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How IRB Leaders View and Approach Challenges Raised by Industry-Funded Research

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Recent controversies involving research funded and conducted by pharmaceutical companies[1] JLL raise critical questions related to research ethics, including the role of institutional review boards (IRBs) in reviewing and approving industry-funded studies. For instance, many questions have been raised about the scope, definitions, and acceptability of postmarking studies. In its report, "The Future of Drug Safety,"[2] the Institute of Medicine (IOM) emphasized the need for postmarketing, or phase FV, studies to increase understanding of the side effects of drug therapies. Yet concerns have been raised that some pharmaceutical companies may be using phase IV studies as "seeding trials" primarily to persuade clinicians to use expensive drugs for patients rather than less expensive alternatives.[3] Questions thus emerge as to the scope, definitions, and acceptability of particular postmarketing studies.[4] Syome critics argue that IRBs and researchers should "just say no" to seeding trials since these studies challenge ethical principles and scientific rigor, as well as squander valuable resources of money and research participants.[5] Sox and Rennie list several clues to help IRBs identify such studies (e.g., no control group), but little is known if IRBs do so—and if they do, how effective their efforts are—or why IRBs don't try to identify such trials.[6]

Concerns have also been raised about "me-too" studies that test the therapeutic value of two or more drugs that are basically similar to each other. Critics contend that me-too drug trials provide little scientific value and thus, like seeding studies, raise ethical concerns. Other areas of concern include pharmaceutical companies using contract research organizations (CROs) to recruit, manage, and sometimes review and approve clinical trials and paying investigators and others on the research team "finder's fees" and per capita payments for recruiting participants into drug trials.[7] How do IRBs approach the issue of these financial relationships in research? How do IRBs address risk-benefit considerations for me-too studies? For instance, social benefits of studies should not outweigh risks to the individual. But how do IRBs review me-too studies if the individual risks and benefits appear reasonable and balanced and are clearly presented, but the company sponsor stands to benefit far more than science and society? Do IRBs vary as to how they approach this issue, and if so, how and why?

This article reports on a subset of findings of a broader study pertaining to research integrity. As presented elsewhere, respondents in that study expressed their views about conflicts of interest in research,[8] relationships with researchers,[9] variation in local[10] and central[11] IRB decision-making, noninstitutional "community" members of IRBs,[12] and research conducted in developing countries.[13] I report here on responses to more detailed explorations about industry-funded trials.

Study Methods

The interview sample for the original research JL integrity study was obtained from a list of the top 240 institutions ranked by National of Institutes of Health (NIH) funding.[14] The

range of NIH funding for these institutions ranged from several million dollars to less than one million dollars per year. Institutions with high amounts of NIH funding may not necessarily all receive high amounts of industry funding, but the range of institutions sampled was very wide in terms of NIH funding, and thus, it seems likely, in industry funding as well.

The leadership of 60 IRBs—representing every fourth NIH-funded institution from the list of 240— was contacted to participate in the research integrity Study. IRB leaders from 34 of the 60 institutions contacted were interviewed (response rate = 55%). In-depth telephone interviews of two hours each were conducted with 46 IRB leaders (IRB chairs, IRB administrators, and regular IRB members). In some cases, both a chair/director (i.e., a director of all IRBs in an institution) and an administrator from the same institution were interviewed (e.g., as the chair thought that the administrator might be better able to answer certain questions). From these 34 institutions in the sample, a total of 39 chairs/directors and administrators were interviewed. Half of these leaders (every other one who was interviewed from the institutional list by amount of NIH funding) were asked to distribute information about the study to members of their IRBs, in order to recruit one member of each of these IRBs to be interviewed for the study, as well. Thus, in addition to the 39 chairs/directors and administrators, seven other IRB members, comprising six institutional members and one noninstitutional (community) member, were also interviewed. Sample sections of the interview guide can be found in Appendix A.

