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Assessing Institutional Ethics Committees in India using the IRB-RAT

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Abstract

Institutional ethics committees (IECs) are currently still in their infancy in low to middle income countries (LMICs), which may have important implications with regard to the oversight of the protection of human participants. Understanding how these IECs currently function is a critical first step in helping LMICs build infrastructures that support the protection of research participants and improve the scientific quality of health research worldwide. We assessed the functioning of the IECs at two medical colleges in Gujarat, India, by administering the Institutional Review Board Researcher's Assessment Tool (IRB-RAT) to 42 IEC and faculty members. The IRB-RAT includes eight scales assessing various domains related to how investigators and members perceive their ethics committees. Results from t-tests revealed significant differences between ideal ratings and descriptive ratings on each of the IRB-RAT scales with ideal ratings being higher than current descriptive ratings on all of the scales ($<.001$). These findings suggest areas that can be targeted for improvement, and also provide important information about the values of Indian IECs.

Keywords

research ethics; ethics committees; review boards; low to middle income countries

Introduction

Establishing institutional review boards to provide oversight for the ethical conduct of research is gradually gaining recognition in low and middle-income countries (LMICs). In India, despite the development of policy related to ethical conduct of human participant research in 1980 by the Indian Council on Medical Research (ICMR), awareness of the need for ethical considerations when conducting research with human participants is scarce among physicians in India (Kumar, Ravindran, Bhan, & Nair, 2008). While the number of institutional ethics committees (IECs) in India are growing, an ICMR survey of over 200 IECs in India revealed that many do not meet the ICMR's ethical guidelines specifically related to structure or function for the conduct of biomedical research with human participants specifically related to structure or function (Muthuswamy, 2005), and there are concerns that ethics committees in India may not meet the regulatory needs for clinical trials, specifically the guidelines set forth by the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines (Dent & Krishan, 2008). In a study of public sector teaching hospitals in Delhi, only 25% of IEC members had been formally trained in bioethics (Singh, 2009). This lack of awareness about research ethics, the lack of research ethics committees and well-trained ethics staff, and the diversity in composition, practice and function of IECs is true of many other low and middle-income countries (LMICs) (Caniza et al., 2008; Falusi, Olopade, & Olopade, 2007; Kass, Hyder, Ajuwon et.al, 2007; Louw & Delpont, 2006; Matar, 2013; Sheikh, 2008; Tindana & Boateng, 2008).

With the advent of human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) research, a host of additional ethical issues have emerged, particularly with the phenomenal growth of international clinical trials and other prevention and treatment research targeting this disease. In search of cost effective and timely recruitment of diverse and drug naïve patients, pharmaceutical and allied industries have targeted India for clinical research (Dent & Krishan, 2008). The efforts of the National Institutes of Health (NIH) Fogarty International Center (FIC) and other agencies in sponsoring the building of ethics infrastructure in LMICs has resulted in improved protection of research participants and increased international collaborative HIV/AIDS and other medical research in many LMICs. Some Indian institutions aligned with priorities similar to the NIH FIC have benefited as well (Kumar, Ravindran, Bhan, & Nair, 2008). While grant funding has set the foundation for some fundamental ethics training for IEC members in HIV and other health research, there continues to be a critical need for continued investment in research ethics and leadership training.

Of the institutions in India that have instituted IECs, little is known about how effectively they function or how investigators who use their services perceive them. Much of the writing on ethics committees to date focuses on the composition of effective committees and the need for universal standards. This is true not only in India, but worldwide. According to Dhai (2005), committee members comprise the most important aspect of ethics committees. Dhai (2005) argues that having an adequate number of members is important as well as having a committee comprised of members who, collectively, understand the priorities of their communities and who are qualified to make important decisions about research. This type of collective expertise requires diverse committee membership that includes not only

academics but also lay people from the community. However, previous research suggests that ethics committees in developing countries often lack member diversity (Matar, 2013).

