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A Case-study of the Resources and Functioning of Two Research Ethics Committees in Western India

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Introduction

As the number of clinical trials being conducted in low to middle income countries (LMICs) increases so is the demand for research ethics committees (RECs) (also known as institutional ethics committees or, in western settings, institutional review boards) that provide quality ethical oversight[1] (Glickman et al., 2009). The importance of competent committees and comprehensive standards for REC functioning in LMICs is highlighted in the literature (Adams et al., 2014; Chenneville et al., 2014; Makhoul et al., 2014; Matar & Silverman, 2013; Silverman, Edwards, Shamoo, & Matar, 2013; Silverman & Sleem, 2014; Silverman et al., 2014). Nonetheless, concerns remain. Previous studies suggest that researchers lack confidence in the quality of REC reviews, have concerns about the actual protection of human research participants (Keith-Spiegel, Koocher, & Tabachnick, 2006; Shaw, 2011), and consider strict procedural compliance required by RECs to sometimes be unreasonable or unfair (Giles, 2005; Keith-Spiegel & Koocher, 2005). Other concerns about REC functioning in LMICs include the inadequate diversity of membership, the lack of financial support and resources provided by institutions, the limited capacity of ethics committee members to adequately review and monitor protocols, insufficient training, and the absence of REC independence (i.e., where RECs have their own set of ethical guidelines within which to operate for the review and approval of protocols) (Kass, Dawson, & Loyo-Berrios, 2003; Silaigwana & Wassenaar, 2015; Sleem, El-Kamary, & Silverman, 2010a). In fact, recognizing the need for global standards to enhance the quality of decision-making,

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[1]We use the term *research ethics committee (REC)* throughout this manuscript to increase readability even when describing studies conducted in settings that use the term *institutional ethics committee (IEC)* or *institutional review board (IRB)*.

the World Health Organization (WHO) (2011) updated its guidelines to incorporate comprehensive standards and operational guidance for health research ethics review. These standards address the establishment, conduct and administration of RECs as well as researchers' responsibilities related to application submission, research implementation, safety, reporting, and ongoing research status.

India has become an attractive location for conducting clinical trials. According to Dent and Krishan (2007), pharmaceutical companies and similar industries have targeted India because of the availability of drug naive patients, a large multi-ethnic population, quick patient recruitment, and cost-effectiveness. Until 2007, there was no clinical trial registry in India (Clinical Trials Registry – India, n.d.) and registration of bioavailability/bioequivalence studies has not been mandatory (George, 2012), thus allowing researchers and clinical research organizations free rein to conduct research studies with little oversight. Additionally, results from a survey by the Indian Council of Medical Research (ICMR) of over 200 RECs in India found that many RECs were not meeting the ICMR's ethical procedures for biomedical research using human participants (Muthuswamy, 2005). Although there are mandatory requirements for physicians who conduct research, there is a pervasive absence of awareness of the actual requirements regulating the conduct of ethical research (Kumar, Ravindran, Bhan, Srivastava, & Nair, 2008). India's REC compliance with the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines for ethical standards has been called into question, and there is concern about whether or not India's RECs meet regulatory compliance (Dent & Krishan, 2007).

Although India has a national regulatory framework, it hosts a fledgling mandatory clinical trials registry (CTRI) that is not well functioning and has limited financial resources. An external accreditation process based on national and WHO guidelines for RECs is being promoted but its implementation is not imminent (Kadam & Kandikar 2012). During this transition, a self-assessment tool may be more practical to help RECs evaluate and improve their process for reviewing ethical research (Silverman & Sleem, 2014). According to Silverman and colleagues (2014), self-assessment tools can also serve as quality improvement measures to help RECs enrich their operations. Indeed, Chenneville and colleagues (2014) found a discrepancy between RECs' ideal ratings and descriptive ratings on the Institutional Review Board Researchers Assessment Tool (IRB-RAT), indicating room for improvement across areas of functioning to include, but not limited to procedural and interpersonal justice, outreach, competence, and proscience sensitivity. The value of self-assessment tools within organizations to improve daily operations, internal functioning, and quality control has been recognized (Silverman & Sleem, 2014; Silverman et al., 2014; Sleem et al., 2010;).

