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Development of an Accessible Self-Assessment Tool for Research Ethics Committees in Developing Countries

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Abstract

In response to increased research being performed in developing countries, many research ethics committees (RECs) have been established, but the quality of their ethics review systems remains unknown. Evaluating the performance of an REC remains a challenging task. Absent an accreditation process, a self-assessment mechanism would provide RECs a way to review their policies and processes against recognized international standards. We describe a self-assessment tool that was developed and reviewed by REC members and researchers from the Middle East. This tool reflects pragmatic aspects of human subjects protection, is based on international standards, is straightforward in its completion, and its items are relevant to the administrative processes that exist in many RECs in the developing world.

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Keywords

research ethics committees; developing countries; human subjects protections; self-assessment; accreditation; Institutional Review Board

Research involving human subjects has increased in the developing world, including the Middle East (Normile, 2008). Accordingly, several international organizations have developed ethical standards for carrying out biomedical research involving human participants (Council for International Organizations of Medical Sciences [CIOMS], 2002; Nuffield Council on Bioethics, 2002; World Medical Association, 2008). Despite these guidelines, commentators have expressed concerns that the intensification of research activities has not been accompanied by a corresponding increase in research ethics capacity in the developing world (Bhutta, 2002; Hyder et al., 2004; Nuffield Council on Bioethics, 2002). For example, several studies have demonstrated insufficient ethics capacity among investigators in the Eastern Mediterranean Region (Abdur Rab et al., 2008; Abou-Zeid, Afzal, & Silverman, 2006). Furthermore, several studies have shown that ethics review systems in the developing world, such as Institutional Review Boards (IRBs) or Research Ethics Committees (RECs), face challenges that prevent their optimal functioning. For example, Sleem, El-Kamary, and Silverman (2010) showed that barriers to the effective functioning of RECs in Egypt include insufficient training of members, lack of diverse membership, and limited resources. At the national level, Abou-Zeid, Afzal, and Silverman (2009) surveyed the National Bioethics Committees (NBCs) in the Eastern Mediterranean (EM) Region and showed that of those NBCs involved in research ethics activities, only 25% of the members and 20% of the Chairs had research ethics training. Studies from other developing countries have also shown that the functioning of RECs is hindered by inadequate training of members, lack of member diversity, scarcity of resources, and lack of national regulations (Kirigia, Wambebe, & Baba-Moussal, 2005; Milford, Wassenaar, & Slack, 2006; Moodley & Myer, 2007; Nyika et al., 2009a, 2009b).

These examples of insufficient research ethics capacity have been highlighted by recent research-related scandals with occasionally tragic consequences (Krishnakumar, 2010; Willyard, 2007).

Accordingly, there has been a growing interest in establishing mechanisms to regulate and assess the operations and functions of RECs. Such efforts have included IRB registration coupled with audits or accreditation processes that assess IRB compliance with established regulations. For example, in the United States, the Office of Human Research Protections (OHRP) is the regulatory body responsible for compliance with the U.S. regulations for Protection of Human Subjects (Office for Human Research Protections, 2005). Institutions engaged in federally funded human subjects research are required to provide written Assurances of Compliance to OHRP that describe the means the institution will employ to comply with the U.S. regulations and IRBs are required to register with OHRP. Similarly, the U.S. Food and Drug Administration (FDA) has jurisdiction over human clinical studies involving pharmaceuticals and medical devices (Food & Drug Administration, 2010). Both OHRP and FDA enforce their regulations by conducting inspections of investigational sites and records of IRBs, sponsors, and principal investigators. In addition to these regulatory bodies, an accreditation effort has been instituted by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). This private organization evaluates an institution’s Human Research Protection Program, including its IRB(s); accreditation is voluntary (Association for the Accreditation of Human Research Protection Programs, 2001). In the United Kingdom, the National Research Ethics Service has developed an

accreditation scheme that includes IRB registration, self-assessment, and regular audits of the IRBs (National Research Ethics Service, 2007).

