

Procedural Misconceptions and Informed Consent: Insights from Empirical Research on the Clinical Trials Industry

ABSTRACT. This paper provides a simultaneously reflexive and analytical framework to think about obstacles to truly informed consent in social science and biomedical research. To do so, it argues that informed consent often goes awry due to *procedural misconceptions* built into the research context. The concept of procedural misconception is introduced to describe how individuals respond to what is familiar in research settings and overlook what is different. In the context of biomedical research, procedural misconceptions can be seen to function as root causes of therapeutic misconceptions.

Quite recently, I was struck by the realization that I did not get truly informed consent from subjects participating in my research project. This is not to say that I violated any federal or institutional regulations. Quite the contrary, I did everything by the book and so did my university institutional review board (IRB).¹ Moreover, the project itself is an empirical study of informed consent in the context of private-sector research within the clinical trials industry, so as I was developing the project, I was keenly aware of my responsibility to be ethically commendable in my own interactions with human subjects. What went wrong? And what generalizable implications does my experience have for thinking about human subjects research and informed consent?

This article is based on 12 months of qualitative research examining the for-profit clinical trials industry in the southwestern United States.² The purpose of the study was to investigate the new relations, structures, and logics that have been produced within the research clinic through the privatization of pharmaceutical research. Using a mode of multi-sited, institutional ethnography,³ my research was particularly attuned to

the roles of the informants—i.e., physician investigators, coordinators, monitors, and even human subject volunteers—and the ethical conflicts, of various degrees of intensity, that they described and that were observed through their practices—e.g., recruitment of subjects, informed consent processes, and study retention and compliance. Studying approximately 20 for-profit research organizations in two major cities, I conducted 57 semi-structured interviews that were clustered to get the perspective of multiple employees at individual investigative sites—i.e., those conducting contract research—including 10 physicians, 18 research coordinators, 9 administrators, and 10 human subjects. Investigative sites represented a diverse sample of organizational forms, such as private practices, dedicated research sites, and large (nonacademic) hospitals. The sample also included interviews at two not-for-profit, nonhospital investigative sites. In addition, the research included attendance at industry conferences, the monitoring of publications produced by industry professional organizations, and participant observation in which I was screened for a Phase I, healthy volunteer clinical trial.

Using this qualitative fieldwork as the starting point for a discussion of informed consent, I draw upon some of my study's findings about practices surrounding informed consent in private-sector clinical trials. The primary purpose of the present paper, however, is not merely to relate conclusions from this larger project and its research questions. Instead, it is to provide a simultaneously reflexive⁴ and analytic framework to think about obstacles to truly informed consent in social science projects as well as in biomedical research. In other words, I aim to reflect upon my own process of informed consent in social science research in order to offer alternative insights into the problems of informed consent and therapeutic misconceptions within the context of biomedical research. I argue that informed consent goes awry due to *procedural misconceptions* seemingly built into various research contexts and often invisible to those involved in the informed consent process.

INFORMED CONSENT IN CONTEXT: SOCIAL SCIENCE RESEARCH

To begin, where did I go wrong with my own human subjects? And why did I not notice the problems with my informed consent process until after I had completed the research? To answer these questions, it is important to know how I was interpreting this process while I was in the field. Having heard from other social science scholars that the formality of the informed consent form could have a chilling effect on interactions

with informants (see Church 2002), I felt quite fortunate to have a research project in which all my own informants had a familiarity with informed consent that far exceeded the average person. In fact, presenting physicians, research coordinators, and others involved in clinical trials with informed consent forms was not only nonthreatening, but it also often proved to be an effective ice breaker that helped to establish a rapport and facilitate the interview. Invariably, my informants could not help but comment on how short my informed consent form was and how long their own forms have become.

I noticed at the time that, in spite of the conciseness of my form and their own understanding of the informed consent process, more often than not my subjects would sign before reading the details on the form. Perhaps this was because I always reviewed with them the highlights of the form: they and their organization would remain anonymous, they could choose to receive a copy of a transcript of the interview to review by checking the appropriate spot, and I would be recording the interview unless they did not wish me to do so. The details I reviewed were the ones that I thought would be most important to my informants, the ones that affected them most directly. I did not review the details of my project (i.e., the specific research questions, hypotheses, and the like), the types of questions I would ask within the interview, or the potential publications that could result from the project, unless the subjects asked directly, which only occurred twice in nearly 60 interviews. Although some informants did express an interest in details of my project or about my degree program *after* the interview was over, I attribute this interest more to their desire to be good conversationalists than to any particular concerns about their personal participation in the project.