In addition to assessing the composition of ethics committees, it is perhaps equally important to assess the activities of these committees. The Institutional Review Board Researchers Assessment Tool (IRB-RAT; Keith-Spiegel & Koocher, 2005) was designed to analyze the functioning of ethics committees. Based on a review of the literature and institutional review board (IRB) documents, the IRB-RAT describes ethics committees' actions and behaviors along a variety of dimensions (e.g., procedural justice, competence). The utility of the IRB-RAT has been verified in several studies (i.e., Keith-Spiegel, Koocher, & Tabachnick, 2006; Reeser, Austin, Jaros, Mukesh, & McCarty, 2008). Keith-Spiegel, Koocher, and Tabachnick's (2006) study of 886 experienced biomedical and social behavioral scientists who completed the IRB-RAT revealed that fairness and respectful consideration were highly valued among all scientists. Reeser, et al., (2008) were the first to use the IRB-RAT as a self-assessment tool and suggest it may provide ethics committees with baseline data that can be used to make changes and compare the effectiveness of said changes in an effort to improve functioning. To our knowledge, the IRB-RAT has not been used outside of the United States (U.S.) despite its potential utility as an effective measure of IEC functioning in LMICs.

Understanding the current functioning of IECs is an important component of building infrastructures in countries such as India, whereby both the rights and safety of research participants can be protected and the quality of health research can be improved. The purpose of this study was to assess the functioning of two medical college IECs in Gujarat, India using the IRB-RAT (Keith-Spiegel & Koocher, 2005) and to determine whether the perceived IEC functioning differed between IEC members and faculty investigators that utilized the two IECs.

Method

Participants

IEC members from two medical colleges in Gujarat, India were contacted and requested to participate. In addition, a convenience sample of faculty members who had previously utilized IEC services at each respective college were also contacted to participate in the study. At the time of data collection, the IECs were comprised of 15 (11 men, 4 women) and 12 (10 men, 2 women) members, respectively, across the two institutions. Both IECs had members who were not affiliated with the institution (i.e., not employed by the institution or related to an employee) and both had members who were non-scientists, defined as not having obtained a terminal degree in a medical or scientific field. Neither institution required IEC members to have training in research ethics although the Chairperson at one of the institutions was required to have prior formal training, which could include workshop training in research ethics. Of the 27 IEC members contacted, 17 completed the survey and 25 faculty members from both institutions completed the survey for a total of 42 participants from both institutions.

Measures

The Institutional Review Board Researcher's Assessment Tool (IRB-RAT; Keith-Spiegel & Koocher, 2005) was used to assess the functioning of the institutional ethics committees (IECs) participating in this study. The IRB-RAT presents 45 different characteristics and activities common to IRBs and asks respondents to rate how important each characteristic or activity would be in achieving the vision of an ideal IRB on a scale from *one* to *seven*, with *one* being "not important" and *seven* being "absolutely essential." Respondents are then asked to rate their own IRB on these same characteristics on a scale from *one* to *seven*, with *one* being "not at all descriptive" and *seven* being "highly descriptive." With permission from the authors, the IRB-RAT was modified slightly to suit the Indian context (G. Koocher, personal communication, 11/15/10). Specifically, IRB was replaced with IEC throughout and references to "federal research policy" on the original IRB-RAT were replaced with references to the Indian Council of Medical Research (ICMR). See Table 1.

The IRB-RAT has been previously normed on a sample of 886 biomedical and social-behavioral scientists in the United States (Keith-Spiegel, Koocher, & Tabachnick, 2006). Confirmatory factor analysis using structural equation modeling indicated that items best load onto eight factors: (a) procedural justice, (b) IRB outreach, (c) interpersonal justice, (d) IRB formal functioning, structure, and composition, (e) pro-science sensitivity, (f) bias, (g) competence, and (h) upholding the rights of human participants. Table 2 describes each of these factors including sample items.

Procedures

As part of a research ethics training grant, the IRB-RAT was administered electronically via Checkbox, an online survey software. Participants were provided with instructions at the start of the survey. Due to technology limitations at the Indian institutions where data was collected, some surveys were completed by hand and the data manually entered. IRB approval was obtained from the University of South Florida to review existing records.

Statistical Analyses

Means were computed for each subscale of the IRB-RAT (procedural justice; IRB outreach; interpersonal justice; IRB formal functioning, structure, and composition; pro-science sensitivity; bias; competence; and upholding the rights of human participants). Descriptive means and standard deviations were examined for every item and subscale. Two-tailed t-tests were performed to examine the difference between the ideal and current means for each scale. Further, current and ideal means of individual items were also compared using two-tailed t-tests. To examine whether gender, research experience, or IEC membership status influenced IRB-RAT subscale scores, differences in subscale means for each group comparison (male vs. female, experience with IEC approved research vs. no experience with IEC approved research, IEC member vs. faculty non-IEC member) were assessed using two-tailed t-tests. Lastly, to examine whether Indian ideals differed from US ideals, sample ideal means were compared to US ideal means using one sample two-tailed t-tests.

