Beyond “Compliance”: The Role of Institutional Culture in Promoting Research Integrity

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Abstract

**Purpose**
To contribute data to conceptual explorations of the role of institutional culture in promoting research ethics and integrity.

**Method**
The authors highlight relevant themes that emerged from a multimodal needs assessment conducted under the Johns Hopkins Clinical Translational Science Award regarding ethical issues encountered in the conduct of clinical and translational research. Qualitative and quantitative data were collected through a short survey targeting research staff, course evaluations from a research ethics and integrity education course attended primarily by faculty and fellows, a review of institutional policies on research ethics education, and in-depth interviews of key administrative officials.

**Results**
Major themes included the relative influence of regulatory compliance and relationships between research personnel at different levels of the organizational hierarchy on the responsible conduct of research. The majority of respondents (85%) expressed comfort with reporting suspected breaches in research integrity, but the others did not feel comfortable doing so for fear of professional repercussions. Respondents provided insight into factors in the research environment they felt were most helpful in fostering research integrity, particularly with respect to relationships and power differentials between individuals or groups.

**Conclusions**
Compliance with research regulations is only one of a number of important factors in an institution’s ethical culture of research. Equally important are a clear articulation of the ethical reasoning that underlies the regulations, and efforts to redress power imbalances by encouraging open communication. Other ways of improving relationships among various members of the academic research team should be the focus of future investigations.

Increasingly burdensome regulations and oversight mechanisms contribute to a compliance-oriented culture of biomedical research. Although rules and regulations can be important in ensuring that research participants are protected, it is arguably desirable to promote the ethical principles behind such guidelines as well. Researchers are continually facing issues that require them to make decisions based on ethical principles rather than simply following rules. Another desirable goal is to prevent problems in research ethics and integrity, rather than react to them, but it is unclear how to formulate policies that will be effective in this regard.

One potential approach would be to address directly the range of environmental factors that can influence research ethics and integrity. Investigations of environmental factors, such as organizational culture, have demonstrated that they may be useful targets of intervention. For example, investigators committed to improving patient safety have noted the prominence of teamwork in their studies of other industries, such as aviation, that also seek to minimize error. Pronovost and colleagues relate how they subsequently employed methods of teamwork-building in patient safety training. Related to this emphasis on teamwork, improvements in patient safety have resulted from a shift away from “individual blame” in which responsibility for problems is attributed to particular individuals, toward a focus on the role of institutional culture in promoting safety. Although much of the work regarding the relationship of research ethics and integrity to cultural factors has largely been conceptual, it draws on relevant analogies suggesting that cohesiveness between members at different levels of an organization is important in decreasing risk.

The purpose of this study is to contribute data to scholarship concerning the role of institutional culture in promoting research ethics and integrity by highlighting relevant themes that emerged from a research ethics needs assessment conducted at our institution. The opportunity to collect the data presented here came through the Johns Hopkins Institute for Clinical and Translational Research (ICTR). The ICTR at Hopkins is supported by an award from the Clinical and Translational Science Awards program, a National Institutes of Health initiative which provides funds to a growing number of U.S. academic research institutions to promote translational research through the investigation of all aspects of research practice, the identification of best practices, and the collaboration and sharing of information within and across institutions. We conducted the needs assessment primarily to inform the development of research ethics education and services for the Johns Hopkins research community.

In the early stages of data collection for the needs assessment, a few informants suggested that there is a “culture of compliance” at the institution, despite the significant changes in research
administration and oversight mechanisms that had already occurred and had major positive effects on research ethics by all accounts. This notion of a culture of compliance guided our subsequent data collection and analysis in the hopes of providing insight into how to further cultivate an environment of continual improvement where possible, and influence the general direction of empirical scholarship, training, and evaluation so that the culture of biomedical research ethics can move even further beyond compliance.

Method
We employed a descriptive, exploratory methodology using a combination of quantitative and qualitative data collection strategies. There were three discrete phases of data collection for the needs assessment, all of which took place between February and September 2008.

Phase I: Convenience sample surveys
Our first source of data came from a brief survey that was administered to convenience samples of research faculty and staff attending three different institutional events. The participants in the first sample were faculty and staff attending a retreat sponsored by the ICTR, participants in the second sample were nurses attending a staff retreat sponsored by one of the units of the hospital, and participants in the third sample were research coordinators attending a lunchtime seminar. Table 1 describes these three samples.