The IRB-RAT, mentioned above, is one of several self-assessment tools designed to measure the functioning of RECs. The Office for Human Research Protections, a US agency that enforces the Federal Policy for the Protection of Human Subjects (1991) known as the Common Rule (currently being revised), which is only binding for RECs that oversee studies funded by the US federal government, also has a tool (Sleem et al., 2010). In addition, the US Food and Drug Administration has a checklist to help RECs assess their own processes and procedures to ensure human research participants are protected (Adam et

al., 2014). However, these measures were designed for RECs in the US (i.e., IRBs). Similarly, the UK created a self-assessment tool that may not be appropriate for use by RECs in LMICs (Sleem et al., 2010).

The Research Ethics Committee Quality Assurance Self-Assessment Tool (RECQASAT) was developed by researchers in the Middle East to measure the efficiency of RECs in LMICs with regard to protecting the welfare and rights of research participants (Sleem et al., 2010). The RECQASAT allows RECs to evaluate their own practices and performance while comparing their findings to international standards. However, the RECQASAT is a structured survey and, therefore, including qualitative information would be invaluable to provide context to the REC assessment. We utilized a case study approach drawing data from the RECQASAT and in-depth individual phone interviews with representative REC members to perform a detailed assessment of the *perceived* capacity of two medical school RECs in Western India and to delineate areas of need for REC improvement.

Methods

Participants

Participants included the Member Secretary from the research ethics committee (REC) for two medical colleges in Western India as well as four other representative members from the two RECs (n=6).

Measures

We used the Research Ethics Committee Quality Assurance Self-Assessment Tool (RECQASAT), a self-assessment tool for RECs in developing countries (Sleem et al., 2010) in this study. RECs can score themselves on individual items across nine domains, comprising a total of 200 points, on the RECQASAT. The RECQASAT provides information about REC functioning along the following domains: (a) organizational aspects; (b) membership and educational training; (c) submission arrangement and materials; (d) minutes; (e) policies referring to review procedures; (f) communicating a decision; (g) continuing review; (h) REC resources; (i) REC workload; and (j) review of specific protocol items (e.g., design and conduct of study, privacy and confidentiality). The REQASAT is scored by assigning each element within a domain a point value of 1, 2, or 5 with higher point values assigned to elements considered most crucial to an effective REC. Total scores range from 0 to 200.

Procedures

After obtaining IRB approval, we drew from two data sources to conduct our assessment. Each REC's Member Secretary (n=2) completed the RECQASAT (Sleem et al., 2010). As a follow up and to gather additional information, we conducted in-depth, unstructured phone interviews with the two member secretaries and four other members (n=6) from the two RECs, focusing on areas reflecting the RECQASAT's overall domains. RECQASAT results were summarized by institution (REC A and REC B) and interview data were analyzed to provide further insight into the RECQASAT findings.

Results

The RECs that participated in this study obtained a total of 123 (62%) and 133 (67%) points, respectively, out of 200 possible points. See Table 1 for a breakdown of RECQASAT scores by domain. More detailed information about REC functioning along the domains assessed by the RECQASAT is provided in the sections to follow. Results include data from the RECQASAT and the in-depth interviews. Table 2 includes a summary common themes that emerged during the interviews.

Organizational Aspects

Both RECs were relatively young; REC A was formed in 2002, and REC B was formed in 2005. Neither was established under a high-ranking authority (e.g., President's office, Ministry of Health). When questioned about whether the REC is subject to registration with a national authority, REC A responded "yes" and REC B responded "no". Both RECs meet as a full committee to review research protocols at least every two months, and each has written Standard Operating Procedures. At REC A, there is a process for appointing an REC chair; at REC B, there is not. However, at REC B, prior ethics training and research experience are among the criteria used to select the REC Chair. At both institutions, there are policies describing the process for appointing members to the REC, which detail the membership requirements and terms of appointment. Both cite ICMR guidelines as criteria used to select REC members while REC B also requires prior research experience. Both RECs have policies for disclosure and management of potential conflicts of interest for REC members and for the research team. REC B reportedly has a quality improvement program for itself, while REC A reportedly does not. Neither institution regularly evaluates the operation of the REC (e.g., budgetary needs, adequacy of material resources, adequacy of policies/procedures/practices, appropriateness of the membership given the research being reviewed, documentation of the training requirements of REC members). REC B reportedly has a mechanism by which enrolled research participants can file complaints or direct questions regarding human participants protection issues (i.e., address and phone number of REC Chair and Secretary, along with contact information for the Principal Investigator, is printed on the Informed Consent document). REC A reportedly has no such mechanism. Both institutions store REC records in paper folders in a locked filing cabinet. Both institutions require a quorum (i.e., that a certain number of members be present in order to make the meeting official), however, the number required for the quorum is unknown. Parenthetically, both the ICMR (2006) and the WHO (2011) guidelines recommend a minimum of five individuals. The WHO suggests including a layperson and one non-affiliated member whereas ICMR has no such requirements unless the review is of a drug trial. Then, the REC quorum must include a basic medical scientist, a clinician, a legal expert, a social scientist/philosopher/ethicist, and a layperson from the community.