Results

Participant Demographics

Participants included 17 IEC members (40.5%) and 25 faculty members (59.5%) from two medical institutions in western India. Participants were fairly evenly distributed between the two institutions (47.6% and 52.4%, respectively). The majority of participants were male (59.5%), and the average age of participants was 45 years. The large majority (83.3%) were medical professionals, the majority of whom (76.2%) conducted research requiring IEC approval.

IRB-RAT Comparison of Mean and Ideal Ratings

Results from the IRB-RAT provided information about the perceptions of IECs at two medical colleges in India. Results from t-tests revealed significant differences between ideal ratings and descriptive rating on each of the scales ($p < .001$); ideal ratings were higher than descriptive ratings on all scales. (Figure 1).

Analyses of individual items revealed a significant difference between the descriptive and ideal means; ideal means were higher on all items except one: “An IEC that is composed of more than one public member.” In comparison to the data collected in a US sample (Keith-Spiegel, Koocher, & Tabachnick, 2006), the ideal means for the large majority of individual items in our sample were significantly higher (Table 3). With few exceptions, the items rated as most or least important differed between our sample and the US sample (Table 4).

To assess whether ideal ratings by Indian participants differed from US ideal ratings, we compared the study participants’ mean ideal ratings to published US ideal means (Keith-Spiegel, Koocher, & Tabachnick, 2006) for each item (Table 3). Overall, participants’ mean ideal ratings were significantly higher than US mean ideal ratings for most of the questions ($p < .05$), indicating that participants in India may have higher ideals across IRB domains. However, there were some exceptions. For example, there were no statistically significant differences between participants’ mean ideal ratings and US ideal means on items assessing the importance of timely, conscientious, and complete review of protocols. Further, there were no differences in ratings of the importance of outside evaluators when IEC or IRB members lack expertise, the importance of detailed feedback to investigators, or on a willingness to work with investigators to find mutually satisfying solutions to problems raised during the review. Both groups – our sample and US sample valued the importance of an ethics committee that is knowledgeable about procedures and federal policy and that is clearly able to distinguish exempt from non-exempt research. Finally, study participants were similar to US participants with regard to the value they placed on seeking a balance between facilitating research and protecting the rights of participants as well as their opinion that ethics committees should not allow their personal biases or use their power to suppress research that is otherwise methodologically sound and consistent with federal regulations.

Further analyses examined whether gender, research experience, or IEC membership status affected IRB-RAT subscale scores. For gender, the only statistically significant difference in ratings was for ideal (but not current) IRB Outreach, with females having significantly higher ratings than males ($t=2.04$, $p=.048$), suggesting that females may value IRB Outreach

more than males. In terms of IEC membership status, IEC members were higher on both current ($t=2.39$, $p=.022$) and ideal ($t=2.08$, $p=.044$) means than faculty non-IEC members. Further, IEC members had higher scores on current (but not ideal) competence subscale ratings ($t=2.05$, $p=.048$). For experience with IEC approved research, individuals with IEC research experience scored lower on current “procedural justice” ($t=2.48$, $p=.018$), current “pro-science sensitivity” ($t=2.32$, $p=.026$), and ideal IRB “formal functioning, structure, and composition” ($t=2.3$, $p=.027$) subscales.

Discussion

To our knowledge, this is the first study to assess IEC functioning in India using a slightly modified IRB-RAT. Our study demonstrated that both IEC members and faculty members at the medical colleges in Gujarat place high expectations on the functioning of their IECs. For all categories, ideal ratings exceeded descriptive ratings at the time of this study, indicating a discrepancy between desired and actual IEC functioning at the Indian medical colleges participating in this study. A discrepancy between actual functioning and desired functioning is likely common and, in fact, may be viewed as a positive indicator for high ideals that may lead to interest in seeking significant improvements in the IEC. Ideal ratings exceeded the ratings of the normative sample for the IRB-RAT on the majority of individual items and in the following categories: interpersonal justice, pro-science sensitivity, competence, IRB outreach, and IRB formal functioning, structure, and composition (Keith-Spiegel, Koocher, & Tabachnick, 2006).