There are several examples of accreditation efforts in the developing world. The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) established a two-step process for accreditation (Strategic Initiative for Developing Capacity in Ethical Review [SIDCER], 2002). The first step involves an REC self-assessment process followed by an external survey mechanism. The survey includes interviews, assessment of documents and procedures, observation of the facilities, and observation of a full-board REC committee meeting. In South Africa and Nigeria, national regulations require RECs to register with their respective National Health Research Ethics Committees (National Health Research Ethics Committee, 2008; National Health Research Ethics Council, 2003). There are also plans to conduct regular audits of the registered RECs that are based on these countries' guidelines for medical research. Finally, Jordan's Law of Clinical Studies requires IRBs to register with the Jordan Food and Drug Administration to ensure that they are meeting requirements related to members' diversity and qualifications; regular audits are not performed (Al-Khateeb, 2008; Jordan Food & Drug Administration, 2001).

Since only a few countries have a legal or regulatory framework for clinical research, an accreditation process consisting of an external review mechanism based on national standards is problematic for many countries in the developing world. Alternatively, one can conduct performance assessments of RECs to ensure the protection of human subjects and efficiency of REC functioning. Evaluating the performance of an REC, however, remains a challenging task. While there are no gold standards for determining effectiveness, suggested measures for assessing performance have focused on objective process indicators, such as turnaround times for research submissions and communications between RECs and investigators; as well as study-specific outcomes, including the number of protocols reviewed, the type of research reviewed, and the frequency of reported adverse events (Burke, 2005; Wolf, Croughan, & Lo, 2002). Other attempts to measure performance have been based on subjective assessments by stakeholders in the research process, such as investigators and members of the RECs (Feldman & Rebholz, 2009; Gray, Cooke, & Tannenbaum, 1978; Rothstein & Phuong, 2007). There have also been attempts to evaluate RECs by the use of external observers (Fauriel et al., 2004; Fitzgerald, Phillips, & Yule, 2006). Finally, a self-assessment method might help RECs evaluate their performances and demonstrate to their stakeholders the legitimacy of their review mechanisms.

Several such self-assessment instruments are available. For example, the Office for Human Research Protections offers a self-assessment tool as part of its Quality Assurance/Quality Improvement Program (Office for Human Research Protections, 2005). However, this tool is mainly based on the U.S. regulations for human subjects protection and, hence, might not be applicable to RECs in developing countries. Similar concerns regarding applicability also apply to the self-assessment tool used by the UK's National Research Ethics Service. WHO/TDR has published two guidelines, "Operational Guidelines for Ethics Committees That Review Biomedical Research" and "Surveying and Evaluating Ethical Review Practices" (WHO/TDR, 2000, 2002). However, the former publication is overly detailed in some subject areas (e.g., "communicating a decision" and "follow-up") and it leaves out important items relevant to REC functioning (e.g., resources and elements of informed consent and continuing review). The latter publication mainly serves as an aid for conducting a process for surveying RECs, including the types of documents to be reviewed. The previously mentioned SIDCER also offers a self-assessment tool, but their tool is long and includes many elements that might not be relevant to human subjects protection. Indeed, several commentators have voiced concerns that the oversight of RECs has been characterized by increasing requirements for meticulous documentation of compliance with regulations that

are unrelated to harms of research participants (Fost & Levine, 2007). It is therefore of little surprise that many requirements imposed by various self-assessment tools and accreditation process have little relationship to the protection of human research participants.

To achieve a more accessible self-assessment tool for RECs, we describe herein the process we undertook to develop such a tool. Our major goal was to develop a self-assessment tool that would reflect pragmatic aspects of human subjects protection, be based on international standards, be straightforward in its completion, and be relevant to the administrative process that exist in many RECs during their early stage of development.

Methods

The design of the self-assessment tool went through two different phases.

Initial Development

The trainees of the Summer 2009 Middle East Research Training Initiative (MERETI) Ethics Training Program formed a Working Group to design an initial draft of a self-assessment tool. The MERETI Program, sponsored by the Fogarty International Center of the NIH, offers a twelve-month certificate course that includes a two-month academic program held at the University of Maryland in Baltimore, followed by distance-learning opportunities (Middle East Research Ethics Training Initiative [MERETI], 2004). This group, comprised of six physicians and one pharmacist, represent researchers and REC members from the Middle East (Egypt, Jordan, Libya, and Saudi Arabia).

The Working Group relied upon several sources to develop its initial draft, which included the following resources: (a) the self-assessment tool used by SIDCER (Strategic Initiative for Developing Capacity in Ethical Review [SIDCER], 2002), (b) the self-assessment tool on the website of the Office of Human Research Protections (Office for Human Research Protections, 2005), and (c) the standards listed in WHO/TDR's Operational Guidelines for Ethics Committees That Review Biomedical Research (World Health Organization [WHO], 2000). Other sources included the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects (Council for International Organizations of Medical Sciences [CIOMS], 2002), the ICH Guidelines for Good Clinical Practice (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use [ICH], 1997), and the AAHRPP standards (Association for the Accreditation of Human Research Protection Programs, 2001).