My informants' good understanding of the informed consent process had made me believe that it ensured that they would be well informed about the research in which they were taking part. And yet, now that the data has been collected, it seems to me that these informed consent savvy subjects might be at the same disadvantage in relation to my research that the human subjects from whom they seek informed consent are in relation to them. From reflecting on this problem with my own research, I came to see that the positional disadvantage that my subjects had within the context of the informed consent process is rooted in a *procedural misconception*.

I define procedural misconceptions as the tendency for individuals to make false assumptions about research by responding to what is similar to

other nonresearch contexts and overlooking what is different.⁵ Individuals respond to certain cues in their social contexts that indicate how they should behave or how they should interact with others in those contexts. Procedural misconceptions, thus, occur at the boundary of what is familiar and what is foreign. Because a novel situation has the contextual cues of something more familiar, there is the potential to ignore other cues that signal what is different.⁶ In cases where procedural misconceptions have occurred, they continue until one recognizes and responds to those differences in the new context or situation.

Putting flesh onto this concept: in the example of my own informed consent process, a procedural misconception occurred because my subjects' familiarity with informed consent in their own context created a false sense of familiarity with *my* project and informed consent more generally. In this case, the misconception was twofold in that I—the researcher—was operating under its logic as well. Because of this procedural misconception, the subjects in my study were actually at a disadvantage for giving informed consent because they were keyed in to different issues, ones that are important in the biomedical sciences, but that are not particularly relevant or are of less concern in the social sciences. In retrospect, the procedural misconception manifested itself in the jokes my subjects made about how the interview was “painless” and they didn't expect any “adverse events” from having participated.

Of course, this is not to imply that all social science research is risk-free to participants; my point is that *false* assumptions of what details are important in informed consent cannot be productive for the researcher or her subjects. This is particularly true when those assumptions foreclose discussion about the research project itself. Here, the assumption shared by my subjects and me was that informants in social science research like mine should be most concerned about their risk—i.e., anonymity—not to what purpose their words would be put. Said differently, if part of the intent of informed consent as a process is to generate discussion among researchers and subjects about their potential participation in a study, false assumptions on the part of researcher and subjects about subjects' understanding of research as a process tends to direct attention to study-specific details rather than to more holistic discussions about the study and the implications of subjects' participation in it.

Thus, in my own example, my subjects had too much knowledge of *their own process* of informed consent, and this became a barrier to truly informed consent for my specific project. As a result, my informants lacked

a clear understanding of what I planned to do with the data gleaned from my interviews with them, and some even seemed to lack a concept of what “research” might mean outside of the context of clinical trials. Although this lack of truly informed consent is not of a variety justifying action by an institutional review board, it does point to potential limitations of informed consent for other types of research, including in the biomedical sciences.

INFORMED CONSENT IN CONTEXT: BIOMEDICAL RESEARCH

For most individuals volunteering to participate in clinical trials, the research relationship is foreign. But what *is* familiar is the setting of medical care in which clinical trials are situated. Although this also applies to academic medical centers, it is particularly true when medical research occurs in the private sector because private investigative sites often either are located within the offices of private practice physicians or have the look and feel of such offices. These settings provide human subjects all the cues of being “patients,” not “subjects.”⁷ The informed consent document itself does not necessarily signal a difference for human subjects because of the ubiquity of consent forms for many medical procedures in hospitals and clinics and the ambiguity of terms used in these documents.⁸ In medical care settings, consent forms have become just one more document to be filled out, like one’s medical history, insurance information, and HIPAA notification, rather than information that requires deliberation or decision making. The cues from subjects’ previous experience of medical care, therefore, do not help to distinguish the unique information that the informed consent form in research settings is trying to communicate about the experimental nature of the research, its risks, subjects’ rights, and the protections afforded to them.