Our study participants rated the majority of individual items on the IRB-RAT as being more important than did respondents in the US or the normative sample, indicating that while functioning may differ between ethics committees in the US and India, the value placed on the actions and functions of IECs may actually be higher in India. This may be a function of the recent attention to research ethics in India given the explosion of clinical trials within the past several decades (Dent & Krishan, 2008). Additionally, the halting of two HPV vaccine demonstration projects in India in April 2010 (Larson, Brocard, & Garnett, 2010) because of alleged adverse events and ethical violations may have potentially influenced the responses. India is increasingly targeted by pharmaceutical and allied industries as a prime location for research trials. Not only are English speaking principal investigators available, but research in India is less costly and time efficient not to mention the availability of ethnically diverse populations of drug naïve patients.. Although the Indian Council for Medical Research (ICMR) dates back to 1911, initial policies were developed only in 1980. Furthermore, the Ethical Guidelines for Biomedical Research on Human Participants were not launched until 2000 and were revised in 2006 (ICMR, 2006), reflecting the recent emphasis on research ethics in India. With the advent of global health initiatives, there has been an increased focus on the importance of international research ethics. Consequently, India and other low to middle income countries appear to be influenced greatly by their collaboration with western cultures such as the US. It may be that Indian ethics committees, which are in their infancy compared to their Western counterparts, are overly idealistic as a function of their relative lack of experience. Alternatively, it could be that the support and infrastructure provided through programs by the US NIH Fogarty International Center are so effective that, in fact, the Indian culture is internalizing Western ideals relative to research ethics to a greater

extent than their US collaborators. It is interesting to consider these dynamics as the U.S. may be inadvertently setting a higher bar for both cultures in an effort to train research collaborators in India. Faculty from both institutions have previously conducted research with US collaborators

In this study, the characteristics most and least valued on the IRB-RAT by our sample compared to the US sample also differed for the most part, which is not entirely surprising given the impact of culture on values and ethics. These findings build upon Klitchman's (2008) comparison of US IRB and South African research ethics committee (REC) members' views of the process and content of ethics reviews. According to Klitchman (2008), REC members in South Africa viewed US regulations as overly rigid and not conducive to taking into account important cultural differences including fundamental differences in how members of different societies view illness.

In our study, 73% and 83%, respectively, of IEC members were male. On the surface, these percentages may seem high, and some might assume these figures reflect documented evidence of India as a male dominated society where females are routinely discriminated against (Sorta-Bilajac, 2004). However, it is interesting to note that these figures mimic the typical gender distribution of US IRBs. In a systematic review of the empirical literature evaluating US IRBs, Abbott and Grady (2011) found that IRBs in the US were predominantly male. Similar to the distribution in our study, Campbell et al (2003) found that 73% of medical school faculty who served on IRBs were male. These findings would suggest more similarities, than differences, with regard to cultural values and norms surrounding gender, at least in academia. It is well established that leadership positions in academia in the US tend to be held by males, as opposed to females, even in female-dominated disciplines. It appears the same may be true in India, which likely accounts for male-dominated ethics committee membership. Regardless of the reasons for this finding, IRBs in the US and IECs in India would be well advised to make efforts to achieve greater gender equity in the composition of their ethics committees. Although there is no rule that males and females be evenly distributed on IRBs or IECs, the female voice as a minority may be particularly problematic when reviewing protocols focused on women's issues (Yaghoobi, 2011). Indeed, both the US Department of Health and Human Services, via the Federalwide Assurance for the Protection of Human Subjects, and the Indian Council of Medical Research uphold the importance of gender equity on ethics committees.

Best Practices

This study suggests the IRB-RAT may be a useful tool that can be used by ethics committees to evaluate their values and functioning across a variety of dimensions of relevance to the protection of human participants. Results can be used to guide interventions for improvement among individual ethics committees and/or as the basic of a values assessment in comparison to other committees within country or abroad. Since the IRB-RAT relies on self-report, it is important to remember the reliability and, consequently, the validity of self-report data can be compromised by a variety of factors to include, but are not limited to, comprehension of items and/or motivation to respond in ways that do not accurately reflect true opinions. In our study, we included faculty members, which

strengthened results by allowing diverse perceptions to be included. Including faculty members' perceptions is encouraged. Also, users of the IRB-RAT are encouraged to modify items to be consistent with the cultural context within which it is being used. In this study, items were slightly modified for this reason. However, it is important to remember the IRB-RAT was designed to assess IRBs in the US and cultural differences may limit the utility of the IRB-RAT in countries other than the US. Further, as indicated by Reeser et al. (2008), the role of respondents completing the IRB-RAT may affect results. In this study, both IEC and faculty members completed the IRB-RAT and results reflect their combined responses, and our findings do reflect that gender, IEC membership status, and IEC experience may impact ratings of IEC functioning at least in some areas.