Each of the three convenience samples responded to survey questions about four issues: (1) their comfort levels in reporting any breaches of human subjects protections or research integrity that they may have witnessed, (2) whether they had witnessed such breaches in research, (3) their thoughts about the ethical culture in their unit and in the institution, and (4) their thoughts about the training and education regarding research ethics and integrity that they had received. The final version of the survey, developed in an iterative process, consisted of 11 items scored on a five-point Likert scale (1 = strongly disagree; 5 = strongly agree). Some of the items were newly generated, whereas others were constructed as parallels to items on the Safety Attitudes Questionnaire (SAQ), which Sexton et al developed by modifying the Intensive Care Unit Management Attitudes Questionnaire (which in turn is derived from a measure called the Flight Management Attitudes Questionnaire used in commercial aviation). The SAQ has been administered at Hopkins annually to assess attitudes toward patient safety.17 Selected items from the convenience sample surveys are listed in Table 2. We also collected qualitative data from respondents by providing space after each item for comments.

The quantitative data were imported into STATA (StataCorp, College Station, Texas) to generate descriptive statistics and conduct exploratory statistical analyses. The qualitative analysis was done using a conventional content analysis approach, first by reading through and transcribing the comments, followed by developing thematic categories based on the text, and finally grouping each comment by theme.

Phase II: The Course on Research Ethics
Our most comprehensive dataset came from course evaluations completed by participants in the Course on Research Ethics (CORE), a one-day training course that is required of all faculty and fellows who partake in clinical research at Johns Hopkins School of Medicine. The course has existed since 2003, and nearly 2,000 completed evaluations had been collected between 2003 and mid-2008, when we began this phase of the data collection. For the purposes of the needs assessment, we included all of the completed evaluations that were available from 2005 to 2008, and we computed comparative statistics using the entire dataset to ensure the representativeness of the sample.

The evaluation contains 27 items that are aimed primarily at assessing the participants’ satisfaction with the course and the fulfillment of course objectives. The evaluation does not contain any items that ask directly about the culture of research ethics at Hopkins, but many of the items are indirectly relevant. We included in our analysis qualitative data from the items that indirectly addressed issues of interest for our needs assessment—for instance, reflections about the IRB that were offered by some participants when asked open-ended questions about their experiences in submitting protocols to the IRB.

In addition, in early 2008, during one of the CORE sessions, we held six focus groups, each of approximately 10 fellows, students, and staff who volunteered to stay and be interviewed after the course had concluded. These sessions were led by faculty with expertise in different areas of research ethics and integrity from the Berman Institute who regularly participate in teaching CORE. During the semistructured discussions, the leaders asked targeted questions about participants’ views of the culture of research ethics and integrity in our institution. For example, the opening question was, “What do you think of how research is conducted at Hopkins?

<table>
<thead>
<tr>
<th>Event</th>
<th>No. (%) of principal investigators (PIs), co-PIs, and faculty</th>
<th>No. (%) of research staff (including coordinators, assistants, and research nurses)</th>
<th>Total no. of respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Institute for Clinical and Translational Research retreat</td>
<td>21 (72)</td>
<td>8 (28)</td>
<td>29</td>
</tr>
<tr>
<td>Nursing staff retreat</td>
<td>0 (0)</td>
<td>78 (100)</td>
<td>78</td>
</tr>
<tr>
<td>Brown-bag seminar for research coordinators</td>
<td>0 (0)</td>
<td>44 (100)</td>
<td>44</td>
</tr>
<tr>
<td>Total</td>
<td>21 (14)</td>
<td>130 (86)</td>
<td>151</td>
</tr>
</tbody>
</table>

Table 1 Characteristics of Survey Respondents From Phase I of Data Collection for a Research Ethics Needs Assessment: Convenience Samples of Participants in Various Institutional Events, Johns Hopkins University, 2008
Table 2

Results by Research Role From Surveys of Convenience Samples of Participants in an Institute for Clinical and Translational Research Retreat (n = 29), a Nursing Staff Retreat (n = 78), and a Lunchtime Seminar for Research Coordinators (n = 44), Johns Hopkins University, 2008