In addition to the setting of clinical research, the context of clinical trials involves the structural variables that bring human subjects to the research. These variables include the type and location of the study; the mode of recruitment, whether directly solicited by physician or in response to an advertisement; and the reasons why the study is attractive to individual subjects, for example, a lack of health insurance, a desire for financial compensation, the hope for a cure. When taking these variables into account, the context of clinical trials further influences the ways in which human subjects enter into the informed consent process.⁹ It is important to understand the ways in which the context of clinical trials enables what I call procedural misconceptions.

The story of an informed consent visit that I witnessed during my fieldwork illustrates this type of procedural misconception in biomedical research. The investigative site was not set in a private practice, but it was located within a medical arts building and resembled a private practice in terms of office location, design, and procedures. A 75-year-old, Hispanic woman and her middle-age son had responded to an ad for an investigational drug for Alzheimer's disease. It was quite apparent that the woman's disease already had progressed to the point that her son was acting as her guardian and making decisions about her care. Because of the perceived complexity of the study, the principle investigator—a white, middle-aged, male neurologist—was conducting the informed consent visit himself rather than leaving it to a research coordinator as is more customary.¹⁰ During the informed consent visit, the mother and son were told that the study was “Phase I” and would not have any therapeutic benefit; rather the study would test the safety of the drug.

To underscore the most important information about the study, the physician-investigator emphasized that the protocol did not even include measures to assess the amount of deterioration associated with Alzheimer's experienced by the patient during the course of the year-long study. The only explicit benefits of participating in the study for the woman were the \$500 stipend awarded at the conclusion of her involvement, access to a battery of examinations and procedures at the outset of the study to assess her memory loss, and an exclusive invitation to participate in any subsequent Phase II studies of the drug, at which point she would be guaranteed to receive the active drug and not the placebo.¹¹

What was striking in my observation of this interaction was that the son actively searched for direct benefits for his mother's condition in spite of the physician-investigator's assurance that there were none. The son hypothesized that, even if the purpose of the study was not therapeutic, his mother might still benefit if the treatment were later to be found efficacious. At that point, the physician explained that the study only involved one single dose, which, by itself, would not produce any benefit for the woman's condition. He continued by telling the son that in order for the experimental drug to have any therapeutic value, it would have to be administered on a monthly basis for a minimum of one year. Eventually the son settled on the diagnostic benefits as sufficient reason for his mother to take part in the study. The woman had inadequate insurance, and this study would give her access to cutting edge tests for Alzheimer's, including a very expensive MRI. The physician-investigator acquiesced that these

tests were indeed a benefit, while reiterating the fact that they would not change the woman's condition.

It is important to underscore that the son *already had decided* that his mother would take part in the clinical trial before arriving at the investigative site and hearing the details of the study. The informed consent process for him served to provide a justification for that decision. From my point of view as an observer, this was illustrated by his disinterest in the risks associated with the study and his active search for a therapeutic benefit to his mother. He told the physician that he had watched his father's slow deterioration from Alzheimer's leading to his father's death a few years before, and he was seeking help to circumvent the same illness from taking hold of his mother next.

By virtue of responding to the investigative site's advertisement, he already had submitted, if not consented, on his mother's behalf to the clinical trial based on his assumption of what benefits it might provide. In other words, it was clear that he had responded to the ad in hope of curing or at least halting the progression of his mother's Alzheimer's disease. Anything that he had known about medical research prior to the informed consent meeting—as he indicated to the physician—was framed in terms of progress and miracles, not in terms of Phase I studies to test the safety of a product in humans. As the son sat in this doctor's office, as he probably had sat in other doctors' offices discussing his mother's treatment and care, he needed to search to understand why they were there and why they should stay. What reason would his mother have to participate if she would receive no therapeutic benefit? And yet, even without any hope of therapeutic benefit and with significant risks, the son took his mother home that afternoon with an appointment scheduled for her to begin the screening process for enrollment in the study. In other words, he already had decided that she should take part in the clinical trial, and the informed consent visit did not, and probably *could not*, change his mind.