Beyond this individual focus within IECs, there is a need for ethics committees across institutions to communicate with one other and with regulatory bodies (Kadam & Karandikar, 2012). Capacity building continues to be important and centralized registration of IECs is recommended as a means by which some level of oversight can be provided to IECs in India. Until registration is mandated, information about the number, composition, structure, expertise, training and functioning of IECs in India is limited to survey research (e.g., Muthuswamy, 2005, Singh, 2009). The European Forum for Good Clinical Practice (2009) provides data on ethics committees in seven non-European countries, providing valuable data for comparing IECs across countries. Kadam & Karandikar (2012) recommend that Indian IECs work closely with the Forum for Ethics Review Committees in India and the Forum for Ethical Review Committees in Asia Pacific.

Research Agenda

Generalizability of our findings is limited by a small and geographically limited sample. More research is needed using larger and more geographically diverse samples to further assess the utility of the IRB-RAT for assessing IECs in low to middle income countries. In addition to the IRB-RAT, there appears to be a need for a comprehensive and culturally relevant instrument to gather further data about the functioning of IECs in LMICs. Current findings support the need for IEC member training in research ethics and formulation of standard operating procedures for IEC functioning. Future research may want to examine role-dependent variations in perceptions of the IRB (Reeser et al., 2008).

Educational Implications

The factors included on the IRB-RAT can be used as the basis for developing education and training for both ethics committee members and research faculty. Specifically, educational or training workshops can be structured around the following topics: procedural justice, IRB outreach, interpersonal justice, IRB formal functioning, structure, and composition, pro-science sensitivity, bias, competence, and upholding the rights of human participants.

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Biography

Biographical Sketches

Tiffany Chenneville, Ph.D. currently serves as a member of the University of South Florida's Institutional Review Board, teaches ethics at the undergraduate and graduate level, and has conducted research ethics training in India with funding provided by the National Institutes of Health. She served as the principal investigator for this project and, in this capacity, was responsible for overseeing all aspects of this paper. Lynette Menezes, Ph.D., has served as a member of the University of South Florida's Institutional Review Board and has conducted research ethics training in India with funding provided by the National Institutes of Health. She served as the co-principal investigator for this project and, in this capacity, was responsible for overseeing all aspects of this paper. Angela Mann, Ph.D. served as a research assistant for this project and contributed to the literature review and the interpretation and reporting of findings. Lauren M. Bylsma, Ph.D. served as a research assistant for this project and contributed significantly to data analysis and interpretation as well as the reporting of findings. Jayendrakumar Kosambiya, M.D., is a member of the Government Medical College Surat's Institutional Ethics Committee and served as a co-Principal Investigator for this project. He was primarily involved with data collection. Rajendra Baxi, M.D. is a member of the Medical College Baroda's Institutional Ethics Committee and served as a co-Principal Investigator for this project. He was primarily involved with data collection.

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Figure 1.

Descriptive versus ideal ratings on 8 subscales of the IRB-RAT by IEC members and faculty participants from two medical colleges in India. N=42.

Table 1

IRB-RAT Ratings

Anchor	“Importance to You” (Ideal) Descriptor	“Description of Your IEC” (Current) Descriptor
7	<i>Absolutely essential</i> to you	<i>Highly</i> descriptive of your IEC
6	<i>Very</i> important to you	<i>Very</i> descriptive of your IEC
5	<i>Generally</i> important to you	<i>Generally</i> descriptive of your IEC
4	<i>Moderately</i> important to you	<i>Moderately</i> descriptive of your IEC
3	<i>Somewhat</i> important to you	<i>Somewhat</i> descriptive of your IEC
2	Of <i>minor</i> importance to you	<i>Minorly</i> descriptive of your IEC
1	<i>Not</i> important to you	<i>Not at all</i> descriptive of your IEC