<table>
<thead>
<tr>
<th>Item</th>
<th>No. (%) of principal investigators</th>
<th>No. (%) of research staff and nurses</th>
<th>Total no. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>If I were to witness a breach [in human subjects protections or research integrity], I would feel comfortable reporting it*</td>
<td>Agree 16 (76)</td>
<td>40 (87)</td>
<td>56 (77)</td>
</tr>
<tr>
<td></td>
<td>Disagree 5 (24)</td>
<td>6 (13)</td>
<td>11 (15)</td>
</tr>
<tr>
<td>I have witnessed a breach in human subjects protections*</td>
<td>Agree 5 (24)</td>
<td>7 (14)</td>
<td>12 (16)</td>
</tr>
<tr>
<td></td>
<td>Disagree 16 (76)</td>
<td>42 (86)</td>
<td>58 (79)</td>
</tr>
<tr>
<td>I have witnessed a breach in research integrity*</td>
<td>Agree 5 (24)</td>
<td>2 (4)</td>
<td>7 (10)</td>
</tr>
<tr>
<td></td>
<td>Disagree 16 (76)</td>
<td>45 (96)</td>
<td>61 (84)</td>
</tr>
<tr>
<td>IRBs are primarily concerned about compliance with research regulations*</td>
<td>Agree 5 (24)</td>
<td>11 (22)</td>
<td>16 (22)</td>
</tr>
<tr>
<td></td>
<td>Disagree 16 (76)</td>
<td>38 (78)</td>
<td>54 (74)</td>
</tr>
<tr>
<td>I would feel safe being a research participant here†</td>
<td>Agree N/A</td>
<td>96 (79)</td>
<td>96 (79)</td>
</tr>
<tr>
<td></td>
<td>Disagree N/A</td>
<td>22 (18)</td>
<td>22 (18)</td>
</tr>
<tr>
<td>In this institution, it is difficult to speak up about problems in research protocols†</td>
<td>Agree N/A</td>
<td>31 (25)</td>
<td>31 (25)</td>
</tr>
<tr>
<td></td>
<td>Disagree N/A</td>
<td>81 (66)</td>
<td>81 (66)</td>
</tr>
<tr>
<td>In this clinical area, it is difficult to speak up if I perceive a problem in patient care†</td>
<td>Agree N/A</td>
<td>13 (21)</td>
<td>13 (21)</td>
</tr>
<tr>
<td></td>
<td>Disagree N/A</td>
<td>38 (60)</td>
<td>38 (60)</td>
</tr>
<tr>
<td>The climate in this institution fosters the highest-quality conduct of research†</td>
<td>Agree 21 (100)</td>
<td>109 (92)</td>
<td>130 (86)</td>
</tr>
<tr>
<td></td>
<td>Disagree 0 (0)</td>
<td>9 (8)</td>
<td>9 (8)</td>
</tr>
</tbody>
</table>

* Item administered to the group of investigators from the research retreat and the research staff from the lunchtime talk only.
† Item administered to the lunchtime talk group and the group of nurses at a staff retreat only.
‡ Item administered to all groups.
§ The percentages in this column do not add up to 100% because of missing data (i.e., when participants left certain items blank).

currently? What is the ‘pulse’ or ‘state’ of issues related to human subjects protection and research integrity?”

The quantitative data from the course evaluations were imported into STATA to generate descriptive statistics. Analysis of qualitative data from the open-ended questions in the CORE evaluation and the focus group discussions was conducted in a manner identical to that of the analysis used for the Phase I (survey) qualitative data, described above. All of the comments were read through completely, and general themes were identified and used to categorize each comment thematically and according to demographic.

Phase III: In-depth and group discussions with key informants
The third source of data came from semistructured discussions with four key stakeholders in research at Hopkins, including two IRB chairs, one IRB director, and one individual with a senior role in research administration. We also took advantage of a regularly scheduled meeting of IRB chairs and cochairs to conduct a “mini-focus-group,” which consisted of 10 participants. These discussions took place between May and September 2008. The discussion guide was the same for both formats. Questions for the guide were developed based on the results from the analyses of the convenience sample surveys and the CORE evaluations and were designed to delve more deeply into and validate the findings from the previous phases of data
collection. For example, because the qualitative data from the surveys mentioned a culture of compliance in several instances, we asked key informants directly about what a culture of compliance meant to them. We also asked interviewees about their perceptions of the general state of research ethics and integrity locally and nationally.