This study drew on the grounded theory method,[15] which starts with data collection and moves toward developing a theoretical framework rather than starting with a hypothesis. To enhance validity, transcriptions and initial analyses of interviews, occurred during the period in which the interviews were being conducted, and these analyses helped guide subsequent interviews. A trained research assistant and I analyzed all interviews. Once the full set of interviews was completed, we examined independently a subset of interviews to evaluate variables that affected the respondents' experiences, identifying recurrent topics to which we then assigned codes. The transcripts were read and sections were systematically assigned "core" codes or categories (e.g., mention of industry-funded protocols). We then independently reconciled the coding schemes into a single scheme to draft a coding manual. Disagreements about codes were resolved by reaching consensus. We examined themes that did not fit into the original scheme and altered the manual as needed. In the next phase of the analysis we independently analyzed the content of the interviews to identify codes and spectrums of variation within each of the core codes. Such subcodes included specific types of differences of concerns and problems that arose regarding industry-funded studies—e.g., about "me-too" drug studies and postmarketing studies. We then used codes and subcodes to analyze the interviews.

Study Results

Table 1 presents descriptive characteristics of the respondents. Of the 46 respondents, 28 were chairs/cochairs of an IRB; one was an IRB director (i.e., director of all IRBs in an institution); 10 were administrators (including compliance administrators); and seven were regular IRB members. In all, 58.7% were male, and 93.5% were Caucasian. Respondents were distributed across geographic regions and institutions by ranking in support from the NIH.

Overall, as. outlined in Figure 1 and described more fully below, industry-funded studies can pose a series of challenges to IRBs, particularly since these studies may be designed to benefit funders more than science or society more broadly. Issues for IRBs include the purpose and social value of certain types of studies (e.g., "me-too" and postmarketing drug

studies), questionable research practices (e.g., incentive fees to physicians to enter their patients into studies), and the use of CROs to manage industry-funded trials. IRBs thus face a series of dilemmas concerning whether to weigh such low social benefit, and if so, bow, when, and to what degree. IRBs often struggle, and members may have different levels of comfort with research and industry that cause them to feel conflicted about the outcome.

Perceived Low Social Benefit

Types of Problematic Studies

IRBs face challenges, as they are often unclear about bow to weigh and view the relatively low perceived social benefit of some industry-sponsored studies and face tensions in doing so. For instance, some industry studies may be of suboptimal design or represent "uninteresting" scientific questions (e.g., with suboptimal design elements, such as use of poor comparators). IRBs may be unsure whether they should approve such studies, even though the balance of risks and benefit for participants may be acceptable.

> These studies tend to be less interesting scientifically, and the consent forms tend to be much more legalistic, and not very informative or useful. It's not clear why. anyone would want to be in the study, comparing the 43rd to the 41st ACE inhibitor. What is the purpose? Why do it? We wrestle with those a lot. (IRB_3)

IRBs may be uncertain, too, about the broader question whether their institutions should be a research site for certain industry-funded trials.

> We've seen protocols that are properly designed, where the consent process is perfectly performed and correct. But questions come up about the motivation of the protocol: is it to add to the body of science, or to market a product—for the university to assist a pharmaceutical company in increasing its market share. Is that appropriate for a university? The protocol might jump all the hurdles, but questions still linger. Our IRB says there has to be a scientific benefit. If there is no scientific question, the benefits of the protocol don't outweigh the risks. But there have been some gray area studies. (IRB_{12})

Other Questionable Research Practices

Several other practices of industry-sponsored research pose additional ethical concerns that diminish aspects of the scientific utility of the research. For instance, studies may alter diagnostic criteria for disorders, which can assist company sales but reduce the study's clinical value and validity of the results.