Table 2**IRB-RAT Factors**

Scale	Purpose	Sample Items
Procedural Justice	Designed to assess how IEC members make decisions	<ul style="list-style-type: none"> An IEC that reviews protocols in a timely fashion. An IEC that conducts a conscientious and complete review of protocols.
IEC Outreach	Designed to assess the extent to which the IEC offers to assist researchers	<ul style="list-style-type: none"> An IEC that offers information to improve the chances of gaining IEC approval. An IEC that offers consultation during the development of research protocols and grant applications.
Interpersonal Justice	Designed to assess the extent to which IEC members treat investigators respectfully and/or the extent to which IEC members lack arrogance with regard to their role and function	<ul style="list-style-type: none"> An IEC that works with investigators to find mutually satisfying solutions whenever disagreements exist. An IEC that is open and pleasant in its interactions with investigators.
IEC Formal Functioning, Structure and Composition	Designed to assess the functioning, structure, and composition of the IEC	<ul style="list-style-type: none"> An IEC that maintains accurate records. An IEC that requires that its Chair be an experienced investigator.
Pro-Science Sensitivity	Designed to assess the extent to which the IEC and its members balance participants' rights with sound conduct of research	<ul style="list-style-type: none"> An IEC that does not use its power to suppress research that is otherwise methodologically sound and in compliance with federal [ICMR] policy whenever it perceives potential criticism from outside the scientific community. An IEC that shows considerable evidence that the advancement of science is part of its mission.
Bias	Designed to assess the extent to which the IEC is impartial or lacks bias	<ul style="list-style-type: none"> An IEC with members who do not allow personal biases to affect their evaluation of protocols. An IEC whose members hold no preconceived biases against particular research techniques.
Competence	Designed to assess the extent to which IEC members have the education, training, and experience necessary to adequately review research protocols	<ul style="list-style-type: none"> An IEC with members who are very knowledgeable about IEC procedures and federal policy. An IEC composed primarily of members regarded as highly competent investigators.
Upholding the Rights of Human Participants	Designed to assess the extent to which the rights of human participants are being upheld by IEC members	<ul style="list-style-type: none"> An IEC that views protection of human participants as its primary function. An IEC that takes timely action when an investigator has violated its decisions.

Note: Items were slightly modified with permission from the authors to reflect the Indian context.