**Results**

**Phase I: Convenience sample surveys**

Table 1 shows the number and role of the participants who completed a survey at each event. The first sample, from the ICTR retreat, consisted of 29 respondents whose roles ranged from principal investigator (PI) to research coordinator and staff; the second sample of 78 respondents from the nursing retreat consisted entirely of nursing staff; and the third sample of 44 respondents was a mix of research assistants, coordinators, and nurses. Overall, 151 participants completed surveys. All of the respondents had participated in research at Hopkins in some capacity.

The results of the convenience sample surveys are presented in Table 2 by respondents’ role in research. The majority of respondents reported never having witnessed problems in research ethics and integrity and feeling comfortable expressing concerns related to research if they were to perceive a problem. Seventy-three respondents (those at the research retreat plus those at the lunchtime talk) were asked if they had ever witnessed a breach in research integrity, and 84% (n = 61) reported that they had not. In addition, 86% (n = 130) of respondents from all three groups combined agreed with the statement, “The climate in this institution fosters the highest quality of conduct of research.”

In focusing on the open-ended responses of the subset of respondents who did report encountering challenges related to research integrity, two themes related to relationships and hierarchy emerged. The first was respondents’ perceptions of others’ preparedness to conduct research. One participant noted a problem with “lack of understanding of protocols by the protocol coordinator … [and] lack of understanding of the underlying safety and medical cause and effect of the protocol” (PI). Another respondent was concerned that “due to poor PI involvement and lack of study coordinator’s medical knowledge, [I] notice [a] decline in patient advocacy as [the] need for subjects increases” (research nurse). The staff’s comments were most often concerned with the PI, as opposed to other staff members; conversely, comments from investigators were most often centered on staff or students. Both staff and investigators suggested that the “other” group undergo more training.

The second theme related to fear of punishment and power differentials was evident in the quantitative data. Although the majority (77%, n = 56) of the 73 participants who were asked about their comfort levels with reporting potential research misconduct agreed that they would feel comfortable reporting such incidents, 15% (n = 11) said they would not feel comfortable reporting or know how to report an observed breach in research conduct. Fewer respondents indicated that they would have difficulty speaking up about problems related to patient care than problems related to research protocols.

**Phase II: CORE**

Of the nearly 2,000 completed evaluations, 700 evaluations met our inclusion criteria. Of the 700 in our sample, 316 were from faculty, 320 were from fellows, students, and staff, and the remaining 64 were from other groups, such as administrators and lab technicians.

The majority of respondents indicated a high level of satisfaction with their experience in conducting research, and many researchers expressed appreciation about the improvements that came with the restructuring of research review at the institution over the past decade. Here again, however, we concentrated on the subset of data that would be useful for our needs assessment, focusing on comments in which problems or suggestions were mentioned. From this subset of course evaluation data, the two themes in the survey data related to relationships and hierarchy were also present.

The first theme was the discrepancy between the attitudes of faculty and those of fellows regarding their relative training needs or, more generally, regarding perceptions of research personnel in different roles. Fellows thought that faculty should receive more training in the responsible conduct of research (RCR). RCR is the focus of the second half of the course and is required for fellows but not for faculty. Fellows frequently commented that faculty should attend that part of the course as well. This idea—that superiors should be included in RCR education—also emerged in the small-group discussions. In addition, fellows commented about the importance of mentors modeling ethical behavior to foster an environment in which these behaviors are effectively taught to trainees. For instance, one participant suggested that framing a practice as good for the integrity of science—as opposed to framing it as good for the purpose of getting published in a top journal—should be a focus for mentors.