The initial aim of the Working Group was to use elements that would measure the effectiveness of REC performance in terms of protecting the rights and welfare of research participants. However, there are no gold standards for determining effectiveness nor are there standards that can actually measure how well human participants are being protected by the use of standards. Instead, the working group considered standards that incorporate surrogate metrics considered foundational for effectiveness and protection. Such standards consisted of elements that refer to the following:

- Policies (e.g., dealing with conflict of interest and establishment of the REC)
- Structural elements (e.g., membership composition)
- Processes (e.g., submission of protocols, communicating a decision)
- Performance measures (e.g., consideration of certain ethical criteria in the review of protocols)
- Human, financial, and material resources.

Final Development

After development of the draft tool, the Working Group sent the tool to bioethics experts and Chairs of RECs in the Middle East (Sudan and Egypt) and asked them the following questions: (a) “Which items are not clear?” (b) “Which items are not important?” and (c) “What other items should be included?” We then presented the self-assessment tool to participants attending the 3rd Egyptian Network of Research Ethics Committees held in December 2009 for their general feedback. After incorporating relevant comments into the final draft of the tool, two of the authors (HJS and HS) weighted and assigned a point value to each element of the standards, which was subsequently reviewed by the other co-authors.

Results

Many of our reviewers submitted helpful comments to revise the initial draft of the tool. These included clarification of several terms (e.g., non-affiliated member, non-scientist); questioning of several items (e.g., importance of having the signature of the department chair on the submission form); and addition of several items (e.g., whether RECs have dedicated resources and whether the REC used a specific checklist in their review of research).

The final self-assessment tool is shown in Appendix A. The tool is divided into the following categories: (a) Organizational Aspects, (b) Membership and Educational Training, (c) Submission Arrangements and Materials, (d) Minutes, (e) Review Procedures, (f) Communicating a Decision, (g) Continuing Review, and (h) REC Resources. The tool shows the points assigned to each of the elements. We assigned 1, 2, or 5 points to each element. A maximum point score of 5 was assigned to those elements that we believed represent significant aspects of effective functioning for RECs. The maximum achievable point total is 200 points.

Discussion

The assurance of protections for research participants requires the establishment of standards for ethical review as well as the evaluation of the performance of RECs against such standards. In response to the increased conduct of clinical trials in the developing world, many RECs have been organized in many institutions. However, the extent to which they function is largely unknown. Ideally, the presence of a formal, external review mechanism can help evaluate and provide feedback to RECs. An accreditation process has been established by several organizations to evaluate RECs (Association for the Accreditation of Human Research Protection Programs, 2001; Strategic Initiative for Developing Capacity in Ethical Review [SIDCER], 2002), but the establishment of formal methods of accrediting RECs requires the acceptance and authority of an external body. Alternatively, a national regulatory body can institute an accreditation process. However, in many countries in the developing world, such regulatory bodies have yet to undertake such an active role in accrediting RECs. In the absence of an external body to perform evaluation and accreditation, an important intermediary step would constitute a self-review mechanism. Accordingly, we have developed a self-assessment tool by which RECs can evaluate their practices and appraise their performance against standards that were drawn primarily from international standards.

To be sure, other self-assessment instruments have been developed. For example, the OHRP has a QA self-assessment tool, but this tool is mainly based on the U.S. regulations and, hence, might not be applicable to countries that refer to international regulations. Also, this tool is lengthy (19 pages) and includes many elements that might not be relevant to human subjects protection. Other self-assessment tools include those developed by SIDCER, the

United Kingdom's NHS, and AAHRP. These tools also suffer from being lengthy and also contain many elements not relevant to human subjects protection.

A major goal of our project was to develop a tool that would be relevant to the early stages of REC development that exist in most of the institutions in the developing countries. Accordingly, such a tool should include standards that are important in the achievement of the protection of research participants, yet avoid including those standards that represent narrow interpretations of guidelines that are not relevant to studies being conducted in their institutions. Also, the inclusion of too many detailed elements would make the use of such a tool overly burdensome to complete. Commentators have voiced concerns that the oversight of RECs has been characterized by increasing requirements for meticulous documentation of compliance with regulations that are unrelated to harms to research participants (Fost & Levine, 2007).

