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# What a Tangled Web We Weave: Ethical and Legal Implications of Deception in Recruitment

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## Abstract

Deception in human subject research is neither uncommon nor prohibited. The use of deception in the recruitment phase of clinical research has received relatively little attention. Given that informed consent is foundational to human subject research, the practice of misrepresenting the study purpose in clinical research would seem to contradict one of the fundamental tenets of ethical human subjects research. Using the example of prodromal psychosis, this article considers the ethical and legal implications of deception in recruitment and the sufficiency of current guidance on the practice when the study involves a stigmatizing condition, the collection of genetic samples, or both. I conclude that when these two elements are present, deception should be used only when absolutely necessary and, if used, researchers should be required to debrief participants before the collection of genetic samples and give particular attention to minimizing risks of privacy breaches.

## Introduction

Deception in human subject research is neither uncommon nor prohibited. In social and behavioral research, the use of deception has become widely accepted, although not entirely without controversy (Nicks et al., 1997). Deception in clinical research involving human subjects tends to be more controversial (Wendler and Miller, 2004), as observation may shift to intervention. Indeed, the ethics of the undisclosed use of placebo as controls for active intervention in research has received considerable attention (Benham, 2008; Joyce, 1982; Macklin, 1999; Miller et al., 2005; Tenery et al., 2002). Less has been written about the use of deception in the recruitment phase of clinical research. Given that informed consent is a requirement of all human subject research that does not qualify for an exception, the practice of misrepresenting the purpose of a study in clinical research would logically seem to contradict one of the fundamental tenets of ethical human subjects research. Yet, deception in clinical research does occur (Colloca et al., 2004; Wendler and Miller, 2004).

This article takes up the question of the use of deception in the recruitment phase of clinical research and examines the ethics and downstream effects of the use of deception when the study involves a stigmatizing condition, the collection of genetic samples, or both. Advances

in genetics in neuroscience hold promise for a greater understanding of the genetic component of psychiatric illnesses and other neurological disorders, making the collection and use of genetic samples in research increasingly valuable. These developments invite re-consideration of current regulatory guidance regarding deception in research. Using the example of prodromal psychosis, this article explores the ethical and legal implications of deception in neuroscience research and the sufficiency of current guidance on the practice. I begin with an examination of the concept of deception in research and then review current regulation of this practice. Next, using the example of research on prodromal psychosis, I discuss the types of vulnerabilities that may be created or exacerbated by the use of deception and explore the complications that can arise when deception is used in research on a stigmatizing condition that also involves the collection of genetic samples. I emphasize that when these two elements are present, deception should be used only when absolutely necessary and, when used, researchers should be required to debrief participants before collecting samples and give particular attention to minimizing risks of privacy breaches.

## The Concept and Hazards of Deception

Deception, like many other value-laden concepts, can elude precise definition. An outright lie or factual misrepresentation is fairly easy to categorize. However, it may be debatable at what point "incomplete disclosure" and "opaque descriptions" cross the line into the realm of deception. It has been suggested that deception occurs when an investigator "intentionally communicates in a way that produces false beliefs" (Wendler and Miller, 2004). Under this definition, it is not clear whether there is a meaningful distinction between "producing" a false belief and "allowing" one. Wendler and Miller's definition requires that the communication "produce" a false belief, and, thereby, appears to suggest a causal requirement. Although this may seem to raise the threshold criteria, what "causes" one to accept as true what is actually false can span the spectrum of communication. Incomplete disclosure, though passive in nature, is a way of communicating that can result in a false belief. Hence, I suggest that deception more accurately includes a passive range of communication, and that a more appropriate definition in the context of human subject research is communication that intentionally produces or induces, or knowingly allows a potential participant to have or maintain, a false belief. Since the guidelines for informed consent require disclosure of the study purpose, it follows that any description of the study that "masks" the true or exact nature of the study either by incomplete disclosure or overly broad descriptions can cause participants to accept as true or valid that which is not. Thus, where an investigator knowingly allows a participant to maintain a reasonable belief about the study that the investigator knows is not true, omission (by not taking the opportunity to disabuse the participant of the false belief) constitutes deception. This broader construction of deception may better achieve the goals of regulatory measures aimed at ensuring adequate protection of human subjects.