Membership and Educational Training

At REC A, the REC is comprised of 15 members (11 men, 4 women). At REC B, the committee is comprised of 12 members (10 men, 2 women). Both RECs have members who are not affiliated with the institution (i.e., not employed by the institution or related to a person who is employed) and both have members who are considered to be a non-scientist

(i.e., no terminal degree in a medical or scientific field). Parenthetically, the non-affiliated member and the non-scientist member may be one and the same. All interviewees appeared satisfied with the composition of their RECs and repeatedly drew attention to the diversity of its membership. Interviewees from both RECs pointed out that having a chair from outside the medical school was a strength of their REC. One interviewee noted that their REC faculty members were high ranking at the associate professor and professor level (Table 2). REC B requires that the REC Chair (or designee) have prior formal training (e.g., research ethics workshop) in the area of research ethics. No such requirement exists at REC A. Neither institution requires that REC members have training in research ethics to be an REC member or that investigators have training in research ethics to submit protocols for REC review. Neither institution conducts continuing education in research ethics for its members on a regular basis, nor do they document in writing the training that its members have received in research ethics. A few of the interviewees expressed concern that REC members were not trained in ethical aspects of human participant research. One interviewee stated: "Members do not receive any formal training for ethical issues and show no inclination or interest in training including GCP guidelines. They use the ICMR guidelines and any information provided by the member secretary regarding ethical issues." A common theme that emerged among the interviewees was that training in human research ethics was essential for all committee members. "I think all committee members should be trained. It is a requirement" noted one study participant (Table 2).

Submission Arrangements and Materials

Both RECs reportedly have written guidelines for the submission of protocols to the REC that include: (a) a requirement for investigators to use a specific application form to submit protocols; (b) a requirement to use an informed consent template that helps guide investigators in the writing of informed consent documents; and (c) a deadline by which investigators must submit protocols. Both institutions also require the following submission materials accompany research protocols submitted to the REC: full protocol, informed consent document, investigator's qualifications, recruitment materials, copies of questionnaires/surveys, and investigator drug brochures. Neither institution requires a conflict of interest disclosure form. At REC A, there is a requirement that the department chair (or another individual) approve and sign off on the research protocol prior to submission to the REC; no such requirement exists at REC B.

Minutes

Minutes of each REC meeting are maintained for both RECs. The following is documented in the meeting minutes: (a) whether or not members were asked whether they had a conflict of interest regarding any of the protocols being reviewed; (b) whether or not a quorum was present for all actions requiring a decision; (c) whether or not at least one scientist, one non-scientist, and one person not affiliated with the institution was included for actions (i.e., participated in review and voted) requiring a decision; and (d) when applicable, a discussion of the controversial aspects of research protocols being reviewed. At REC A, the names of REC members who were excused due to a conflict of interest from any action requiring a decision are documented in the meeting minutes. These names are not included in the

meeting minutes at REC B. The names of REC members who abstained from a vote and the reason for abstaining are not included in the meeting minutes at either institution.

Policies Referring to Review Procedures

Both REC A and REC B reported having a policy that addresses how protocols will be reviewed and a requirement that REC members receive the protocol and supporting materials at a specified time prior to the meeting. At both institutions, policies include: (a) a description of how decisions are made (e.g., consensus vs. vote); (b) a requirement that REC members be asked about a conflict of interest regarding any of the protocols to be discussed at the beginning of each meeting; (c) a description of the process for communicating REC decisions to investigators; (d) a requirement that principal investigators submit Continuing Review reports; and (e) a description of the process for early termination or suspension of protocols. Neither REC A nor REC B outlines a requirement that all items be reviewed (e.g., protocols and supporting documents, continuing reviews, amendments, adverse events, modifications to protocols, termination/suspension). At REC A, policies include a requirement that reviewers use a checklist to document their ethical assessment of the research submission and the conditions for expedited and exempt review. These items are not included in policies at REC B. However, all of the interviewees from both RECs stated that although a checklist would be helpful, no checklist was being used to ensure a thorough assessment of all ethical aspects during protocol review. One participant pointed out that their REC members rely on the ICMR guidelines and any information provided by the member secretary or the REC members that were assigned to review the protocol (Table 2).