A major limitation of the use of a self-assessment tool is the objectivity and accuracy with which an REC would have in completing such a tool. Such a limitation, however, is inherent in any attempt at quality improvement. It is difficult to know whether an REC's use of our developed tool to evaluate and revise their practices achieves a level of human subject protection that would compare with the use of any of the previously mentioned longer self-assessment tools. Without a gold standard for effectiveness, such a comparison would be difficult to achieve. However, we believe that the elements contained in our developed tool capture the essential aspects of a functioning REC. As such, we do not believe that obtaining a high score on our tool would provide a false sense of reassurance of an REC's functioning. Although our self-assessment tool (as similar to the other self-assessment tools) does not measure directly the effects of an REC on human subjects protections, we have included standards that evaluate surrogate indices of functioning, which include the presence of policies, structural elements, review processes, and resources.

Our major goal was to ensure that RECs would actually use some kind of self-assessment tool that would help them evaluate and enhance their operations. As such, our tool is only nine pages long and, hence, would not be overly burdensome to complete. Also, our use of a scoring system would allow other RECs to gauge how they compare with the aggregate scores obtained from other RECs in their region. Such a scoring system is lacking in the previously mentioned self-assessment tools. Finally, our tool may also serve as a useful guide to assist National Regulatory Bodies or Ministries of Health in developing their own accrediting standards.

Best Practices

The self-assessment tool developed for RECs represents a quality improvement process, whereby such committees can obtain a measure of the appropriateness of their policies and processes in reviewing research that is based on recognized international standards. Such a process would enable RECs to ensure that they achieve best practices regarding their policies on conflicts of interest, membership requirements, education requirements for their members, review requirements, meeting requirements, and communications with other stakeholders involved in the research endeavor. Such a quality improvement process would enhance the public trust in the performance of research.

Research Agenda

While we had several Chairs of RECs review this tool and offer feedback, the next logical step would be to have several RECs use the tool, and thereby obtain more generalizable data on the usefulness of such a tool in assessing and enhancing REC operational performance. Also, feedback from a range of different RECs would be instrumental in understanding

better the relevance of the items on the self-assessment tool, thereby resulting in a product that gains more universal acceptance. Furthermore, since the individual items of the self-assessment tool have been scored, it would be possible to obtain aggregate data from different RECs. Such data would serve as a benchmark from which individual RECs can compare their results. Accordingly, we have plans to conduct an anonymous web-based study collecting the self-assessments of different RECs in the Middle East. Such a study would provide additional support for the instrument's validity and utility. We welcome collaborators from the other regions of the world.

Educational Implications

The use of a self-assessment tool provides several educational opportunities. First, its individual use can provide RECs a better understanding of the necessary changes they need to incorporate in their policies, processes, and educational requirements of their members. Second, the collection of aggregate data would provide national policymakers and international organizations an opportunity to better understand the state of affairs regarding the maturity and functionality of RECs in the developing world. Such information can help with the allocation of necessary resources as well as the development of educational opportunities that can optimize the functionality of these RECs.

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Biographies

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Appendix A: Research Ethics Committee (REC) Quality Assurance Self-Assessment Tool

The maximum total number of points is 200.

For ‘yes/no’ questions, points are given for a ‘yes’ response.

ORGANIZATIONAL ASPECTS (Maximum 54 POINTS)

What year was the REC established? _____

1. Is the REC subject to registration with a national authority? ___ Yes ___ No **2 points**
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

For meeting frequency equal or greater than once/month, 1 point

3. Was the REC established under a high ranking authority (e.g., President's office, Ministry of Health, etc.)? ___ Yes ___ No — **5 points**

4. Does the REC have written Standard Operating Procedures? __ Yes __ No — **5 points**

5. Does the REC have a policy that outlines the process for appointing the REC Chair? ___ Yes ___ No — **2 points**

6. Which of the following criteria are used to select the Chair of the REC? (Check all that apply.)

   ___ prior training in ethics — **1 point**

   ___ publication in ethics — **1 point**

   ___ prior research experience — **1 point**

   ___ other (please describe) _____

7. 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 — **2 points**

8. Which of the following criteria are used to select REC members? (Check all that apply.)

   ___ prior training in ethics — **1 point**

   ___ publication in ethics — **1 point**

   ___ prior research experience — **1 point**

   ___ other (please describe) _____

9. Does the REC have a policy for disclosure and management of potential conflicts of interest for the members of the REC? ___ Yes ___ No — **5 points**