That potential subjects already have decided to participate in a research protocol before reading the informed consent forms is not, in and of itself, a new finding.¹² What has not been discussed is the degree of responsiveness that the informed consent process could or should have in light of these *a priori* decisions being made by human subjects. For example, what this particular informed consent visit lacked was a discussion about what research means and what role humans are expected to play in drug development. From one perspective, it could be said that the son in this example already was suffering from a therapeutic misconception about

research in general when he brought his mother to the clinic. Although this assertion is not inaccurate, it obscures the contextual factors that encourage continuation of that misconception. I characterize this broader problem as a *procedural misconception* within the realm of biomedical research. For instance, in the context of the Alzheimer's study, neither the doctor nor the investigative site itself provided the necessary cues for the son to understand the nature of clinical trials in general, let alone of this study in particular. It is interesting to note that in this example the informed consent process could be considered to be exemplary because the physician succeeded in communicating the lack of therapeutic benefit to the woman's son. Nonetheless, as in many other cases of procedural misconceptions, the problem for the woman and her son was not the *details* of the study, but rather the foreignness of the research process. Because the procedural misconception is rooted in misleading contextual cues, the informed consent form and its study-specific contents cannot, by themselves, clear up the son's confusion or provide the basis for truly informed consent.

Furthermore, the example of the Alzheimer's study illustrates that the conditions that produce the procedural misconceptions *enable* therapeutic misconceptions. To clarify the difference between therapeutic misconceptions¹³ and what I mean by procedural misconceptions: therapeutic misconceptions are specific and individualized—i.e., an individual incorrectly believes that a specific study in which he or she is participating will have therapeutic benefit for him or her—whereas procedural misconceptions are general and organizational—i.e., individuals have false assumptions about what research is and how it is conducted. In biomedical research, it is the foreignness of medical research as a process—e.g., Who funds it? What are its principles? Who participates? What constitutes positive or negative results?—that feeds therapeutic misconceptions and not the informed consent form or process itself. This is an important distinction because the physical, organizational, and structural contexts of human subjects research, including power relations,¹⁴ are often overlooked in discussions of informed consent and therapeutic misconception. And it is these variables that are becoming ever more important in light of the increasing privatization of clinical trials where drug studies have become a revenue stream for private practice physicians trying to make up their losses due to managed care and high malpractice insurance premiums.¹⁵

Drawing a distinction between procedural misconceptions and therapeutic ones is valuable for identifying misunderstandings that human

subjects have about research more generally, whether it is social science or biomedical research. Moreover, procedural misconceptions provide a different point of intervention from those targeting therapeutic misconceptions. Remedies for therapeutic misconceptions tend to focus on the content of informed consent forms or on making informed consent an ongoing process of reviewing the same information at different stages of a study. The emphasis on informed consent as a means of supplying specific information about particular studies replaces and often forecloses more general discussions about the broader issues at stake in research. By recognizing and addressing procedural misconceptions, researchers can be more attentive to the need to provide broader explanations of the research context, in addition to the details of specific studies.

In the case of my own research involving physicians and research coordinators in private-sector clinical trials, I failed to obtain truly informed consent because my informants and I assumed that they already understood the nature of research and the concept of informed consent sufficiently to give valid consent. Most of my informants did not, however, understand the nature of *sociological* research, including the types of “results” that might be generated. Contributing to the procedural misconception in my case is the problem that I flagged earlier: As the researcher, I also was operating under the assumption that my informants understood the nature of research and the informed consent process and would ask questions about the research if they had any. What I did not understand at the time was how difficult it is for researchers to know what their participants do *not* know but *should* know before participating in research. Certainly in the example of the Alzheimer’s study, the doctor did not recognize how completely out of context the mother and son really were and, therefore, could not help the son shift as completely into the framework of medical research as he might have. The physician was operating under the assumption that the study-specific information in the consent form was sufficient for the son to make an informed decision about enrolling his mother in a pharmaceutical study. He did not recognize the additional value that general information about drug development and the role of human subjects participating in it might have for the patient and her son. In both cases, the researchers held false assumptions about what information was necessary for truly informed decision making.

PROCEDURAL MISCONCEPTIONS:
CHALLENGES AND IMPLICATIONS FOR RESEARCH

I have argued that in both social science and biomedical research procedural misconceptions occur because researchers rarely supply broader information about the nature and goals of the type of research into which their projects fall, resulting in human subjects forming (false) assumptions about the studies in which they are participating. Given this problem, what can be done to remedy these types of misconceptions, to help informed consent better meet its ideal, and to combat therapeutic misconceptions? Here, I examine factors that encourage procedural misconceptions and potential ways to combat these false assumptions about research. By again drawing upon examples from my own research and the results of that research, I show the parallel problems that exist in social science and biomedical research and suggest the different effects associated with those problems in each domain.