> Industry-sponsored studies are driven by the inclusion/ exclusion criteria of the company, which may or may not be related to the inclusion/exclusion criteria by syndrome. Years back, a company was trying an anti-nausea drug out for social phobia. They changed their inclusion criteria to include people that were nauseous when they were public speaking, which isn't a DSM criteria. But how relevant is that going to be, even if it worked—which it didn't? So there are concerns when the researchers are changing their clinical criteria for a sponsor to make the drug look better. … Such a participant is probably not the same kind of person that you'd see clinically with this disorder. It's hard to know what the clinical utility will be because the companies are not following disease categories. You then have the ethical issues about putting people at risk, if it's not going to be useful or generalizable knowledge. (IRB_3)

Questions also arise as to whether certain industry-funded studies even constitute research, as opposed to clinical care. For instance, hospitals may only get reimbursed when clinicians

use medical devices under an IRB-approved protocol, even though the use of the device represents clinical care more than research.

> Hospitals are interested in industry-sponsored device studies of the new stent, pacemaker, or implantable defibrillator, because the hospitals get big bucks for the procedures. But they're not allowed to be reimbursed by Medicare unless it's a study. A lot of these [protocols] actually aren't really studies, but just demonstration things. So should they even be reviewed by the IRB? [Hospitals] are told that they need IRB approval or won't get funded, and the hospital puts pressure on the IRB to approve it. Medicaid will pay for them, though they're experimental, if they are part of a study. (IRB_3)

Another challenge IRBs face is when industry-sponsored trials of new products use a randomized control but are designed using a weak comparison. Although such studies may not constitute "bad science" per se, they may be suboptimal in terms of the usefulness of the knowledge they produce. As one respondent explained, such research may

> compare our new drug to a "standard regimen." But they either design a standard regimen badly, or use a really inferior one, trying to tweak the comparator so it's more likely to be a good outcome. You get a feeling there is a little bit of underhandedness here. (IRB_{14})

Industry-funded studies may also raise concerns about conflicts of interest that can be indirect and ambiguous, relying not on present or short-term financial gain to investigators at NIH-funded institutions, but only on potential future activities not readily detectable at the time the IRB is reviewing the protocol. Investigators at NIH-funded institutions may agree to conduct such a study in order to possibly obtain future financial benefit through ongoing work with a pharmaceutical company. Although IRBs may be concerned about indirect conflicts of interest, they may not be entirely sure whether such conflicts are present, and, if so, how and to what degree to consider and weigh them. These phenomena raise questions of how to define, detect, and view such indirect conflicts of interest and how high the ethical bar regarding such conflict should be set.

> Studies that are not great science strain integrity. Our researchers think: we can make good relationships with this drug company that has a good pipeline. The company might be able to help us out with interesting drugs five years from now, but we first have to make a name with them. So we will take on these ho-hum scientific studies now. It's more political posturing kinds of research for the occasional researcher for whom research is a way of spinning wheels rather than advancing science. (IRB_{14})

Other industry practices can present additional strains—e.g., compensating physicians with incentives to enter patients into studies.

> Industry will pay if you reach certain recruitment goals. Our IRB thinks that that is potentially coercive, and we have stated that will not be allowed. Some PIs resisted, overall, we're sticking by our guns. (IRB_{27})

In interacting in various ways with CROs, IRBs may also observe financial strains posed by industry. IRBs may be aware of "research mills" where the data collected and the rigor of the science and of other IRB reviews may be suboptimal. Some IRBs feel that if they are not directly involved, such phenomena are not their concern, even if investigators from their institutions may be involved in some way.

> At some research mills, people are cutting corners on inclusion/exclusion criteria—just enrolling people. Most of the data is being organized away from the PIs. Who knows what Pharma's up to? But at least it's not. the investigator fudging data to

> make the results look good. The company could be doing it, but that's not an IRB issue. (IRB_3)

A few academic institutions have also set up their own research organizations that become de facto CROs, with separate IRBs, giving their investigators choices of where to submit protocols. At institutions that provide such options of which IRB to use, it's possible that investigators may engage in "IRB shopping" based on their sense that one IRB may be more or less favorably inclined to approve the study. According to one respondent, "Researchers game the system, submitting at different times of the month to dry to get an easy IRB." (IRB_3) Institutions vary in whether they then try to prevent such behavior. "We don't allow investigators to 'IRB shop,' "said one respondent. "They can't stipulate where their protocol ends up." (IRB_{40})