10. Does the REC have a policy for disclosure and management of potential conflicts of interest for members of the research team? ___ Yes ___ No — **5 points**

11. Does the REC have a quality improvement (QI) program for itself? ___ Yes ___ No — **5 points**

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

12. Does the institution/organization 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 — **5 points**

13. Does the REC have a mechanism whereby enrolled research participants can file complaints or direct questions regarding human subjects protection issues? ___ Yes ___ No — **5 points**

    If yes, please describe the mechanism.
    _____

14. How are records of the REC stored? — **(1 point maximum)**

    ____ Paper folders in a locked file cabinet — **1 point**

    ____ Electronic in a password-protected computer — **1 point**

    ____ On an open shelf ____ Other

15. Quorum: Does the REC require that there be a certain number of members present in order to make the meeting official to review protocols? ___ Yes ___ No — **5 points**

MEMBERSHIP AND EDUCATIONAL TRAINING (Maximum 30 POINTS)

1. How many members are there on the REC? ____ — **If ≥ 5 members, 2 points**

2. How many are women? _____ How many are men? ____

If female/male gender ratio is between 0.4 and 0.6, then 2 points

3. Are any of the members not affiliated with the institution, that is, the member is not employed by the institution and is not related to a person who is employed? ___ Yes ___ No — **2 points**

4. Are any of the members considered to be a non-scientist? ___Yes ___ No (A **Non-Scientific Member** is any member who does not have a terminal degree in a medical or scientific field.) — **2 points**

Please note that one member may fulfill both criteria of non-scientist and non-affiliated, in which case, please check Yes for both #3 and #4.

5. 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 **5 points**

   If yes, what type of training is required? (Check all that apply.)

   ___ web-based training ___ workshop in research ethics

   ___ course ___ other (please describe) _____

6. Does the institution require that REC members have training in research ethics in order to be a member of the REC? ___ Yes ___ No **5 points**

   If yes, what type of training is required? (Check all that apply.)

   ___ web-based training ___ workshop in research ethics

   ___ course ___ other (please describe) _____

7. Does the institution require that investigators have training in research ethics in order to submit protocols for review by the REC? ___ Yes ___ No **5 points**

   If yes, what type of training is required? (Check all that apply.)

   ___ web-based training ___ workshop in research ethics

   ___ lecture ___ course

   ___ other (please describe) _____

8. Does the REC conduct continuing education in research ethics for its members on a regular basis? ___ Yes ___ No **5 points**

9. Does the REC document the human subjects protection training received by its members? ___ Yes ___ No **2 points**

SUBMISSION ARRANGEMENTS AND MATERIALS (Maximum 12 POINTS)

Submission Arrangements of Research Protocols	**1 point each**	
Item	**Yes**	**No**
Does the REC publish guidelines for submission of applications for the review by the REC?		
Does the REC require investigators to use a specific application form for the submission of their protocols to the REC?		
Does the REC have an informed consent template to help guide investigators in the writing of their informed consent forms?		
Does the REC require approval and signature of the department chair (or another individual) of the research protocol prior to the submission?		
Does the REC require a deadline for investigators to submit protocols for full committee review?		

Submission Materials		
Which of the following items are requested from the Principal Investigators when they submit their research protocol to the REC?	**1 point each**	
Item	**Yes**	**No**
Full protocol		
Informed consent form		
Investigator's qualifications [e.g., CV, medical license(s), etc.]		
Conflict of interests disclosure forms for members of the research team		
Recruitment material (e.g., advertisements, signs, posters, etc.), if applicable		

Submission Materials		
Which of the following items are requested from the Principal Investigators when they submit their research protocol to the REC?	**1 point each**	
Item	**Yes**	**No**
Questionnaires/surveys that will be used in the research, if applicable		
Investigators' Drug Brochure or materials describing the nature of the drug being used in a clinical trial, if applicable		

MINUTES (Maximum 13 POINTS)