The second theme related to relationships and hierarchy was the fear of punishment and retribution on the part of fellows and trainees or, more generally, concerns related to differential levels of power over others. Several respondents discussing the second half of CORE, in which only fellows, staff, and students participate, expressed the view that “this was a great venue to ask open questions without fear of punishment or humiliation” (i.e., because faculty were not present). Other respondents discussed their reluctance to acknowledge their own mistakes in research, because they felt that such acknowledgments would not be beneficial or actually could even be harmful to their careers. The high expectations of superiors governing research trainees was one reason given by respondents in attempting to explain their hesitation to openly discuss their mistakes in performing research. This theme about rules and punishment also came through in comments about the IRB and compliance. Whereas many participants described positive experiences with the IRB and the improvements that they had noticed over time, others suggested that they would like to have a different relationship with the IRB. One participant wrote that “many investigators do not feel comfortable with the IRB. It doesn’t feel like a partnership, but rather an adversarial relationship” (PI, CORE evaluation). Another proposed that...
“investigators should have a more personal relationship with the IRB and IRB staff” (fellow, from small groups). At times, concerns with a culture of compliance caused a conflict for participants. For example, one participant in the small groups noted that “regulatory oversight and scrutiny is a double-edged sword. Sometimes the institution gets mired in detail and loses sight of what’s important” (fellow, from small groups).

Phase III: In-depth and group discussions with key informants

When asked about the culture of research ethics and the general environment of research, all of our key informants were confident that the system was working to promote ethical research conduct overall. Our informants also noted that researchers were often enthusiastic about becoming involved in discussions related to research ethics and integrity when such opportunities arose.

With respect to the theme of training needs of different types of research personnel, the focus of the conversation tended to be on the training and responsibilities of investigators versus IRB members. One informant stated that

Most investigators presume that the design of their studies is ethical and tend to focus more on the details of research regulations, which should really be the IRB’s function. The only rule that investigators need to remember is to adhere to their approved protocol; everything else should be the IRB’s job.

This informant explained that regulations are important but that the abundance of rules can distract conscientious investigators from focusing on the ethical underpinnings of the regulations, saying that “regulations cannot possibly cover every situation, and it is in the areas that regulations do not reach where ethical problems often arise.” This respondent also thought that training of investigators should focus less on the specific details of regulations and more on broader concepts in designing ethical research, provided that the IRB accepts the task of handling these details to ensure compliance with regulations. This would allow investigators the freedom to focus on a broader concept of research ethics while delegating some of the compliance responsibility to the IRB.

Discussion

Amidst substantial expressions of confidence in the current system and comfort in the local research environment, some respondents noted that, in a highly regulated environment, there may be subtle attitudes or patterns of behavior that are ethically problematic, even when blatant misconduct is not an issue. Many of our participants understood that attention focused on compliance does not mean that the ethical underpinnings of the regulations are less important. However, some less experienced investigators, in particular, described a conflict between the need to navigate complex rules and regulations, and the importance of considering the ethical principles while designing and conducting research. This perceived conflict may reflect an incomplete understanding of the ethical foundations of the regulations or a belief that concerns about compliance should be privileged. Although compliance is important for both investigators and the IRB, there is confusion about the relative attention that each party should pay to it.

Although we have very limited data comparing people’s comfort reporting problems in the clinical and research settings, the trend that we observed toward higher reported levels of comfort in the clinical compared with research settings may reflect the success of institutional interventions focused on patient safety that have been implemented with an explicit intention to reduce the perceived risk associated with reporting. Evidence suggests that one of the foundational features in the evolution of institutional cultures is the deconstruction of hierarchy and power differentials, such that any member of the organization feels free to raise questions or concerns. This interpretation is supported by our data, particularly from students and less experienced investigators who expressed some discomfort and hesitation to voice their concerns. A significant minority of our respondents are reluctant to report a problem in research ethics and integrity if they observe one. The reasons for such hesitation are unclear and may relate to concerns about challenging superiors, uncertainty about whether in fact something is problematic, or that the appropriate mechanisms for reporting potential problems are unclear. Our data contribute to the nascent body of empirical information regarding the influence of hierarchy on the culture governing research ethics and integrity within an institution. A common theme was the hierarchy evident in the relationship between PIs and junior researchers or staff. We also noted a discrepancy between the attitudes of faculty and those of fellows regarding who is responsible for ensuring sound research ethics and integrity as well as who needs more training. For example, some of the fellows thought that faculty needed more training in RCR, whereas some of the faculty did not think they needed additional training in research ethics at all. Moreover, some junior researchers and staff expressed a fear of punishment or humiliation by their superiors if they acknowledged their own mistakes. Others were reluctant to question their PIs’ mistakes regarding the eligibility of patients for a particular protocol. These findings support the observation made by others that progress in the culture of biomedical research can be hampered by power imbalances and the absence of “blame-free” reporting systems. They also reflect the structure of federal regulations on reporting, which place responsibility at the individual, not institutional, level, as has been pointed out in discussions of whistle-blowing.19