Table 3

IRB-RAT Individual Item Analysis

IRB-RAT Question	Sample Ideal Mean (SD)	Sample Descriptive Mean (SD)	U.S. Ideal Mean (SD)
(1) An IEC (or IRB) that reviews protocols in a timely fashion.	6.43 (0.91)	4.76 (1.70)**	6.43 (0.80)
(2) An IEC (or IRB) that conducts a conscientious and complete review of protocols.	6.10 (1.22)	4.65 (1.59)**	5.86 (1.24)
(3) An IEC (or IRB) that recognizes when it lacks sufficient expertise to evaluate a protocol and seeks an outside evaluator.	5.59 (1.37)	4.27 (1.66)**	5.28 (1.41)
(4) An IEC (or IRB) that gives a complete explanation for any required changes to or disapprovals of protocols.	6.24 (1.18)	4.56 (1.82)**	5.73 (1.21)*
(5) An IEC (or IRB) that includes a complete explanation when it denies or mandates changes in a protocol based on criteria that are more stringent than or different from ICMR (or federal) policy.	5.78 (1.58)	4.20 (1.73)**	5.59 (1.35)
(6) An IEC (or IRB) that is open to reversing its earlier decisions.	6.19 (1.19)	5.23 (1.35)**	5.52 (1.34)*
(7) An IEC (or IRB) that invites investigators to present their position whenever a question or concern about a research protocol arises.	6.10 (1.30)	4.97 (1.50)**	5.51 (1.33)*
(8) An IEC (or IRB) that offers consultation during the development of research protocols or grant applications.	5.34 (1.76)	3.60 (2.03)**	4.40 (1.76)*
(9) An IEC (or IRB) that offers investigators opportunities to be educated about ICMR (or federal) policy.	5.59 (1.60)	3.88 (1.89)**	4.03 (1.68)**
(10) An IEC (or IRB) that offers editorial suggestions regarding consent documents and protocols.	5.30 (1.51)	3.71 (1.89)**	3.20 (1.82)**
(11) An IEC (or IRB) that offers investigators information to improve the chances of gaining IEC (or IRB) approval.	5.93 (1.42)	3.80 (1.69)**	5.31 (1.45)*
(12) An IEC (or IRB) that is willing to work with investigators to find mutually satisfying solutions whenever disagreements exist.	5.58 (1.66)	4.18 (1.51)**	5.71 (1.27)
(13) An IEC (or IRB) that responds in a timely manner to investigators' inquiries about its processes and decisions.	6.33 (1.18)	4.53 (1.70)**	5.80 (1.15)*
(14) An IEC (or IRB) that treats investigators with respect.	6.52 (1.09)	4.71 (1.83)**	5.45 (1.45)**
(15) An IEC (or IRB) that acknowledges full responsibility for its errors or delays in processing protocols and attempts to correct them as expeditiously as possible.	6.17 (1.22)	4.23 (1.80)**	5.33 (1.44)**
(16) An IEC (or IRB) that is open and pleasant in its interactions with investigators.	6.31 (0.19)	4.89 (1.58)**	4.72 (1.61)**
(17) An IEC (or IRB) that maintains complete and accurate records.	6.45 (1.21)	5.24 (1.32)**	5.50 (1.50)**
(18) An IEC (or IRB) that monitors the progress of each approved research project in line with ICMR (or federal) policy.	6.14 (1.26)	4.46 (1.89)**	4.39 (2.16)**
(19) An IEC (or IRB) that requires that its Chair be an experienced investigator.	6.18 (1.34)	5.03 (1.57)**	4.75 (1.76)**
(20) An IEC (or IRB) that has a diverse membership	6.00 (1.34)	4.95 (1.63)**	4.07 (1.93)**
(21) An IEC (or IRB) that is allocated sufficient resources to carry out functions efficiently and thoroughly.	6.39 (1.09)	4.44 (1.73)**	5.38 (1.44)**
(22) An IEC (or IRB) whose members fully understand and act within the scope of their function.	6.40 (1.50)	5.11 (1.45)**	5.67 (1.27)**
(23) An IEC (or IRB) that is composed of more than one public member.	5.30 (1.83)	5.03 (1.56)	2.68 (1.69)**