Review of Specific Protocol Items

Scientific Design and Conduct of the Study—At both REC A and REC B, review of protocols include (a) the suitability of the investigator's qualifications to conduct the study; (b) the adequacy of the clinical site (e.g., supporting staff, available facilities, emergency procedures); and (c) scientific reviews completed by other committees.

Considerations of Risks and Benefits—At both REC A and REC B, the following are reviewed: (a) different risks of the research protocol; (b) whether risks have been minimized; (c) whether the risks are greater than minimal risk based on a written definition of minimal risk; (d) the potential benefits of the research to the participants; (e) the importance of the knowledge to society that may reasonably be expected to result from the research; and (f) 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.

Selection of Research Participants—At both REC A and REC B, the following are reviewed: (a) the investigators' plans to identify and recruit potential participants; (b) whether the recruitment plans ensure that the selection of subjects will be equitable in regards to gender, religion, and ethnicity; (c) whether any of the potential participants are from vulnerable groups (e.g., children, prisoners, persons with mental disabilities, or persons who are economically or educationally disadvantaged); (d) the justification for including vulnerable populations in the research; and (e) whether additional safeguards are needed for vulnerable persons that will further protect their rights and welfare. The appropriateness of

any financial or other incentives offered to participants for their participation in research is reviewed at REC B, but not REC A.

Privacy and Confidentiality—At both REC A and REC B, the methods for protecting the confidentiality of the collected data and whether the settings in which participants are recruited protect their privacy are reviewed.

Community Consultation—At both REC A and REC B, committees review 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 ends. Neither REC A nor REC B review/consider, when applicable, whether the community was consulted regarding the design and implementation of the research.

Safety Monitoring and Adequacy of Insurance to Cover Research-Related Injury—Both RECs include as part of their review whether the sponsors of the research have adequate insurance to cover the treatments of research-related injuries. At REC A but not REC B, committee members review whether the research plan, when applicable, includes adequate provisions for monitoring the data collected to ensure the safety of participants.

Pediatric Research—At REC A, but not REC B, members must review the need to obtain the child's assent in pediatric research.

Informed Consent—At both REC A and REC B, members review the process by which informed consent will be obtained (e.g., How are potential participants identified? Where does informed consent take place? Are participants allowed to take the informed consent documents home? Are participants given enough time to ask questions?). Both RECs also review whether the informed consent documents are understandable to the participant populations (e.g., reading level of document assessed, having community member read the consent form, requirement that investigator assess participant's comprehension of consent documents). At REC B, but not REC A, the committee reviews/considers which members of the research team approach potential participants to obtain informed consent. Also, at REC B but not REC A, the REC reviews/considers whether the informed consent requirement can be waived (based on written criteria). Neither REC A nor REC B review/consider whether the requirement to have a written signature on the informed consent document can be waived (based on written criteria). A few interviewees expressed concern that in the past RECs were not very strict in monitoring informed consent procedures and participants often were not aware that they were enrolled in a study/trial. One interviewee remarked, "Informed consent is now mandatory and templates are located on the website along with participant information sheet. All investigators must get an informed consent from study participants" (Table 2).

Basic Elements of Informed Consent—At both REC A and REC B, committees evaluate whether the informed consent contains the following basic elements: (a) an explanation of the purposes of the research; (b) the expected duration of the subject's

participation; (c) a description of the study's procedures to be followed; (d) identification of any experimental procedures; (e) a description of any reasonably foreseeable risks or discomforts to the participant; (f) a disclosure of appropriate alternative treatments that might be available to participant if they decline to participate in the study; (g) a statement describing the extent to which the data will be kept confidential; (h) for research involving more than minimal risk, an explanation as to whether any treatments are available if injury occurs; (i) an explanation of whom to contact for questions about the research; (j) an explanation of whom to contact for questions about research participants' rights; (k) a statement that participation is voluntary; and (l) a statement that participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled. At REC A but not REC B, committees also check whether a description of any benefits to the participant or to society that might reasonably be expected from the research. At REC B but not REC A, the committee also looks to see if there is a statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.