Limitations

This study has a number of limitations. The needs assessment was only conducted at one institution and was initially designed for internal purposes rather than as a research project about how to shift institutional culture. Our original intention was to inform the development or modification of training programs in research ethics and integrity, not to characterize organizational influences on the responsible and ethical conduct of research. We relied on convenience sampling instead of a more systematic data collection strategy to take advantage of the range of opportunities to gain as many perspectives as possible—PIs, coinvestigators, research coordinators, faculty and students, research nurses and staff, and administrative officials—in a short period of time. However, there are limitations of this methodology. Our sample was not drawn in a representative fashion, and our sample sizes were not large enough to conduct statistical
Implementing a mechanism to facilitate reporting suspicious behavior and violations in the research environment, such as the airline industry, is well documented in the literature. A first step toward this goal might be the creation of a blame-free system for reporting suspected breaches, near breaches, or violations in human subjects protecting and RCR. The importance of such a system is well documented in the literature about patient safety and other risky fields, such as the airline industry. Implementing a mechanism for reducing tension between researchers and staff at different levels of the hierarchy will not only be particularly beneficial for less vocal researchers or those at lower hierarchical rungs in the organization, but it is one place to start to shift the culture.

Another target for culture change in biomedical research may be facilitating a shift from a dominant culture of compliance to a culture that emphasizes the moral reasons behind the rules, self-regulation, and prevention of problems. The proactive prevention of incidents is a strategy that has been adopted in the patient safety movement, and it is a characteristic of an advanced culture. Of course, the already-controlled environment of research that is driven by prospectively reviewed protocols and routinized systems should theoretically have substantially lower frequency of relevant incidents than the clinical setting that typically does not follow such approaches. Some commentators on the field of biomedical research as a whole have come to question the pervasive preoccupation with compliance and propose that an overhaul of the system may be necessary. For instance, some have argued that the “master–apprentice” model used to train PhD researchers promotes competition and is suboptimal for promoting RCR. As a remedy, these critics have suggested replacing this educational strategy with an entirely new paradigm that substantially increases the collaboration and interaction between the supervisor and student. Although the oversight of biomedical research by institutions and federal agencies is dependent on an overwhelming number of often complex regulations, current methods of training and education that focus on those regulations may benefit by devoting more time to broader aspects of research ethics and integrity. Adapting the wider perspective of advancing institutional culture may be helpful, for instance, in addressing and preventing conflicts of interest, an issue that has received increasing attention from federal bodies as well as from the realm of biomedical research.

We believe that the biomedical research enterprise can learn from improvements made in other sectors and that self-examination is a necessary first step toward the goal of preventing problems in research conduct. Our data point to the need for training that is specifically and uniquely targeted for different groups of stakeholders based on their status and responsibilities in the research enterprise. Also, given that the relative research ethics and integrity training of investigators in different roles was a source of concern for some of our respondents, a more uniform policy or the requirement of continuing education for more senior investigators may be useful. Modeling is another key issue in training that arose in our data. Titus et al. recommended to research universities that they begin to “repair research integrity” by focusing on “modeling ethical behavior” and “training the mentor.” Although some argue that breaches in research ethics will not be solved by closer supervision of trainees, junior researchers and staff in our study looked to their supervisors to “walk the walk,” not just “talk the talk,” with regard to research ethics and integrity.

In summary, these preliminary data will hopefully advance the discussion of how the culture of research ethics and integrity can and should progress, particularly with respect to issues of relationships and hierarchy. Future research should systematically and prospectively validate our initial attempt to characterize the components of organizational climate that influence the responsible and ethical conduct of biomedical research.