IRB-RAT Question	Sample Ideal Mean (SD)	Sample Descriptive Mean (SD)	U.S. Ideal Mean (SD)
(24) An IEC (or IRB) that views its role as being an investigator's ally rather than as being a hurdle to clear.	6.32 (1.19)	4.69 (1.62)**	5.57 (1.44)**
(25) An IEC (or IRB) that does not use its power to suppress research that is otherwise methodologically sound and in compliance with ICMR (or federal) policy whenever it perceives potential criticism from outside the scientific community.	6.00 (1.40)	4.63 (1.49)**	6.08 (1.19)
(26) An IEC (or IRB) that shows considerable evidence that the advancement of science is part of its mission.	6.17 (1.29)	4.78 (1.65)**	4.82 (1.79)**
(27) An IEC (or IRB) that does a good job of upholding participants' rights while, at the same time, facilitating the conduct of research.	6.20 (1.23)	4.72 (1.52)**	6.10 (1.11)
(28) An IEC (or IRB) that is empathetic with the difficulties that can present themselves during the design or conduct of research.	5.90 (1.26)	4.56 (1.76)**	4.66 (1.60)**
(29) An IEC (or IRB) whose membership does not allow their personal biases to affect their evaluation of protocols.	6.48 (1.17)	4.86 (1.65)**	6.17 (1.10)
(30) An IEC (or IRB) that requires members to remove themselves from evaluating protocols whenever there might be a real or apparent conflict-of interest.	6.00 (1.29)	5.15 (1.68)*	5.44 (1.46)*
(31) An IEC (or IRB) that holds no preconceived biases against particular research techniques.	6.15 (1.30)	4.94 (1.67)**	5.43 (1.47)*
(32) An IEC (or IRB) that holds no preconceived biases against particular research topics.	6.31 (1.22)	5.19 (1.37)**	5.45 (1.46)**
(33) An IEC (or IRB) that is open to innovative approaches to conducting research.	6.17 (1.36)	4.76 (1.65)**	5.28 (1.43)**
(34) An IEC (or IRB) that can competently distinguish exempt from nonexempt research.	5.71 (1.42)	4.62 (1.56)**	5.48 (1.44)
(35) An IEC (or IRB) whose membership is very knowledgeable about IEC (or IRB) procedures and ICMR (or federal) policy.	6.21 (1.30)	4.59 (1.70)**	6.01 (1.16)
(36) An IEC (or IRB) that is composed primarily of highly competent investigators.	5.93 (1.35)	4.29 (1.73)**	4.46 (1.70)**
(37) An IEC (or IRB) that provides a comprehensive training program for its new members.	6.02 (1.46)	3.92 (2.02)**	4.43 (1.64)**
(38) An IEC (or IRB) that is composed of members who arrive at meetings well-prepared.	6.31 (1.20)	4.80 (1.64)**	5.07 (1.52)**
(39) An IEC (or IRB) whose Research Compliance Officer or Member Secretary has a background in conducting research.	5.74 (1.62)	4.81 (1.60)**	4.68 (1.66)**
(40) An IEC (or IRB) that conducts a conscientious informed analysis of potential benefits weighed against potential risks before making decisions.	6.26 (1.23)	5.05 (1.45)**	5.54 (1.29)**
(41) An IEC (or IRB) that has at least one member who is knowledgeable about the content domain and discipline of investigators' protocols.	5.95 (0.24)	5.22 (1.42)**	5.13 (1.55)*
(42) An IEC (or IRB) that views protection of human participants as its primary function.	6.38 (1.21)	5.75 (1.20)**	5.80 (2.83)*
(43) An IEC (or IRB) that takes timely action when an investigator has violated the specifications of its rulings.	6.45 (1.11)	4.94 (1.88)**	5.22 (1.51)**
(44) An IEC (or IRB) that applies appropriately flexible standards regarding voluntary and informed consent requirements.	5.62 (1.46)	4.89 (1.24)**	5.23 (1.52)**
(45) An IEC (or IRB) that takes timely and appropriate action whenever scientific misconduct is alleged.	6.50 (1.17)	5.20 (1.62)**	5.52 (1.42)**

Note:

**
p<.001;

* p<.05 in comparison to sample ideal mean ratings.

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Table 4

Comparison of Top Ranked Items between Indian sample and US normative sample

Most Important Ideal Characteristics	
Indian Sample	U.S. Sample
(43) An IEC (or IRB) that takes timely action when an investigator has violated the specifications of its rulings.	(35) An IEC (or IRB) whose membership is very knowledgeable about IEC (or IRB) procedures and ICMR (or federal) policy.
(17) An IEC (or IRB) that maintains complete and accurate records.	(25) An IEC (or IRB) that does not use its power to suppress research that is otherwise methodologically sound and in compliance with ICMR (or federal) policy whenever it perceives potential criticism from outside the scientific community.
(29) An IEC (or IRB) whose membership does not allow their personal biases to affect their evaluation of protocols.	(27) An IEC (or IRB) that does a good job of upholding participants' rights while, at the same time, facilitating the conduct of research.
(45) An IEC (or IRB) that takes timely and appropriate action whenever scientific misconduct is alleged.	(29) An IEC (or IRB) whose membership does not allow their personal biases to affect their evaluation of protocols.
(14) An IEC (or IRB) that treats investigators with respect.	(1) An IEC (or IRB) that reviews protocols in a timely fashion.
Least Important Ideal Characteristics	
Indian Sample	U.S. Sample
(10) An IEC (or IRB) that offers editorial suggestions regarding consent documents and protocols.	(23) An IEC (or IRB) that is composed of more than one public member.
(23) An IEC (or IRB) that is composed of more than one public member.	(10) An IEC (or IRB) that offers editorial suggestions regarding consent documents and protocols.
(8) An IEC (or IRB) that offers consultation during the development of research protocols or grant applications.	(9) An IEC (or IRB) that offers investigators opportunities to be educated about ICMR (or federal) policy.
(12) An IEC (or IRB) that is willing to work with investigators to find mutually satisfying solutions whenever disagreements exist.	(20) An IEC (or IRB) that has a diverse membership
(3) An IEC (or IRB) that recognizes when it lacks sufficient expertise to evaluate a protocol and seeks an outside evaluator.	(18) An IEC (or IRB) that monitors the progress of each approved research project in line with ICMR (or federal) policy.