IRB Decisions and Responses

Given these challenges, IRBs face dilemmas of how to respond—whether to consider low social benefit or suboptimal research design in their review of industry-sponsored studies. The science may appear adequate in several regards, but scientifically "uninteresting" or "not great." Thus, IRBs have to decide how to assess and weigh these considerations against potential benefits to research participants, and to what degree. IRBs will generally not approve studies whose scientific design is unclear or equivocal (e.g., statistically underpowered to provide useful answers). But the quality of industry studies they review falls across a wide and varied spectrum, and gray areas emerge regarding questionable aspects of some of them.

IRBs may vary in how they see the scope of their role in these situations and—depending on aspects of the specific study—may focus primarily on the consent form to ensure that it fully and accurately presents the risks and benefits involved and emphasizes the participants' alternatives to enrolling in the study. For instance, in the case of a study of an expensive new drug, IRBs may seek to highlight that a cheaper, proven generic medication may be just as effective.

> We worry about marketing studies, and have had lengthy discussions about what our role should be, because it's very clear that some studies are just for marketing. We feel that it comes down to: making sure the subjects are very well informed about exactly why the study is being done, and what their alternatives are, particularly that they can maybe obtain these drugs outside the study. These experimental drugs may be just new variations of a drug that is soon going to be a generic—the company is coming up with a new, slightly different formulation of it so that they can still charge a lot of money. We want to make sure that patients understand that an alternative, FDA-approved drug may help them just as much. (IRB_{11})

This respondent went on to reflect about his personal struggles with these types of studies: "Those are upsetting studies, because what can we do? Personally, I wouldn't be the investigator doing that study, but that's the nature of the game." (IRB_{11})

While some IRB members may feel that they should merely ensure that potential research participants are fully informed about a study's potential risks and benefits, others think their role should extend to setting a higher ethical standard. Several respondents felt the former approach may be "passing the buck" to potential participants, who then have to decide what to do. One respondent felt that IRBs have a role to play in ensuring that when a study has low social benefit, it should not only have a low-risk profile, but should also advance science.

> There may not be much scientific good or social benefit to the study when it's just helping the drug company. Some people think that's not enough, particularly if there's any risk. There's a role for the IRB—determining whether a study gets put in front of a prospective subject. Informed consent is crucial, but not the only consideration. Our protective role is to stop studies that should never be before a subject. Informed consent is a flawed process. People will agree to a study for all sorts of wrong reasons, or incomplete information. So we have a duty to keep those sorts of studies from even getting to that spot in the first place. Bad science is bad ethics. A bad study that's not going to tell you anything—even if it doesn't expose people to risk, but only inconvenience, and takes time, just to facilitate marketing—doesn't make any sense to me. That's our role. (IRB_{40})

But questions then arise about *how much* scientific advancement is necessary and sufficient, how that should be determined, and by whom. Even if a study entails only minor risk, participants may be expecting benefit—e.g., because of therapeutic misconception.[16] Hence, when participants themselves will not benefit, *some* social good may be necessary. Still, IRBs can be very divided on these issues. The IRB leader above went on to say,

> Committee members who voted to approve this protocol said, "It's not hurting anyone. The subject is being paid, and has the choice. Subjects can choose if they want to be in it. Who's being harmed?" But some risks were involved, even if minor. It's ethically flawed if you're going to take up people's time and expose them to whatever risk there is, even if only minor. A number of subjects feel that if they're in a study, they're going to benefit—they're expecting benefit, which they probably won't get. Or you're never going to be able to tell them, because it's designed so poorly you're never going to contribute anything useful to the field. (IRB_{40})

Competing notions of IRB roles emerge here: to ensure that potential research risks are minimized and to inform research participants adequately about such risks versus to ensure that a study will produce a certain level of social benefit. Thus, disagreements may arise concerning studies that pose low risks—whether to approve such a study because it minimizes risks versus to balance the risk-social benefit profile. Yet assessing limitations in the scientific benefit of studies and detecting whether the protocol may primarily benefit the funder more than science is not always easy. The IRB leader above also pointed out that the IRB rejected a study that was perceived as having low social benefit:

> The IRB recently had a pharma-sponsored protocol in which we couldn't really see a strong, sensible, meaningful study design. An investigator more experienced than me who had interacted with the PI said it was a marketing study—gathering data to promote their marketing. We ended up disapproving the study, because there was some risk to subjects, and we didn't think any meaningful information would come out of it that would advance the field. (IRB_{40})

Yet the fact that a study is basically a marketing study may not always be readily apparent to all IRB members. Sufficient expertise in the specific type of study may be necessary, but may not always exist on an IRB.

IRB members can vary considerably across a spectrum from pro- to anti-industry. Some IRB members tend to be relatively wary of industry but may vary in how and to what extent this stance affects their decisions. "Some reviewers are anti-industry, but I don't think they treat projects differently, based on the sponsor." (IRB_9) Still, differences that emerge may concern not whether IRBs abide by human research regulations, but *how* they do so in reviewing a particular study. Moreover, IRBs may review nonfunded studies more carefully in part because an external funder did not externally review these studies.

> Departmental projects, not sponsored by NIH or industry, are generally not of the same quality, because the PIs are not applying for money, which vets them…So, our members need to take a second look at nonsponsored new studies. But we apply the same standards. (IRB_9)

Yet other respondents seemed warier of industry, given its profit-making agenda. These attitudes may reflect broader political and economic views concerning the roles of private for-profit industry in health care and the pharmaceutical sector. “The relationship between industry and the FDA is much closer than it should be. It’s unhealthy for the safety of the American public.” (IRB_4)

However, IRB members may hesitate to question a study too much because the industry sponsors might then simply “pull out” and take the funding to another institution, thereby impeding colleagues’ careers. Especially with broader financial constraints limiting NIH funding, some investigators may have increased needs for drug company support. With a divided vote, one IRB leader, for instance, turned down a marketing study.

> We had a split vote disapproving a drug marketing study. The majority of the board felt this should not be approved. But a strong minority felt we weren’t being consistent here: “We approve studies like this all the time. There’s not much risk.” Perhaps money coming to the institution was part of the reason. That was never explicitly stated. (IRB_{40})

The intense disagreement here may result in part from the fact that despite apparent lack of social benefits, researchers and the institution may accrue valuable resources from industry-sponsored trials. This conflict thus pits pursuing higher possible research ethics against assisting one’s institution, which IRB members may also value. Nonetheless, at many institutions these studies generally seem to go forward, despite the IRB’s lack of enthusiasm and the suboptimal research design.

> We are approving most of them, even though we are not *enthralled* with the study design. Usually, we conclude that the study design is not horrible. It’s not optimal, but the risk is low, so we let it go. (IRB_{40})

It’s unclear, though, what standards IRBs should use to distinguish between “not horrible,” “not optimal,” and/or “not good.” Another respondent added, “It is really unusual for our IRB to disapprove a study. We usually give PIs an opportunity to fix it.” (IRB_{40})

IRBs may interact with industry sponsors not only at the initial protocol review stage, but also when monitoring a study over time. Sponsors may vary in their responsiveness to concerns that IRBs raise. “If we bring these things up, some companies give us a hard time, some are pretty flexible.” (IRB_3) Many IRBs tended to rely on industry monitors for compliance and research integrity since these companies were invested in managing their data well and avoiding noncompliance. As one IRB chair said, “For clinical trials with FDA involvement, drug companies’ monitors are pretty good, telling you what to do. We haven’t had that much trouble with that.” (IRB_3)

Problems concerning industry funding can become exacerbated in settings with relatively fewer resources—whether in the United States or abroad. Especially in developing and resource-limited countries, wide gaps in health and resources may raise concerns about exploitation and lack of social benefit. In some of this research, drug companies may “shop” for a population, a CRO, or possibly an IRB, which—as one respondent notes—is worrisome.