Communicating a Decision (Approval Letter)—At both REC A and REC B, approval letters include a requirement that investigators submit to the REC any changes that occur in the research plan (e.g., change in investigators, change in drug doses, change in sample size), any adverse events, and/or any protocol deviations. Neither REC A nor REC B include an expiration date for the conduct of the research that is one year from the date of the convened REC meeting in which the study was approved. In addition, neither REC A nor REC B requires investigators to use an REC-approved informed consent document that is stamped with an expiration date. At REC A but not REC B, termination/suspension letters are issued with the reasons for the suspension/termination.

When communicating protocol approval or denial decisions, interviewees from both RECs said that the decision letters were sent out within 14 days from the REC meeting. If protocols were not approved because of scientific or ethical reasons[2], the investigators are invited to the next meeting to present their case. One challenge that an interviewee noted was that "if the research topic/area is not of interest to the REC or is controversial, the REC is more likely to not approve the proposal even if it is scientifically sound and ethically correct." Furthermore, other serious issues that a few interviewees found during the meetings were members' conflict of interest or other biases. Committee members did not recuse themselves during the REC meeting but instead were more likely to approve proposals from investigators they knew or if they were involved with the proposal in some way even "if the proposal was not completely worthy" as one interviewee remarked. On the contrary, a few interviewees reiterated that there was no misuse of power by the committee members when making decisions regarding protocol approval (Table 2).

Continuing Review—At both REC A and REC B, committees require a continuing review report from investigators annually (at minimum). Both institutions require that

[2]It is important to note that scientific review and ethical review should not be considered mutually exclusive; rather, it can be argued that a study that is not scientifically sound is inherently unethical. See Emanuel, Wendler, & Grady (2000); Emanuel, Wendler, Killen, & Grady (2004); and Emanuel et al., 2004) for more information about this topic.

investigators include in their review the number of participants enrolled, the number and description of adverse events in the previous year, a list of any protocol violations or deviations, and submission of any safety monitoring reports. For studies completed, both institutions require submission of a final report describing the results of the study. REC A but not REC B also requires investigators to report the number of participants who withdrew from the study. Neither REC A nor REC B requires the following in their continuing review report: (a) gender, ethnic, or religious breakdown of enrolled participants; (b) the reasons why participants were withdrawn from the study; (c) number of participants who decided to drop out of the research; (d) the reasons why participants dropped out; and (e) verification that informed consent was obtained from all participants and that all signed consent forms are on file.

REC Resources

At REC A, but not REC B, the committee has its own budget. However, this budget does not include the allocation of monies for training REC members. At REC B, but not REC A, the committee has administrative staff (half-time) assigned to the REC. At both institutions, the following resources are available to the REC: access to a meeting room, a computer and printer, a fax machine, and cabinets for storage of protocol files. REC B also has access to the Internet.

Workload of the REC

Annually, REC A reportedly reviews an average of 20 protocols per year. When questioned further, however, they reported an average of 15 clinical trials per year, an average of five survey/interview studies, and an average of five epidemiologic/observational studies (these numbers total 25 protocols per year, exceeding the annual average reported). REC meetings last an average of three hours.

Annually, REC B reportedly reviews an average of 110-120 protocols per year. When questioned further, however, they reported an average of eight to ten clinical trials per year, an average of 15-20 survey/interview studies, and an average of 30-40 epidemiologic/observational studies. (these numbers total 53-70, which is less than the annual number reported). REC meetings last an average of two to three hours.

Discussion

Findings from this case study suggest significant room for improvement in functioning for both of the RECs that participated. The RECs in this study obtained only 62% and 67%, respectively, of the allowable points on the REQASAT. These percentages are slightly lower than the aggregate mean percentage of 68.5% reported by Silverman and colleagues (2014) based on a study of RECs from several LMICs to include Egypt, South Africa and India. In that study, researchers found a relationship between mean scores and the presence of an REC budget. They found no relationship between mean scores and duration of existence of the REC, the frequency of REC meetings, or the inclusion of national guidelines. Similar to those findings, RECs in this study have inadequate resources including minimal staff to assist the member secretaries and limited space for maintaining documentation and records.