**Implications**

Despite these limitations, our findings shed light on some of the organizational characteristics that may influence the responsible and ethical conduct of biomedical research. These results are useful both for understanding the current situation with respect to how the system of oversight of research ethics and integrity is working and for identifying the areas in which an intervention would be most useful. It is likely that the culture of research, or indeed any organizational culture, would profit from better communication between researchers at different levels of the hierarchy. A first step toward this goal might be the creation of a blame-free system for reporting suspected breaches, near breaches, or violations in human subjects protections and RCR. The importance of such a system is well documented in the literature about patient safety and other risky fields, such as the airline industry. Implementing a mechanism for reducing tension between researchers and staff at different levels of the hierarchy will not only be particularly beneficial for less vocal researchers or those at lower hierarchical rungs in the organization, but it is one place to start to shift the culture.

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Despite these limitations, our findings shed light on some of the organizational characteristics that may influence the responsible and ethical conduct of biomedical research. These results are useful both for understanding the current situation with respect to how the system of oversight of research ethics and integrity is working and for identifying the areas in which an intervention would be most useful. It is likely that the culture of research, or indeed any organizational culture, would profit from better communication between researchers at different levels of the hierarchy. A first step toward this goal might be the creation of a blame-free system for reporting suspected breaches, near breaches, or violations in human subjects protections and RCR. The importance of such a system is well documented in the literature about patient safety and other risky fields, such as the airline industry. Implementing a mechanism for reducing tension between researchers and staff at different levels of the hierarchy will not only be particularly beneficial for less vocal researchers or those at lower hierarchical rungs in the organization, but it is one place to start to shift the culture.

Another target for culture change in biomedical research may be facilitating a shift from a dominant culture of compliance to a culture that emphasizes the moral reasons behind the rules, self-regulation, and prevention of problems. The proactive prevention of incidents is a strategy that has been adopted in the patient safety movement, and it is a characteristic of an advanced culture. Of course, the already-controlled environment of research that is driven by prospectively reviewed protocols and routinized systems should theoretically have substantially lower frequency of relevant incidents than the clinical setting that typically does not follow such approaches. Some commentators on the field of biomedical research as a whole have come to question the pervasive preoccupation with compliance and propose that an overhaul of the system may be necessary. For instance, some have argued that the “master–apprentice” model used to train PhD researchers promotes competition and is suboptimal for promoting RCR. As a remedy, these critics have suggested replacing this educational strategy with an entirely new paradigm that substantially increases the collaboration and interaction between the supervisor and student. Although the oversight of biomedical research by institutions and federal agencies is dependent on an overwhelming number of often complex regulations, current methods of training and education that focus on those regulations may benefit by devoting more time to broader aspects of research ethics and integrity. Adopting the wider perspective of advancing institutional culture may be helpful, for instance, in addressing and preventing conflicts of interest, an issue that has received increasing attention from federal bodies as well as from the realm of biomedical research.

We believe that the biomedical research enterprise can learn from improvements made in other sectors and that self-examination is a necessary first step toward the goal of preventing problems in research conduct. Our data point to the need for training that is specifically and uniquely targeted for different groups of stakeholders based on their status and responsibilities in the research enterprise. Also, given that the relative research ethics and integrity training of investigators in different roles was a source of concern for some of our respondents, a more uniform policy or the requirement of continuing education for more senior investigators may be useful. Modeling is another key issue in training that arose in our data. Titus et al. recommended to research universities that they begin to “repair research integrity” by focusing on “modeling ethical behavior” and “training the mentor.” Although some argue that breaches in research ethics will not be solved by closer supervision of trainees, junior researchers and staff in our study looked to their supervisors to “walk the walk,” not just “talk the talk,” with regard to research ethics and integrity.

In summary, these preliminary data will hopefully advance the discussion of how the culture of research ethics and integrity can and should progress, particularly with respect to issues of relationships and hierarchy. Future research should systematically and prospectively validate our initial attempt to characterize the components of organizational climate that influence the responsible and ethical conduct of biomedical research.

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**References**


19. Roland M. Who is responsible? Supervisors and institutions need to focus on training in the responsible conduct of research and change the culture in the laboratory. EMBO Rep. 2007;8:706–711.