> Pharma can be very destructive—for example, in India or Eastern Europe—if Pharma is not working with an academic institution that has certain investment in

> high standards for ethics. The company is going to basically be hiring a CRO, and *shopping* for the most convenient, cheapest, easiest population in which to do research. It's dangerous because, not to derogate some of the independent IRBs, in some places the oversight system is weak. There may not even be IRB review, because they can get away with it. Maybe it's not going to be FDA regulated. Or the study could be from some middle-income country that can manage to market a product without IRB approval. With Pharma, there's always a danger: the profit motives outweighing other concerns. (IRB_{18})

Discussion

To our knowledge, this is the first empirical study that examined how IRB leaders at NIH-funded institutions perceived and wrestled with challenges raised by industry-funded studies. These studies may be problematic because they test "me-too" drugs or engage in questionable research practices that undermine the potential social benefits of the knowledge gained. The scientific quality of studies may range across a wide spectrum, with some having adequate statistical power but "uninteresting" questions, and others using diagnostic criteria that do not conform to standard clinical practices or comparisons that are not the most robust possible. These elements of suboptimal design may help the industry funder far more than provide social benefit per se. And while these problematic aspects of a study's design can be criticized on scientific grounds, they may not always be readily identified by IRBs. Other studies may not contain problematic elements of scientific design, but simply have low social benefit. Yet IRBs may have difficulty identifying these types of studies, too, or may struggle with disapproving them when risks to participants are low and competing interests—such as financial needs of colleagues and institutions—are present.

One can argue that considering whether a proposed study has low social benefits (i.e., the individual risks and individual benefits appear reasonably balanced) is beyond the scope of IRBs. Federal regulations governing research with humans state that IRBs should not include long-term effects in public policy as risks, but it is not clear how and to what extent IRBs should take into account low (but not absent) amounts of social benefit. Social benefits can ultimately aid individuals, and NIH-funded institutions may benefit from industry-funded research in other ways. Yet social benefit is not always predictable. Moreover, pharmaceutical companies may argue that even me-too drugs can potentially help some patients more than currently marketed compounds. But key questions arise as to how much potential social benefit is realistic and sufficient in a given study, and how IRBs should know and assess such benefit.

Although changes to the federal regulations governing research with humans were proposed recently,[17] the suggested changes do not address these issues. Yet this study's findings highlight how IRBs may benefit from federal guidance and clarification of regulations. Moreover, clarification and guidance are needed about how and to what extent IRBs should weigh industry versus social benefit. Clearly, high social benefit should not trump low individual benefit, but if individual risks and benefits appear fairly well-balanced, should low social benefit matter, and if so, to what extent?

These data pose larger questions of how narrowly or broadly and directly or indirectly IRBs should define their roles. IRB chairs and members may vary widely in their views toward these issues—e.g., in the extent to which they may be pro- or anti-industry. These attitudes may in turn reflect these individuals' broader political attitudes and medical centers' other priorities—to obtain funding for research and faculty salaries, for example. Whether these other priorities may influence IRBs—and, if so, when and to what extent—requires further investigation. Such conflicts of interest may not be direct, but rather subtle and even

unconscious.[18] Though IRBs may rely on monitoring that is arranged and funded by industry, an outside observer might question whether such assessment might potentially differ from other, university-initiated monitoring. Broader quandaries arise, too, as to whether IRBs should be more cautious with industry studies than with other protocols, and if so, how much, when, and why. Further debate and research about these issues is vital to optimize beneficence and justice.

These findings have important implications for future research, highlighting the need for further investigation of how social benefits are and should be measured and weighed, and when and how often industry-sponsored studies include questionable practices (e.g., altering standard criteria for diagnoses), as well as how IRBs respond, when they do. Yet difficulties may arise in making these assessments due to underlying questions of how socially beneficial the science should be. Metrics do not exist for assessing this concept, and long-term benefits are by definition unknown. Moreover, some studies may have little clear social benefit now, but potential long-term benefit.