Does the REC maintain minutes of each meeting? ___Yes ___No	**5 points**	
If minutes are kept, please answer the following questions regarding the minutes.	**1 point each**	
Item	**Yes**	**No**
Do the minutes reflect that members were asked whether they had a conflict of interest regarding any of the protocols to be discussed and indicate that such members did not participate in the decision making process of the relevant protocols?		
Do the minutes document that a quorum was present for all actions requiring a decision?		
Do the minutes document that all actions included at least one scientist in the review and participated in the decision making process?		
Do the minutes document that all actions included at least one non-scientist in the review who participated in the decision making process?		
Do the minutes document that all actions included at least one person who is not affiliated with the institution in the review and participated in the decision making process?		
Do the minutes record the name of REC members who abstained from the decision making process and provided the reason for abstention?		
Do the minutes record the name of REC members who were excused from the discussion and decision making process due to a conflict of interest?		
Do the minutes reflect, when applicable, a discussion of the controversial aspects of the research protocol?		

POLICIES REFERRING TO REVIEW PROCEDURES (Maximum 11 POINTS)

Policies Referring to Review Procedures	**1 point each**	
Item	**Yes**	**No**
Does the REC have a policy regarding how protocols will be reviewed?		
Does the REC bring in a consultant when necessary to provide scientific or other relevant expertise for review of a particular protocol?		
Do REC members receive the protocol and other materials at a specified time prior to the meeting?		
Does the REC require that reviewers use a checklist to document their ethical assessment of the research submission?		
Does the REC have a policy on the conditions for expedited REC review?		
Does the REC have a policy on the conditions for when studies may qualify for exempt status?		
Does the REC determine the interval of continuing review based on the risk of the study?		
Does the REC have a policy for how decisions are made (e.g., consensus or a vote)?		

Policies Referring to Review Procedures	1 point each	
Item	**Yes**	**No**
Are members asked at the beginning interest regarding any the meeting as to whether they had a conflict of the protocols to be discussed and indicate that such members did not participate in the decision on the relevant protocols?		
Does the REC have a policy for communicating a decision?		
Does the REC have a policy for follow-up review?		

REVIEW OF SPECIFIC PROTOCOL ITEMS (Maximum 43 POINTS)

Scientific Design and Conduct of the Study	1 point each	
Item	**Yes**	**No**
Does the REC review the suitability of the investigators' qualifications to conduct the study?		
Does the REC review the adequacy of the clinical site, including the supporting staff, available facilities, and emergency procedures?		
Does the REC take into account prior scientific reviews or do they review the appropriateness of the study design in relation to the objectives of the study, the statistical methodology, and the potential for addressing the objectives with the smallest number of research participants?		

Considerations of Risks and Benefits	1 point each	
Item	**Yes**	**No**
Does the REC identify the different risks of the research protocol?		
Does the REC determine whether risks have been minimized?		
Does the REC determine whether the risks are greater than minimal risk based on a written definition of minimal risk?		
Does the REC evaluate the probable benefits of the research to the participants?		
Does the REC evaluate the importance of the knowledge to society that may reasonably be expected to result from the research?		
Does the REC evaluate 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 by society?		

Selection of Research Participants	1 point each	
Item	**Yes**	**No**
Does the REC review the methods to identify and recruit potential participants?		
Does the REC review recruitment processes to ensure that the selection of subjects will be equitable in regards to gender, religion, and ethnicity?		
Does the REC identify the potential of the research for enrolling participants who are likely to be vulnerable to coercion or undue influence (such as children, prisoners, persons with mental disabilities, or persons who are economically or educationally disadvantaged)?		
Does the REC consider the justification for including vulnerable populations in the research?		
Does the REC consider and require that additional safeguards be included in the study to protect the rights and welfare of the subjects?		

Selection of Research Participants	**1 point each**	
Item	**Yes**	**No**
Does the REC consider the appropriateness of any financial or material incentives offered to participants for their participation in the research?		

Privacy and Confidentiality	**1 point each**	
Item	**Yes**	**No**
Does the REC preserve privacy by evaluating the setting in which participants are recruited?		
Does the REC evaluate the methods for protecting the confidentiality of the collected research data?		

Community Consultation	**1 point each**	
Item	**Yes**	**No**
Does the REC review whether the potential benefits of the research are relevant to the health needs of the local community/country?		
Does the REC review whether any successful study product will be reasonably available to the concerned communities after the research?		
Does the REC review whether the community was consulted regarding the design and implementation of the research, if applicable?		

Safety Monitoring and Adequacy of Insurance to Cover Research-Related Injury	**1 point each**	
Item	**Yes**	**No**
Does the REC require, when appropriate, that the research plan include adequate provisions for monitoring the data collected to ensure the safety of subjects?		
Does the REC consider whether the sponsors of the research have adequate insurance to cover the treatments of injury related to the research?		