There are two types of challenges to the prevention of procedural misconceptions in social science and biomedical research: (1) human subject volunteers' lack of interest in the details of research studies, and (2) the general population's lack of knowledge about research in specialized fields. These challenges are interrelated but have different ethical implications that should be addressed.

Volunteers' Lack of Interest in Study Details

The case of individual human subjects' lack of interest has been examined as one of the problems of the informed consent process in biomedical research.¹⁶ I contend that the part of the potential for procedural misconception lies in the problem of getting human subjects to care about the information that is contained in the informed consent forms.

What should one do when participants do not seem to *want* to be informed? In biomedical research, I found that the details of clinical trials are not particularly important for some participants because their doctor recommended that they take part in the study. For example, a patient with cancer whom I interviewed was adamant that her doctor would not have offered her the trial if it were not the best chance she had for survival, and so she felt that the informed consent form and information about the study more generally were not necessary elements for her decision to enroll in the study. In cases of more mundane clinical trials, human subjects participating in insomnia, arthritis, and diabetes trials told me that they lost interest in the details of the studies when they realized they were

nonnegotiable due to the fixity of the protocol. Many subjects reported in interviews that what mattered the most to them was that the clinical trials provided them with (limited) access to the medical establishment that they otherwise would not have due to their lack of health insurance. As a result, their decisions to participate were made independently of the details of any specific clinical trials and their respective informed consent forms.

Similarly, this lack of interest in the details of specific studies spills over to social science research as well. As I previously described, in the case of my own research, very few of my informants were interested in the details of my project and already had made up their minds to participate in the study before reading the informed consent form. What I found upon reflection about my own recruiting was that informants often took part in the interviews because they were quite flattered that I had contacted them, that I considered them experts, and that I was interested in their opinions and perspectives about their position within the larger clinical trials industry. In retrospect, this is why these informants did not need to engage me in a conversation about the research project: what mattered to them is that they mattered to me.

In short, human subjects often express a lack of interest in study details and in informed consent forms in both social science and biomedical research because their reasons for participating are outside the scope of any given study. When decision making about participation occurs prior to meeting with the researcher or staff and is influenced by a host of contextual factors, the informed consent process is not neutral, but valenced toward consent. Because human subjects consent to research under these circumstances, it is no surprise that procedural misconceptions occur. Logistical details of the studies, the extent of subjects' participation, possible risks associated with the study, and the potential outcomes of the research all may be unclear to the potential subjects. From the mundane to the critical, these types of misconceptions must be considered ethical issues in research because they are barriers to truly informed consent.¹⁷

What seems to be absent from informed consent forms and frequently from the consent process is an understanding of the structural conditions that limit one's autonomy.¹⁸ Because individuals do not make decisions in a vacuum, structural conditions can and do derail the mission of informed consent. For example, it is not a coincidence that the people who participate in Phase I studies on healthy humans, which carry the highest risk with no individual benefit and therefore often provide high monetary

or other compensation to enrollees, are the people in our society who are most in need of material resources.¹⁹ Likewise, the motivation to participate in later phase trials, particularly Phase III studies or cancer trials, usually is based on illness prognosis, access to healthcare, and educational level. These motivations all point toward structural variables that frequently take precedence in people's participation decisions over information that is communicated about specific research studies.

As ethicists or ethical researchers, it may be quite alarming to realize that human subjects participating in biomedical research often are not interested in the details that would render truly informed consent. And yet, it should come as no surprise given that informed consent forms have become preposterously lengthy, particularly for pharmaceutical research, that monetary incentives need to be high for early-stage human testing of new biomedical products, and that research is often nestled within medical care settings. What regulators and ethicists want human subjects to know about research is not necessarily what those human subjects want to know. Informed consent forms are composed in such a way as to reduce the liability of research sponsors, whether pharmaceutical companies, government agencies, or universities; to prevent the grossest forms of deception and coercion; and to act as symbols to human subjects that their rights are being protected.²⁰ This last category, the symbolism of informed consent, seems to be especially meaningful for those who work in the clinical trials and bioethics industries.

