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How IRBs view and make decisions about coercion and undue influence

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Abstract

Introduction—Scholars have debated how to define coercion and undue influence, but how institutional review boards (IRBs) view and make decisions about these issues in actual cases has not been explored.

Methods—I contacted the leadership of 60 US IRBs (every fourth one in the list of the top 240 institutions by National Institutes of Health funding), and interviewed 39 IRB leaders or administrators from 34 of these institutions (response rate=55%), and 7 members.

Results—IRBs wrestled with defining of 'coercion' and 'undue inducement', most notably in deciding about participant compensation. IRBs often use these terms synonymously and define undue inducement in varying ways, often wrestling with these issues, relying on 'gut feelings', and seeking compromises. Ambiguities arose, partly reflecting underlying tensions: whether subjects should 'get paid' versus 'volunteer' (ie, whether subjects should be motivated by compensation vs altruism), and whether subjects should be paid differently based on income, given possible resultant selection bias. Lack of consistent standards emerged between and even on single IRBs. Questions arose concerning certain aspects and types of studies; for example, how to view and weigh providing free care in research, whether and how recruitment flyers should mention compensation, and how to avoid coercion in paediatric, developing world, or students research.

Conclusions—These data, the first to probe qualitatively how IRBs view and approach questions about coercion, undue influence and participant compensation, and to examine how IRBs have reviewed actual cases, reveal several critical ambiguities and dilemmas, and have vital implications for future practice, education, policy and research.

INTRODUCTION

Debates have arisen in recent years about how to define and apply the terms coercion and undue influence, but how institutional review boards (IRBs) and research ethics committees view and make these decisions—for example, whether certain payments are too much—has received little attention. Federal regulations require that research minimises the 'possibility of coercion or undue influence',[1] but do not define these terms. The *Belmont Report* states

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that coercion involves '…an overt threat of harm…to obtain compliance, and offer of excessive, unwarranted, inappropriate reward…'.[2]

More recently, on its website, the US Office for Human Research Protections states that:

> Coercion occurs when an overt or implicit threat of harm is intentionally presented by one person to another in order to obtain compliance…[U]ndue influence, by contrast, often occurs through an offer of an excessive or inappropriate reward or other overture in order to obtain compliance…undue influence also can be subtle… Because of their relative nature and lack of clear-cut standards on the boundaries of inappropriate and appropriate forms of influence, investigators and IRBs much be vigilant…[3]

Historically, abuses have occurred in which researched individuals participated in research without voluntary consent: for example, in Nazi concentration camps, and the US Army and Willowbrook.[4,5] More recently, coercion has been found to be rare overall in research studies,[6] but has been demonstrated to occur in clinical care in psychiatry.[6–8] Emanuel[9] and others have criticised IRBs for being overly concerned about possible coercion, arguing that such focus is overblown, and may in fact impede research.

Wertheimer and others have argued that IRB members may mistakenly see offers of payment as coercive.[10–12] Yet, these authors conclude that 'Ethical concerns about undue influence remain insofar as payment has the tendency to promote irrational decision-making. The question as to when the offer of financial payment actually constitutes an undue influence is a topic that merits separate analysis'.[10]

To avoid undue inducement and coercion in research, differing ways of approaching decisions of how much to pay participant compensation have been explored. Dickert and Grady[13] have outlined several models for determining appropriate amounts of participant payment and have advocated a 'wage payment' model (providing a low, standardised wage that could be raised for uncomfortable or other onerous tasks), over either a 'market model' (based on supply and demand, and potentially offering more payment for taking on more risk) or a 'reimbursement model' (covering expenses, including costs from missed work).

But few studies have examined how often participants actually get paid. Most journal articles do not mention whether or how much participants have been compensated,[14] though online recruitment sites in diabetes and depression usually offer compensation.[15]

Given these wide variations in theoretical views and definitions concerning undue influence and coercion, questions emerge of how IRBs perceive and make decisions about these areas. Largent *et al*[1112] recently found, using a quantitative instrument, that in the abstract and in hypothetical scenarios, IRB members vary widely in their views of coercion and undue influence. But many questions remain about how IRBs themselves actually make decisions concerning studies they review, and how they perceive and experience these issues.

