approved.

- ◯ Yes
- ◯ No

2. That investigators are required to submit to the REC any changes that occur in the research plan; for example, change in investigators, change in drug doses, change in the sample size, etc.

- ◯ Yes
- ◯ No

3. That investigators are required to promptly report to the REC any serious adverse events (SAEs).

- ◯ Yes
- ◯ No

4. That investigators are required to promptly report to the REC any protocol violations.

- ◯ Yes
- ◯ No

5. That investigators are required to use the REC-approved informed consent form that is stamped with an expiration date.

- ◯ Yes
- ◯ No

## 16. CONTINUING REVIEW (Maximum 16 points)

1. Does the REC request a continuing review report from the investigators at least once a year?

- ◯ Yes
- ◯ No

**If yes, then please proceed to the section below.**

2. Which of the following items are requested in the continuing review report?

| | Yes | No |
|---|---|---|
| Number of participants enrolled. | ○ | ○ |
| Gender, ethnic, or religious breakdown of enrolled participants. | ○ | ○ |
| Number of participants withdrawn from the research by the investigators. | ○ | ○ |
| The reasons why participants were withdrawn from the study. | ○ | ○ |
| Number of participants who decided to drop out of the research. | ○ | ○ |
| The reasons why participants dropped out. | ○ | ○ |
| Verification that informed consent was obtained from all participants and that all signed consent forms are on file. | ○ | ○ |
| Number and description of serious adverse events (SAEs) in the previous year. | ○ | ○ |
| List of any protocol violations or deviations. | ○ | ○ |
| Submission of any safety monitoring reports. | ○ | ○ |
| If the study is completed, then a final report is submitted describing the study results. | ○ | ○ |

## 17. REC RESOURCES (Maximum 16 points)

1. Does the REC have its own budget?

- ◯ Yes
- ◯ No

2. If there is a budget, are monies designated for training of administrative staff and REC members?

- ◯ Yes
- ◯ No

3. Please check below the following resources available to the REC (check all that apply)

- ☐ access to a meeting room
- ☐ access to a computer and printer
- ☐ access to the internet
- ☐ access to a fax machine
- ☐ access to cabinets for storage of the protocol files

4. Does the REC have an administrative staff assigned to the REC?

- ◯ yes
- ◯ no

5. If yes, then choose one of the below:

- ◯ The administrative staff is full-time
- ◯ The administrative staff is half-time
- ◯ None of the above

## 18. Work Load of the REC

1. Average number of protocols reviewed annually?

2. Average number of clinical trials reviewed annually?

3. Average number of survey/interview studies reviewed annually?

4. Average number of epidemiologic/observational studies reviewed annually?

5. Average duration of the REC meetings.

## 19. Evaluation of Self-Assessment Tool

1. Assessment

Please choose the best answer for each of the following statements.

| | Strongly Agree | Agree | Uncertain | Disagree | Strongly Disagree |
|---|---|---|---|---|---|
| The time to complete this survey was reasonable. | ○ | ○ | ○ | ○ | ○ |
| The instructions were easy to follow. | ○ | ○ | ○ | ○ | ○ |
| The questions were clear and understandable. | ○ | ○ | ○ | ○ | ○ |
| The questions on the survey were appropriate. | ○ | ○ | ○ | ○ | ○ |
| This survey will produce useful information. | ○ | ○ | ○ | ○ | ○ |

2. Please select the choice that best represents the time it took to complete this survey:

- ○ less than 30 minutes
- ○ between 30 and 60 minutes
- ○ between 1 and 2 hours
- ○ greater than 2 hours

3. Which items on the survey are not important?

4. What other items should be on the survey?

5. Please add any additional comments

20. Thank you for completing this survey!!!