Lack of Knowledge about Research in General

The second challenge in the prevention of procedural misconceptions is tied to the lack of knowledge about research within the general population. Whether social science or biomedical, the general population has limited understanding of the scope, methods, rationales, outcomes, and politics of research. For individuals participating in studies, this means that there is little basis for knowing what questions to ask or information to seek about specific research projects. To make matters worse, researchers and their staff—or students—often take for granted their knowledge about the research process so that they cannot see that human subjects do not have the same familiarity with research that they themselves do.

Here, I should emphasize that education alone does not determine understanding. Higher levels of education improve general knowledge about research, but they are not sufficient in and of themselves to provide people with an understanding of the specific context out of which informed

consent forms are produced. For example, having a doctoral degree in English literature does not prepare one to be a subject in a clinical trial. On a more personal note, reviewing my own interviews with those employed or participating in the clinical trials industry, I can see the development of my questions—and hence thinking!—from fairly naïve to rather insightful. In other words, only now, after spending 12 months doing fieldwork on the clinical trials industry, having studied multiple types of companies, and having interviewed people in many positions throughout the industry, do I feel confident that I could ask the important questions about a clinical study to inform my own decision about whether to participate.

This is to say that the more one understands the context for the research and the more the researcher can understand the context of the human subject, the better the basis there is for a discussion that can lead to truly informed consent. In academic contexts, this is taken completely for granted. The best conversations we have about our research or our scholarly work occur with colleagues who are engaged in similar conversations, either disciplinarily or topically. The challenge, then, is to engage with human subjects in conversations about research that are broader than the details of the particular studies and that better align with human subjects' concerns and constraints.

One reason that procedural misconceptions about research occur is human subjects' lack of familiarity with research in general and the resultant tendency to make false assumptions based on their experiences in other domains. Recognizing the communication of general information about social science or biomedical research as important emphasizes a reorientation in the ethics of human subjects research. The implication of this standpoint is that the problems with informed consent are not rooted solely in specificity of information but also in generality. Informed consent forms should reflect the broader context of the research to structure conversations between researchers and subjects. Although this may not solve the problem of the level of interest that human subjects have in informed consent forms or in the study details, it does mean that researchers would be doing even more to signal to subjects that they are indeed participating in research.

Another, perhaps deeper and intractable, reason for procedural misconceptions has to do with broader issues of inequality in society. This is especially true in the United States, where access to healthcare is restricted or precluded for about 20 percent of the population who have no or very limited health insurance and where extreme economic inequality prevails

(see Quadagno 2005). Within this political and economic context, informed consent alone cannot hope to be more than a formality most of the time for these populations. Any accurate appraisal of the informed consent process and research ethics more broadly must take these social facts into account because the decisions one makes about participating in research are undeniably shaped by one's social, cultural, and economic position (see Fisher 2005).

The examples and findings of my research on the clinical trials industry, including my reflexivity about my own informed consent process, show how obstacles to informed consent are rooted in contexts that can enable or diminish informed consent. Although most of my informants who are employed as researchers and staff on clinical trials have internalized the concept of informed consent as a process, their apparent failure to appreciate the differences, and implications thereof, between biomedical and social science research indicated an underlying inability—or undeveloped ability—to relate the research enterprise in a way that makes sense to others for whom research is foreign. With respect to my research project, this negligence was my own in terms of not ensuring that the subjects in my study truly understood the type of project they were participating in. But the potential for procedural misconceptions exists in all informed consent processes and research settings. Until researchers learn to better communicate to potential human subjects the larger details of the research enterprise of which they are a part and to compensate for asymmetrical power relations in society as a whole, it will be impossible to protect against these misunderstandings and against the more serious problem of therapeutic misconceptions in biomedical research.

NOTES

1. This project was reviewed by the Rensselaer Polytechnic Institute IRB in 2003, and approval was renewed in 2004.
2. The research was supported by the National Institutes of Health under Ruth L. Kirschstein National Research Service Award 5F31MH070222 from the National Institute of Mental Health.
3. Methodologically, my research was informed by the work of George Marcus (1998) and Dorothy Smith (2005).
4. I am using the term “reflexive” here in the sense that feminist philosopher of science Sandra Harding (1991) argues for in her definition of “strong objectivity,” wherein the researcher positions herself within analyses of her findings and claims. It is distinct from being “reflective” in that the reflexive

researcher also assumes that the creation of knowledge in which she takes part is a contingent and partial process influenced by her own positioning and the knowledge she sought. See also Donna Haraway (1991).