I recently conducted interviews exploring how IRBs in fact make decisions, focusing on their views and approaches toward research integrity (RI), broadly defined.[16] In these interviews, issues concerning coercion and undue influence frequently arose. Interviewees' perceptions of RI were related to how they saw and addressed conflicts of interest,[17] central IRBs,[18] relationships with researchers[19] and the so-called 'community' members,[20] variations between IRBs[21] and research in the developing world.[22] Interviewees also discussed how they saw and approached issues related to coercion and undue influence. Since the study used qualitative research methods, it permitted further exploration of these topics, which are thus examined in this paper.

METHODS

In brief, as described elsewhere,[16–22] I conducted indepth telephone interviews of approximately 2 h each with 46 chairs, directors, administrators and members. I contacted the leadership of 60 US IRBs (every fourth one in the list of the top 240 institutions by National Institutes of Health funding), and interviewed IRB leaders from 34 of these institutions, yielding a response rate of 55%. In certain cases, both the chair/director and administrator from an institution were included (eg, if the former thought that the latter could better provide details about certain areas). Thus, in all, I interviewed 39 chairs/directors and administrators from these 34 institutions. To understand the impact of varying social and institutional milieus in these domains, I included a range of non-profit institutions (academic medical centres and non-profit research institutes) in terms of location, size and public/private (eg, state vs private universities) status. I asked every other interviewee to distribute information about the study to their IRB, to recruit one member from each committee, and thus included seven additional members.

As summarised in table 1, the 46 interviewees included 28 chairs/cochairs; 10 administrators; a director of a compliance offices; and seven members. In all, 58.7% were male subjects, and 93.5% were Caucasian. Interviewees were distributed across geographic regions and institutions by ranking in National Institutes of Health funding.

The interviews explored participants' views of RI, but shed important light as well on many other, broader issues that arose concerning the decisions of IRBs, and interactions and relationships with PIs. Online supplementary appendix A presents relevant portions of the semistructured interview guide. I sought to obtain a 'thick description': to understand aspects of interviewees decisions, lives and social situations.[23] I adapted elements from grounded theory,[24] engaging in techniques of 'constant comparison' and analysing data from different contexts for similarities and differences.

The study has been approved by the Columbia University Department of Psychiatry IRB. All interviewees gave informed consent.

After completion of all of the interviews, a trained research assistant (RA) and I conducted additional analyses in two phases. In the first phase, we analysed a subset of interviews independently to gauge factors that affected interviewees' experiences, identifying sets of recurrent issues and themes to which we then gave codes. Each interview was read, and blocks of text were assigned 'core' codes or categories (eg, instances of IRB discussions about compensation of participants). We then reconciled these independently-developed coding schemes into a coding manual.

In the second phase of the study, we independently content-analysed the interviews, examining the main subcategories and ranges of variation in each of the core categories. Subthemes included, for example, specific types of challenges that arose in discussions about compensation (eg, in the developing world). We then used codes and subcodes in the analysis of all of the interviews, with two coders analysing all interviews.

RESULTS

Overall, as summarised in box 1, several key themes emerged. When considering appropriate compensation to subjects, IRBs struggled with a series of questions, interpreting and applying notions of 'coercion' and 'undue influence'. IRBs wrestled with dilemmas of how much, what, when and who to compensate, often relying on 'gut feelings', and using these two terms interchangeably. A lack of consistent standards emerged between, and even on single IRBs, in part reflecting the underlying tensions in beliefs concerning the degrees to

which subjects should be motivated by altruism versus compensation. Interviewees generally expressed their views about coercion and undue influence within the context of discussing decisions that their IRBs made. These decisions and views are thus inextricably entwined. The decisions themselves often involve complex aspects of specific protocols. To present the full range of issues IRBs confront concerning coercion and undue influence, this paper focuses, given space limitations, more on participants' views, though at times reflecting specific decisions as well. Quotations from interviews, below, are each followed by an ID number, referring to the interviewee.