Deception in research, generally, has a long history (Nicks et al., 1997). The Milgram study on obedience (1974) may be partially responsible for bringing this research practice under scrutiny and certainly provides a reference event for many. Indeed, the Milgram study challenged the research oversight institution to revisit and refine the propriety of studies that, for reasons of scientific integrity, do not inform participants of the true nature of the study (Herrera, 2001).

Several ethical issues have been raised regarding the use of deception in research, and recommendations have been offered to guide its use and minimize its potential harms (Benham, 2008; Bok, 1995; Levine, 1982; Miller et al., 2005; Wendler and Miller, 2004). Among the concerning issues are erosion of public trust (Benham, 2008; Miller and Kaptchuk, 2008), impact on the doctor-patient relationship (Bok, 2002), and autonomy and informed consent (Benham, 2008; Bok, 1995; Dowrick et al., 2007; Hechem and

Gonorazky, 2005). Given the foundational biomedical ethics principle of autonomy (Beauchamp and Childress, 2001), any practice that compromises an individual's ability to choose what will and will not be done in a medical context is immediately suspect.

Deception in research can occur at two main phases of research — recruitment and intervention. It is accepted that in certain circumstances, particularly in studies on behavior, a study participant's knowledge of the true purpose of a study may affect behavior, bias the study results, and compromise scientific integrity (Nicks et al., 1997). Consequently, recruitment materials and the informed consent document may describe the study and its objectives in such a way that obscures the true nature of the study.

Misrepresentation of the study purpose at the outset raises significant questions about the validity of the consent and a myriad of downstream ethical concerns. This misrepresentation can occur in many ways, including by omission of key facts, inclusion of misleading facts, or a combination of both. Indeed, 45 CFR 46 116(a)(1) states that a valid informed consent must provide "[a] statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental". Nevertheless, in recognition of instances where important scientific objectives may best be served by the use of deception in research, exemptions from the requirements of informed consent are allowed (45 CFR 116(d)). Under this provision, deception in research may be permitted if certain requirements are met.

## Regulation of Deception in Research

In 1979, the Belmont Report on "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" was issued. It emphasized the importance of informed consent but also acknowledged that there may be research activities for which deception could be necessary. The Report explicitly observed that in many cases a statement indicating that disclosure will be incomplete until the conclusion of the study might be adequate. Nevertheless, the Report also stated that such research must demonstrate 1) that incomplete disclosure is necessary to the goals of the research; 2) that all risks have been disclosed; and 3) when appropriate, there is a plan for debriefing participants (Department of Health Education and Welfare, 1979).

These concerns have been incorporated into the Code of Federal Regulations where four criteria are stipulated for a waiver of informed consent requirements, or in the case of deception, altered.

Section 45 CFR 46.116(d) states:

> (d) An Institutional Review Board (IRB) may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:
>
> 1. The research involves no more than minimal risk to the subjects;
>
> 2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
>
> 3. The research could not practicably be carried out without the waiver or alteration; and
>
> 4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Together, these four requirements seek to ensure that the participant is not harmed by the deception, that this deviation from foundational ethical principles is necessary to the scientific integrity, and, if possible, that appropriate disclosure to participants will take place after the conclusion of their participation in the study, usually by debriefing. In the current climate of research, in which data is acquired for future or different uses, and when the condition under investigation is one that is associated with stigma, the use of deception requires greater scrutiny to ensure that regulatory objectives are met.