Overall, these findings are consistent with existing research examining the resources and functioning of RECs in LMICs. In their study of two RECs, clinical and non-clinical, at a medical school in Thailand, Adams and colleagues (2014) identified the need for improvement of internal processes. Makhoul and colleagues (2014) also identified areas of concern in their study of RECs in Lebanon and Qatar, specifically with regard to the inadequacy of resources for the REC, poor communication between REC members and researchers, and REC application requirements considered to be overly rigid and insensitive of context. Matar and Silverman (2013) used in-depth semi-structured interviews to assess the functioning of RECs in the Middle East, namely Egypt, and identified themes related to the composition of membership, the training needs of REC members, the need for resources (human and capital), the impact of the national government on REC functioning, and the issues surrounding informed consent, among others. These and other Indian RECs are likely to be affected by the recent Indian legislation for injury related to clinical trials, which enforces the monitoring and reporting of any trial related patient injuries (Singh 2013). Going forward, institutions will need to clearly delineate the responsible party for monitoring and RECs will have to decide the quantum of compensation (Singh 2013, Faculty of Clinical Research, 2015).

In a collective review of the structure, functioning, and outcomes of RECs in sub-Saharan Africa, Silaigwana and Wassenaar (2015) described challenges to effective REC functioning. We observed many of these themes in our study related to the need for regular ethics related training for REC members, an increase in resources, and monitoring the implementation of informed consent. An important issue that elicited a mixed response in our study involved the misuse of power during the decision-making process for protocol approval or denial. Personal relationships with investigators, members' lack of interest in the research topic, and controversial research studies were reasons cited by a few participants as influencing committee members' perception of or input about a protocol. However, other interviewees reiterated that there was no misuse of power by members. One surprising absence in the interview responses was related to membership composition. Clearly, both RECs had a gender bias with only two women out of 12 members in one REC and four women out of 15 in the second REC. Yet, all interviewees thought that the membership was quite diverse and representative.

Results from this study, combined with findings from similar studies, provide evidence of the need for continued support and infrastructure for RECs in LMICs such as that provided by the National Institutes of Health (NIH) Fogarty International Training Programs. The utility of such programs has been documented. For example, Silverman, Edwards, Shamoo, and Matar (2013) describe the benefits of a Fogarty-sponsored and other sponsored ethics training programs in the Middle East, and Ndebele and colleagues (2014) provide a review of Fogarty-sponsored programs addressing research ethics capacity building in sub-Saharan Africa. Training programs should be tailored to the needs of the institution and its members and may range from short-term intensive one-week fundamental ethics trainings for REC members and faculty to long-term (six months to two years) training programs for a smaller number of interested REC members and faculty. Additionally, using a train-the-trainer model, trained faculty from low-resource settings can provide one-day ethics related training

to all REC members and faculty within the institution followed by annual recertification trainings that are of shorter duration.

It is important to note some of the limitations associated with the use of the RECQASAT, which may have affected findings. For example, the RECQASAT asks raters to indicate whether or not submission materials include conflict of interest (COI) disclosure "forms" for members of the research team, not whether or not COI statements are required even if captured elsewhere. Also, the RECQASAT does not ask raters about whether or not investigators are required to submit proof of ethics or GCP training. As another example, from the wording of the RECQASAT, one can glean whether or not protocol changes must be submitted to an REC, but not whether or not such changes must be approved before they are implemented.

This study had several other limitations including the use of a small convenient sample of only two RECs that were participating in efforts to improve their functioning. Also, the reliability and validity of data reported are unknown although, as Silverman and colleagues (2014) note, this is a potential concern when collecting data related to quality improvement. The inclusion of multiple raters at each REC partially addressed this issue. Finally, this study assessed *perceived* capacity. Absent criterion referenced objective measures, it is impossible to verify if perceptions reflect *actual* REC effectiveness. This is not uncommon in research on RECs despite the fact that benchmarks for ethical research exist (e.g., Emanuel et al., 2004). In fact, in a systematic review of empirical studies of RECs (i.e., IRBs) in the US, Abbott and Grady (2011) found many studies that evaluated the structure, process, and outcomes of RECs but not a single study that truly evaluated the effectiveness of RECs. The complexity of this issue is demonstrated in other writings on this topic as well (see Grady, 2010; Kass et al., 2007; Schuppli & Fraser, 2007). Combined, these factors may limit the generalizability of findings. However, this case study also has several strengths to include the use of multiple sources for data collection. Our findings suggest that the REQASAT is a comprehensive structured self-assessment tool to examine the functioning of individual RECs in low-resource settings such as India. It is particularly useful among RECs such as those in our study that have been established for some time but have neglected to evaluate their processes and operations regularly or standardize their policies and procedures. Additionally, combining the REQASAT with in-depth individual interviews provides context, thus allowing further insight into REC issues, particularly contentious ones related to REC members' conflict of interest, and some members' misuse of power for protocol approval and denial.