Box

Dilemmas and ambiguities faced by institutional review boards (IRBs) concerning coercion and undue inducement

IRBs struggle with dilemmas concerning:

- How much to give subjects
  - Whether subjects should get paid differently based on their income
  - Effects on selection bias?
  - Provision of free care as coercive?
  - What to give subjects (eg, cash vs vouchers)
  - What types of studies
- Added challenges in several situations
  - Paediatric research
  - Research in the developing world
  - Standards may differ between countries
  - Research on students
- Whom to compensate
- When to compensate subjects
- Whether, when and how to inform potential participants about compensation
- Definitions of undue influence vary
  - Based on 'gut feelings' and 'common sense'
  - But can be subjective

PROCESS

- IRBs can take time to make these decisions
- Decisions often reflect compromises
- Underlying tensions
  - 'Undue inducement' as inherently subjective and difficult to assess in others
  - Whether subjects should 'volunteer' versus do it for the money
  - Lack of a consistent standard
- Between IRBs

- Even in one IRB over time

Avoiding undue inducement and coercion

How much to give subjects—IRBs struggle with definitional quandaries concerning 'undue inducement' and coercion: how much is 'too much', and how one should decide. Yet, defining at what point exactly an amount becomes too much is hard. As one administrator said,

> Researchers were approved to pay the participants $225 in a longitudinal study with follow-up interviews. They wanted to increase it to $300 due to the length of time. The chair said, "That's coercive." There was a compromise of $250. I was an RA on a study, and we weren't getting people. My boss said, "We're paying them $30. Let's change it to $50." IRB23

But this respondent did not want to increase this amount, feeling that it would then be too much. Debates thus occur concerning relatively small differences in amounts of money, more than concerning larger explicit conceptualisations or definitions of these terms. Nonetheless, IRBs express rationales for their decisions. The administrator above felt that though a person may get paid relatively a lot to be a sanitation engineer or soldier in Afghanistan, 'Research just seems different. It's a voluntary thing, and you don't want people to be trying to put up with something just because they're going to get paid' (IRB23). Yet, the full reasons for these views may not be wholly clear. This perspective—that research should not participate for the money, and hence that subjects should be volunteers—appears to reflect the notion that the ethos of science should be 'pure' and not involve profit or conflicts of interest. IRBs may extend this view to participants as well. Of note, this interviewee also criticises a position that lies at one end of a continuum—that subjects should not participate 'just' because of payment. Subjects may in fact also enrol in a study because of altruistic desires, though these may be insufficient in and of themselves to motivate participation.

IRBs also tend to use the terms coercion and undue influence interchangeably. They often see both terms operationally as how much is too much; that is, in the end, they try to decide on a definitive fixed sum. Yet, though this operationalised definition (ie, how much is too much) may apply more closely and directly to undue influence, IRBs appear to use *both* terms to justify their feelings that additional amounts would be too high. A lack of standards for interpreting undue inducement emerged here, fuelling wide variations among and within IRBs.

These committees appear divided on whether it is permissible that compensation may at times motivate individuals to participate in studies. Given these ambiguities, and lack of clear standards, decisions can be idiosyncratic, and IRB debates about this issue can consume much time and attention. As one vice-chair said:

> We spend an inordinate level of time on compensation levels, and whether it is adequate, or too much and coercive. We don't apply a common standard across all studies—developing countries vs the U.S., and within the U.S., impoverished communities vs volunteers through Craigslist—on what should be the basis for compensating subjects. Investigators may get quite different, and inconsistent advice from the committee depending on what it feels like that day. I don't think there's any agreement in the field. Someone needs to lay out what's the acceptable basis on which compensation may be set. You come up with different numbers if you think it's just to pay for people's transport vs opportunity costs of being away from work. IRB15

Interviewees thus see inconsistencies and needs for guidelines to grapple with these decisions.

IRBs wrestle, too, with questions of whether subjects should each be paid either a different amount (based on how much they usually earn) versus a single, established set amount, regardless of income level. In the latter case, selection bias may occur, skewing the sample.

> Should you compensate a radiologist much more than a laborer? Or should they get the same? In the US, it's harder to recruit people. So, you get into this gray area of enticing people: if you pay people differently, or the same, you're going to attract different groups of people, and that may cause adverse selection or targeting. IRB15

Thus, in these decisions, IRBs may also consider the consequent generalisability of the eventual research findings (ie, the extent of social benefit).

When to compensate subjects

These issues can become particularly murky in several situations, such as research conducted in low income countries. As one vice-chair said, 'In the developing world, in our experience, people only get paid for transport costs. These large HIV studies have not had the budget to pay more' (IRB15).