Though 58.7% of the interviewees were from private institutions, concerns about industry arose among individuals from both private and public institutions. However, future research can assess in further detail, with larger samples, whether these views may differ systematically between these types of institutions.

Several limitations of this study should be noted. The findings are based on in-depth interviews with individual IRB leaders and members, not on direct observations of IRB deliberations at meetings or examination of written IRB records. Future studies could involve observation of IRB meetings and examination of meeting documents. Yet such data may be hard to obtain, since anecdotal reports indicate that some IRBs have required researchers to obtain consent from all IRB members, the PIs, and study funders when collecting data from and about IRBs. Another limitation is that only one current nonscientific or unaffiliated (“community”) member was included. Finally, because the sampling frame consisted of institutions from a list of the top 240 NIH-funded institutions, the findings about IRBs at these institutions may not be generalizable to IRBs at other institutions that conduct human subjects research.

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18. See ref. 14, Klitzman 2011d.

Appendix A. Sample Questions from Semistructured Interview

- How do you define research integrity (RI)? What has been the most difficult case concerning RI that you have faced? What kinds of issues arose? Do you think IRBs and PIs view RI differently or apply RI standards differently, and, if so, how? Have you seen problems in researcher noncompliance with IRB regulations or mandates? If so, what kinds of problems?
- What are the barriers and facilitators in IRBs monitoring and addressing RI problems? Do you perceive any gray areas or problems weighing issues about RI? If so, what?
- Have you faced issues concerning RI with industry-sponsored studies? If so, when and how? What issues arose, and how did you address these? Was there disagreement on your IRB about these industry-related studies, and, if so, what? How was it resolved?
- What do you think makes an IRB work well or not in monitoring and responding to RI and threats to RI?
- Do you have any other thoughts about these issues?

Note: From Klitzman R. Views and experiences of IRBs concerning research integrity. *Journal of Law, Medicine & Ethics* 2011; 39(3): 513–528. Additional follow-up questions were asked, as appropriate, with each participant.

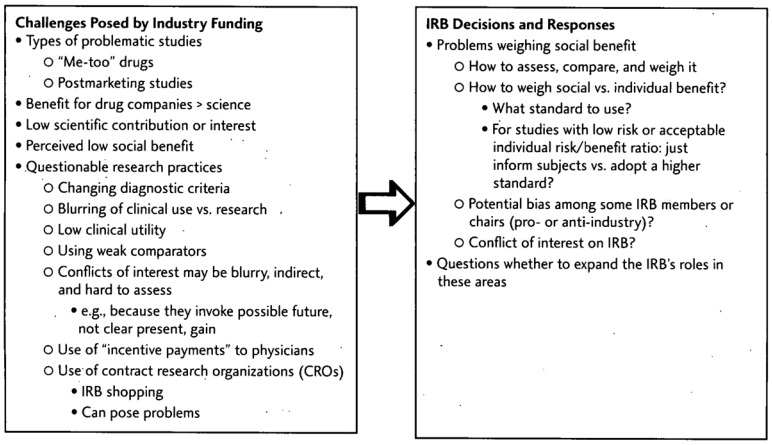

Figure 1.
Challenges Posed by Industry-Funded Research and IRB Responses

Table 1

Characteristics of the Sample

	Total	%(N = 46)
Type of IRB staff		
Chairs/Cochairs	28	60.87%
Directors	1	2.17%
Administrators	10	21.74%
Members	7	15.22%
Gender		
Male	27	58.70%
Female	19	41.30%
Institution rank		
1–50	13	28.26%
51–100	13	28.26%
101–150	7	15.22%
151–200	1	2.17%
201–250	12	26.09%
State vs. private		
State	19	41.30%
Private	27	58.70%
Region		
Northeast	21	45.65%
Midwest	6	13.04%
West	13	28.26%
South	6	13.04%
Total # of institutions represented	**34**	

From Klitzman R. Views and experiences of IRBs concerning research integrity. *Journal of Law, Medicine & Ethics* 2011; 39 (3): 513–528.