Pediatric Research	**1 point each**	
Item	**Yes**	**No**
Does the REC evaluate the need to obtain the child's assent?		

Informed Consent	**1 point each**	
Item	**Yes**	**No**
Does the REC review the process by which informed consent will be obtained (e.g., 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 given enough time to ask questions, etc.)?		
Does the REC review which members of the research team will approach potential participants for their informed consent?		
Does the REC ensure that the informed consent document is understandable to the subject population?		

Informed Consent	**1 point each**	
Item	**Yes**	**No**
Suggested ways to assess the consent form might include: • evaluate the reading level of the consent document • have a community member read the consent form • require investigators to assess subjects' understanding of the consent form		
Does the REC waive the requirement to obtain informed consent that is based on written criteria?		
Does the REC waive the requirement to have a written signature on the informed consent document that is based on written criteria?		

Basic Elements of Informed Consent		
Does the REC evaluate whether informed consent forms contain the following basic elements of informed consent?	**1 point each**	
Item	**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 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 others that might reasonably be expected from the research		
A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject		
A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained		
For research involving more than minimal risk, an explanation as to whether any medical treatments are available if injury occurs and, if so, what the treatments consist of or where further information may be obtained		
An explanation of whom to contact for answers to pertinent questions about research		
An explanation of whom to contact for answers to pertinent 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		

COMMUNICATING A DECISION (APPROVAL LETTER) Maximum 5 POINTS

Please answer the following questions regarding the approval letter sent to the PI. If no approval letter is sent to the investigator, please skip this section.

Which of the following items are in the approval letter?	**1 point each**	
Item	**Yes**	**No**
Provide an expiration date that is 1 year from the date of the convened REC meeting in which the study was approved.		
Require the investigators to submit to the REC as an amendment any changes that occur in the research plan; for example, change in investigators, change in drug doses, change in the sample size, etc.		
Require the investigators to promptly report to the REC any adverse events or unanticipated problems.		
Require the investigators to promptly report to the REC any protocol deviations.		
Require investigators to use the REC-approved informed consent form that is stamped with an expiration date.		

CONTINUING REVIEW (Maximum 16 POINTS)

Does the REC request a continuing review report from the investigators on at least a yearly basis? ___Yes ___No	**5 points**	
If yes, which of the following items are requested in the continuing review report?	**1 point each**	
Item	**Yes**	**No**
Number of subjects enrolled		
Gender and ethnic/religious breakdown of enrolled subjects		
Number of subjects withdrawn from the research by the investigators		
The reasons for withdrawal		
Number of subjects who dropped out of the research		
The reasons why subjects dropped out		
Verification that informed consent was obtained from all subjects and that all signed consent forms are on file		
Number and description of serious adverse events in the previous year (SAEs)		
List of any protocol violations or deviations		
Any safety monitoring reports		
If the study is completed, submit a final report describing the study results.		

REC RESOURCES (Maximum 16 POINTS)

1. Does the REC(s) have its own yearly budget? __ Yes __ No **5 points**

   If yes, is there a budget for training of administrative staff and REC members? __ Yes __ No **1 point**

2. Please check below the physical resources of the REC (check all that apply): **1 point each**

   __ access to a meeting room

   __ access to a computer and printer

   __ access to the internet

   __ access to a facsimile

   __ access to cabinets for storage of the protocol files

3. Does the REC have administrative staff assigned to the REC? __ Yes __ No **5 points**

   If yes: Is the person full-time? __ Yes __ No

   Is the person half-time? __ Yes __ No

WORKLOAD OF THE REC (0 POINTS)

Average number of protocols reviewed annually? _____

Average number of clinical trials reviewed annually? _____

Average number of epidemiologic/observational studies reviewed annually? _____

After a brief review of three recent REC minutes, complete the following table with a specific number or N/A (not applicable).

REC Workload Table	1st Meeting	2nd Meeting	3rd Meeting
Duration of the meeting			
Number of new protocols reviewed by full committee			
Number of protocols disapproved			
Number of continuing review protocols approved by expedited review that were reported to the REC			
Number of continuing review protocols reviewed by full committee			
Number of amendments approved by expedited review that were reported to the REC			
Number of amendments reviewed by full committee			
Number of adverse reactions reviewed by full committee			