In resource-poor countries, compensation amounts can range widely based, too, on differing regional practices. Projects may pay only transportation expenses, either as cash or vouchers. As one administrator said:

> How much to pay people in the developing world varies according to the region, the local economy, and the local research economy. In some countries, people don't expect to get paid cash for their time. But we reimburse for travel. If subjects don't expect payment, we look for other ways to show appreciation. In China, they might be paid a day's wage. IRB18

But larger questions then arise of whether paying only in certain countries, and not others, is fair. Low amounts of compensation also pose questions of possible exploitation. The administrator above continued:

> I asked one researcher, "Aren't you exploiting subjects?" He answered, "It could cut both ways: if you're offering *money*, it might be coercive because they are so poor." IRB18

This interviewee and others perceived tensions between exploitation due to overly low amounts versus undue influence due to overly high sums. IRBs frequently realise that they do not sufficiently understand the economic and cultural contexts that may shape views about undue inducement, coercion and autonomy. These committees thus often look to *local* IRBs within these foreign countries for input and decisions, though these foreign committees may not necessarily fully understand these issues.

Many IRBs still assess acceptable amounts of compensation for each study on a case-by-case basis, but inconsistencies can then ensue. 'We take it one study at a time. We look at: what are you expecting people to do in the study?' (IRB39). IRBs may alter their policies over time, though at any one point, they generally appear to see their approach as 'right', not merely 'relative'.

What to compensate subjects

IRBs face quandaries, too, of *what* to compensate subjects; for example, whether cash might be inappropriate. Many IRBs wondered, for instance, whether the provision of free care in a study might unduly influence potential participants to enrol. Interviewees want to avoid such inducement; but are not always clear how to do so.

> We have an 80% Medicaid population, so there are coercion issues: are people participating in studies because it gives them free medicine, not because there's any *real benefit* to it? In a trial, you get a free appointment and physical. Otherwise, they won't get treated. IRB3

An implicit definition thus emerges here, too: that subjects should derive 'real benefit' from the study. Yet, that concept can be defined differently, and participants may not always gain in this way.

Whom to compensate

At times, IRBs face related questions of *whom* to compensate. Dilemmas emerge concerning compensation in particular research areas such as paediatrics; for example, how much to pay parents who have their children enrol in studies. IRBs may vary widely here as well.

> Regulations are silent on that. Young minors should definitely not be paid in dollars. So the IRB is working on who should get the money, the parents or the child. The parent is taking the time off as the escort. There should be something for the parents as well. But you have to worry about undue inducement. Sometimes the researcher wants to pay hundreds of dollars to the parents. We'll limit the dollar amount, and talk about what the children should get. It's age-driven: we don't like to put a lot of money into young adolescents' hands. But it's on a case-by-case basis, depending on the nature of the study, the circumstances, the age of the children, and what's involved. We really just use common sense. We polled other IRBs if they had a policy. Nobody did. IRB16

This lack of established policies can fuel variations as well. Questions emerge, too, when students may be required to participate in research as part of a class. Subjects receive not money or services, but academic course credit. They may be given a choice of which study to enrol in, but some interviewees nevertheless expressed concerns regarding the motives, whether such participation indeed primarily benefitted students' education or teachers' careers. As one chair said:

> Psychology professors' students get extra credit if they participate in the study. Students can earn that same amount of credit if they complete an extra paper. That doesn't feel like extra credit. That feels like coercion to me. Is it part of their practicum, or are they doing this to satisfy something for a professor? IRB29

This chair appears to misuse the term coercion, since no threat is involved. The choice that students face may be unfair and unbalanced since participation in a study may take much less time than writing a paper. But, IRBs may thus use coercion as a catch-all phrase for incentives that may motivate participation that might not otherwise occur.

Whether and how to inform potential participants about compensation

Dilemmas arise about how much to offer and when and how to inform potential participants. Here, too, an IRB may shift over time. Committees may allow or prohibit mention of compensation in recruitment flyers, or vary, depending on the amount. As one social scientist and chair said:

> We used to not allow people to put a monetary amount on recruitment flyers, because we thought it was a little coercive: "You'll get $20 if you participate." But we've concluded that a gift card for an hour interview is probably not particularly coercive. If you were to say, "We'll pay $600 if we can take blood," that might be a little coercive. So we're trying to decide what the standard is, and how to handle that. IRB39

The reason that a gift card, but not cash, may be acceptable is not always clear. Presumably the *meanings* of a gift as either direct versus indirect compensation differ.