5. I use the term “procedural” because human subjects apply the assumptions and norms of a more familiar—and often banal—context or procedure to research in order to make sense of the unknown. Additionally, these misconceptions flourish when the quotidian procedures of the researchers obscure what human subjects do not know or understand about research.
6. Context is complex because it has rituals built into it that one often does not recognize as such. For example, medical encounters or doctor-patient relationships are highly ritualized and even choreographed. When medical research borrows from these rituals, human subjects are cast or cast themselves into the roles of patients rather than research subjects or participants. See Katherine Young (1997) for an in-depth analysis of the rituals and choreography that make up the doctor-patient relationship in internal medicine, gynecology, surgery, and pathology.
7. The importance of setting and its impact upon informed consent has been noted already by Paul Appelbaum, Charles Lidz, and Alan Meisel (1987). Setting is a crucial component of what I am referring to as the “context” of clinical trials.
8. Research by Ronald Butters, Jeremy Sugarman, and Lyla Kaplan (2000) illustrates the problem of semantics or the variability in medical research terms that makes informed consent forms less than clear at best, and most likely ambiguous and even misleading to many potential research subjects. Similar semantic analyses have been done by Jan Marta (1996).
9. Sheldon Zink (2001) argues that researchers need to start paying more attention to who is participating in medical research and what their motivations are. She makes a compelling case that this type of understanding of participants will help guide discussions about informed consent and compensation for participation.
10. Elsewhere (Fisher 2006), I describe the role of coordinators within the research enterprise, focusing on their construction of research ethics.
11. The study for which the woman was being recruited also had a placebo arm into which 25 percent of the subjects enrolled in the study would be randomized. It is important to note that the guarantee of receiving the active drug in future studies clearly also gives an advantage to both the pharmaceutical company and investigative site because it assists their recruitment for future studies.
12. Appelbaum, Lidz, and Meisel (1987) noted this occurrence nearly 20 years ago, and others have continued to document it (e.g., Zussman 1997), yet in general it hardly is acknowledged in discussion of therapeutic misconceptions.

13. Sam Horng and Christine Grady (2003) have discussed their own typology of therapeutic misunderstandings in clinical research.
14. For a thought-provoking discussion about power and informed consent, see Pam McGrath (1998).
15. See Jill Fisher (2005) for more discussion about the privatization of clinical trials. CenterWatch (2003) has many statistics about these trends in the pharmaceutical and clinical trials industries.
16. Robert Zussman (1997) cogently argues that one of the problems with discussions about informed consent is that bioethics has ignored the problem that patients are often indifferent to informed consent. Framing what sociology can teach bioethics about informed consent in research, Zussman draws attention to the role of power in defining relationships in the research context. These relations contribute to, if not shape, individuals' indifference to informed consent.
17. Recent attention to the need to communicate the results of clinical trials to those who have participated in them attests to the fact that we are generating new ways of thinking about the ethics of research and the need to show respect to those who are enrolling in these studies (Fernandez, Kodish, and Weijer 2003; Markman 2004).
18. Some scholars who emphasize the importance of structural conditions for participants' context include Larry Churchill (1997); Rebecca Dresser (2001); Lisa Eckenwiler (2001); Nancy King, Gail Henderson, and Jane Stein (1999); and Robert Zussman (1997).
19. Trudo Lemmens and Carl Elliott (2001) point out that informed consent is not the primary problem with Phase I research even though it is often the focus of discussion. Their greater concern is the systematic exploitation on which this part of drug development is founded: "Like it or not, research on healthy subjects has become a commercial transaction" (p. 52). I strongly second their call to see this branch of research for what it is—part of a multi-million dollar industry—and to find better ways to regulate it according to its differences from research involving sick people.
20. Leslie Cannold (1997) writes about the inadequacy of informed consent because of the way that information is disclosed to patients. Sheldon Zink (2004) also indicates the need for more direct information about studies. She faults researchers for being afraid to say it like it is when it comes to financial conflicts of interest in research and risk. Until researchers stop presenting information about studies in euphemisms, how can participants be expected to have a truly informed sense of the research enterprise?

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