We hope to re-assess the RECs that participated in this study using the REQASAT to determine the impact of collaborative efforts to improve REC functioning. In addition to self-assessment, research is needed to assess the opinions of key stakeholders (e.g., researchers, research participants) regarding the perceived efficacy of RECs. Research also is needed to determine best practices for improving REC capacity. Future studies that objectively measure REC effectiveness in ways that can be externally verified would be valuable.

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Biographical Sketches

Tiffany Chenneville, Ph.D. is an Associate Professor in the Department of Psychology at the University of South Florida (USF) St. Petersburg with a Joint Appointment in the USF Department of Pediatrics. Her primary research interests are in the areas of pediatric HIV and global research ethics. Dr. Chenneville served as the principal investigator for this project and, in this capacity, was responsible for overseeing all aspects of this paper.

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Jayendrakumar Kosambiya, M.D. is a Professor in the Department of Preventive and Social Medicine at the Government Medical College Surat in India. He served as a co-Principal Investigator for this project and was involved primarily with research design and data collection.

Rajendra Baxi, M.D. is a Professor of Preventive and Social Medicine at the Medical College Baroda in India. He served as a co-Principal Investigator for this project and was involved primarily with research design and data collection.

Eliana Aguilar is a graduate student earning her Master's degree in Psychology at USF St. Petersburg. Sarah Jenkins is an undergraduate Honors student earning her Bachelors degree in Psychology at USF St. Petersburg. Eliana and Sarah both served as research assistants for this project, contributing to the literature review and preparation of this manuscript.

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Table 1

Institutional ethics committee scores on individual domains of the RECQASAT

Domain	IEC A	%	IEC B	%	Total Possible Points
Organizational Aspects	29	54%	36	67%	54
Membership and Educational Training	6	20%	11	37%	30
Submission Arrangements and Materials	10	83%	11	92%	12
Minutes	8	62%	7	54%	13
Policies Referring to Review Procedures	10	91%	7	64%	11
Review of Specific Protocol Items	37	86%	38	88%	43
Communicating a Decision (Approval Letter)	3	60%	3	60%	5
Continuing Review	11	69%	10	63%	16
REC Resources	9	56%	10	63%	16
Total	**123**	**62%**	**133**	**67%**	**200**

Table 2

Common themes that emerged during in-depth individual interviews with members from both IEC A and B.

Dimensions	Themes
Organizational Aspects	• Use ICMR guidelines to select members • IEC chair is not employee of medical college • Need to expand ethical guidelines for social and behavioral research
Membership and Educational Training	• No training on ethical issues provided for IEC members • IEC members show no interest in receiving training • Training on ethical issues of human participant research is essential for IEC members • IEC membership is diverse with experience from different disciplines • Need to sensitize investigators about ethical issues
Policies Referring to Review Procedures	• No checklist for scientific or ethical assessment of submitted protocol • A checklist documenting their ethical assessment is not being used but is necessary
Review of Specific Protocol Items	• Use ICMR guidelines regarding ethical issues • Use information provided by member secretary or person designated as primary reviewer of protocol for ethical issues • IECs not strict in monitoring informed consent procedures previously ○ Participants not aware of their enrollment in a clinical trial or study ○ Currently all investigators must document informed consent from their participants ○ More check needed for informed consent • Protocol objections sometimes because of lack of understanding regarding medical aspects of studies • Decisions based on perceptions rather than objective guidelines
Communicating a Decision (Approval Letter)	• Decision letters sent timely; within two weeks • Often conflict of interest present wherein some IEC members favor protocols from certain investigators • Research protocol might not be approved if topic is controversial or of little interest to IEC members • If protocol not approved, PIs allowed to present at next meeting • Mixed response regarding misuse of power by IEC members
Continuing Review	• No documentation of study/trial completion or continuance
REC Resources	• No secretarial or funding help • No autonomy for IEC members