Underlying tensions

As illustrated above, IRB debates about these questions reflect in part underlying tensions concerning ambiguities and subjectivities in determining when an amount becomes 'undue', and whether subjects should be paid or volunteer and receive minimal or token compensation. These ambiguities foster a lack of consistent standards that in turn fuel these debates.

CONCLUSIONS

These data—the first to explore qualitatively how IRBs perceive and approach issues of undue inducement and coercion, and view and make decisions about these issues in actual cases they confront (ie, rather than in the abstract or in hypothetical scenarios)— elucidate how IRBs struggle with several questions. These dilemmas manifest themselves concretely in debates about how much, what, when and how to compensate participants. IRBs wrestle with a variety of ambiguities and quandaries that can lead to wide variations between these committees.

Though Wertheimer and Miller[10] have distinguished between the terms coercion and undue influence, clarifying that coercion necessarily involves threats, much more remains to be done in this area.[25] Moreover, the present data suggest that in reviewing particular protocols, many IRBs appear to use these terms interchangeably without distinguishing them. Many uncertainties persist in applying definitions of undue influence, which IRBs are charged with avoiding. While external threats may be objectively verifiable, that is not the case with undue influence since application of this term intrinsically involve matters of interpretation; that is, assessing whether someone else's rational judgment is being impaired by an offer. Such assessment of another individual's internal state in research is generally not objectifiable. Given that IRBs, scholars and others define undue differently, the ordinarily understood definition in *The Oxford English Dictionary* (OED) may be illuminating. The *OED* defines undue as: 'that ought not to be or to be undone; inappropriate, unsuitable, improper…going beyond what is warranted or natural; excessive…'. [26] Application of the term undue thus remains subjective and normative in that it involves questions that external observers may interpret differently; for example, excessive according to whom, how an outsider observer is to know, who should make that determination and on what external objective evidence. Person A may feel that he, she or another person is being paid appropriately, while Person B may feel that that amount is excessive in that the recipient is not sufficiently weighing the risks versus the benefits. Moreover, participants in a study vary socio-economically, psychologically and educationally, and thus in the degrees to which they may be influenceable, especially across diverse countries. By subjective, I do not mean that all definitions are simply 'in the eyes of the beholder', but rather that applications of the term to specific individuals are not objectively verifiable in an external way, and instead depend on perceptions of another individual's internal mental state, which may not be reliably and objectively ascertainable, and is thus open to a range of interpretations. An individual may feel that he or she is being rational, while an external observer may disagree.

Hence, IRBs will no doubt continue to encounter ambiguities and variations in applying the term undue in specific protocols. Since IRB members appear to use this term and coercion interchangeably, far greater precision in usage is clearly needed. As Largent *et al*[1112] argue, IRBs should avoid mistaken use of the term coercion, but these committees will still face dilemmas about undue influence.

Important questions arise, too, of why IRBs continue to misuse the word coercion. Linguistically, in daily discourse, IRBs may use this term to describe particular amounts of compensation (eg, '*that's* coercive') because it is a single adjective, and hence easier to use and apply, while undue influence as an adjective and a noun, may thus seem longer, more awkward and difficult to apply (eg, '*that* represents undue influence'). In arguing to sway an IRB, members may feel that the former statement is shorter, stronger, more persuasive and effective.

These data highlight, too, other dilemmas concerning undue influence that IRBs face: for example, how to address compensation both in recruitment materials and in research conducted in the developing world, where individuals may assess and weigh the risks and benefits of a study very differently.

These interviews reflect IRB perceptions of whether amounts are undue rather than definitely addressing whether these amounts are in fact, objectively undue. These data focus on IRB beliefs about these issues, which reflect underlying questions and ambiguities of whether these amounts exert undue influence. Assessing the exact point at which a potential participant is in fact no longer 'rational' may be very hard to determine. Importantly, these interviewees see themselves as charged with determining at what point undue influence may occur, and they struggle in doing so.

These quandaries faced by IRBs reflect other underlying tensions as well. Ambiguities emerge concerning the term 'voluntary', which the *OED* defines as 'Of a feeling…arising or developing in the mind without external constraint; purely spontaneous in origin or character…not required or imposed, optional'.[26] Yet, IRBs may feel that participation should be voluntary in the sense that subjects are not enrolling just because of the money. Questions arise, however, of whether money may serve as added incentive—necessary, but not sufficient. 'Voluntariness' may thus fall across a spectrum. With financial inducement, participation may be neither 'imposed' on individuals nor 'purely spontaneous', but lie somewhere between these two extremes. Such a spectrum no doubt fosters IRB debates and variations.

These controversies may reflect, too, IRB members' views of the role of money in science. Merton[27] and other sociologists of science have described the ethos of science as involving universalism, communalism, disinterestedness and organised (or systematic) scepticism. Barber[28] added to this list ethical neutrality. Another possible explanation of the present findings is that IRBs may at times mistakenly apply these principles to study participants as well. Frequently, social groups also vigorously seek to remain pure and avoid danger, and establish practices and boundaries to do so.[29] IRBs may thus see the 'taint of money' as a threat that can undermine an ethos of science, making IRBs nervous, and resulting in efforts to avoid financial motivations. These committees may worry excessively about compensation, misapplying this notion that scientists should somehow be pure. IRBs may fear that undue influence because of money may 'taint' subjects by undermining full, free and voluntary consent. Money may thus be seen as tainting both researchers and subjects, though for very different reasons. Yet for IRBs, these distinct reasons may blur, and committees may thus become overly concerned about the threat of overcompensation. IRB members and scientists are paid for their work, but are generally not thought to be tainted,

perhaps because the critical questions that arise concern not *whether* IRBs, researchers or subjects should get paid, but *how much*. Future research and scholarship can explore these issues further.

Importantly, paying participants adequately need not sully the purity of the research enterprise. Commercialisation in research and possible COIs that may result should be closely monitored, but need not prevent subjects from receiving appropriate compensation.

These issues may become exacerbated when IRBs review research to be conducted in the developing world, since US IRBs may rely on foreign IRBs for input, but the latter may not be fully knowledgeable about US IRB regulations or may not feel empowered to alter US IRB decisions.[22]

These data have several important implications for future practice and policy. Recently, the US Office of Management and Budget released the Advanced Notice of Proposed Rulemaking, seeking to improve IRBs, in part by minimising variations between IRBs in multi-site studies.[30] But the present data highlight how key terms in the regulations governing IRBs (particularly, undue inducement) may remain inherently subjective, perpetuating variations among IRBs.

Nonetheless, the present findings can improve how IRBs and research ethics committees view and approach these issues. IRBs should recognise more fully the differences between definitions of coercion versus undue influence, and not use the two terms interchangeably. Committees should also be more explicitly aware of these underlying ambiguities and dilemmas concerning definitions and interpretations of undue inducement, and work to address and resolve these tensions as effectively as possible. Wider discussions regarding these issues among policy-makers and others can help in developing consensus about how to approach these uncertainties. The Office for Human Research Protections, the Institute of Medicine, Public Responsibility in Medicine and Research or other entities could issue guidance clarifying these issues: for example, how to decide exactly what constitutes undue inducement, and how much to compensate participants in particular types of protocols.

These data can also help improve education of IRB members, chairs and administrators, highlighting inherent tensions and ambiguities, and needs to develop rigorous training for these individuals. Such education could ideally use standardised protocols on which consensus has been reached, in order to ensure that these personnel are using terms correctly and appropriately, and in order to help reduce variability. Though some chairs, members and administrators may voluntarily get accredited, the regulations do not now require them to undergo any ethics training concerning their IRB responsibilities.

These findings have implications, too, for future research, to investigate these issues more fully among larger samples: for example, how often exactly IRBs differ in these decisions, what ranges of compensation they choose and why.

This study has several potential limitations. The study includes IRB chairs and members, not observations of IRB meetings, or written IRB records. Future studies can gather such additional data. But doing so may be hard since anecdotally, IRBs have generally required researchers to obtain consent from all IRB members, PIs of protocols discussed, and funders. This study is based on qualitative data, and thus is not designed to quantify responses. Instead, qualitative data are important in suggesting hypotheses and research questions, and elucidating critical meanings and practices that future studies can also measure among larger samples, exploring statistical associations with other variables.

In conclusion, these data—the first to examine qualitatively how IRBs view and approach questions about undue influence and coercion, and how IRBs view and make decisions reviewing actual studies they confront (rather than in the abstract and in hypothetical scenarios)—highlight several key sets of ambiguities and dilemmas, and have critical implications for future practice, education, policy and research.

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Table 1

Characteristics of the sample

	Total %	(N=46)
Type of institutional review board 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 versus private research institutions		
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	