## Prodromal Psychosis

Psychosis is a disorder that is characterized by the presence of delusions, hallucinations, incoherence and/or grossly disorganized or catatonic behavior (American Psychiatric Association, 1994). It has been estimated that lifetime prevalence of psychotic disorders in the general population exceeds 3% (Suvisaari et al., 2007) and that worldwide, schizophrenia affects 1% of the population (Austin, 2005), with a lifetime morbid risk of 7.2% (Saha et al., 2005). A prodrome can be defined as a "warning" symptom of a disease or disorder or may indicate "at-risk" status (see, e.g., Corcoran et al., 2005). Thus, "prodromal to psychosis" or "prodromal psychosis" refers to the mental state that precedes the onset of frank psychotic symptoms, occurring between an individual's premorbid functioning (Beiser et al., 1993) and the onset of psychosis. It has been asserted that the prodrome can only be identified retrospectively, i.e., after the disorder has manifested (Addington, 2003). For example, a prodrome may be merely a risk factor for psychosis, in which case not everyone manifesting these symptoms will develop psychosis, or the prodrome may be the early stages of schizophrenia, for example, in which case psychosis will certainly develop absent intervention (Addington, 2003; McGorry et al., 2001).

Research is increasingly targeting the prodromal stages of psychosis and the development of effective preventive interventions (Corcoran et al., 2005). Yet, there are risks inherent in prodromal research on psychosis (Corcoran et al., 2005). Exposure to medication and its side effects (Addington, 2003; Corcoran et al., 2005), as well as the stigma resulting from false-positives (Corcoran et al., 2005), are among the concerns that have been put forth. Specifically, issues typically associated with predictive information, such as confidentiality and insurability, have been raised (see, e.g., Corcoran et al., 2005). Nevertheless, given that longer periods of untreated psychosis are associated with worse outcomes (McGorry and Yung, 2003), research that is likely to enhance the ability to identify, diagnose, and treat individuals who may be prodromal to psychosis has the potential to be of considerable benefit in reducing the onset and severity of psychosis among the prodromal population.

In seeking a better understanding of the genetic components of psychosis, researchers may design some studies on prodromal psychosis that seek to obtain genetic samples from participants. There are legitimate and possibly compelling reasons for seeking genetic samples from this population (Austin and Honer, 2004; R. Pierce Cannon et al., 2003). Since early diagnosis and treatment are associated with better outcomes (McGorry and Yung, 2003), genetic associations could facilitate early diagnosis, which could, in turn, allow for earlier interventions. Additionally, prodromal stages of psychosis are often impossible to differentiate regarding the specific disorder that might develop, thus making treatment decisions more difficult. As such, discovery of genetic associations for specific types of psychosis could also be highly beneficial to this population. Yet the use of deception to recruit this population to a study on a stigmatizing condition that involves the collection of genetic samples may create significant problems. The following discussion explores why this may be problematic and suggests that incorporation of certain procedures ensuring privacy and truly informed consent as to the use and collection of the samples may resolve this dilemma without negatively affecting the scientific integrity of the research.

**Deception in Prodromal Psychosis Research**

Because of the nature of psychotic disorders and the symptoms that may lead to a diagnosis, especially in the prodromal (early) stages, recruitment can present numerous challenges that may not be present in other types of clinical research. Some members of the prodromal stage population may not see the need to seek medical attention, thus making attempts to study the early or mild forms of psychosis more difficult because people eligible for a study on early psychosis may not readily be found in the patient population. Consequently, researchers may perceive a need to turn to the general population to recruit participants. Moreover, if researchers were to try to openly recruit persons with psychosis, perhaps listing the symptoms and using the term "psychosis" in the recruitment materials or in the informed consent document, potential participants may either not report symptoms accurately or simply decline to participate altogether. Anticipation of these two behaviors could lead researchers to not fully disclose the study purpose when recruiting for prodromal psychosis studies, particularly when recruiting from the general population.

It is not uncommon for recruitment ads to target specific behaviors or symptoms of the disorder to be studied. Thus, advertisements, flyers and posters may invite potential participants to consider whether they would be appropriate for a particular study based on self-screening for the behaviors. "Do you sleep less than 4 hours per night? Do you smoke more than one pack of cigarettes per day? Do you have an alcoholic drink more than five days a week?" "If so, then you may be eligible to participate in our study." After a series of screening questionnaires and tests, truly eligible participants are entered into the study. In these examples above, even if the exact nature of the study were not to be disclosed, a respondent would not be surprised to discover that these are studies on sleeplessness, smoking, and alcohol consumption.

However, consider the following advertisement: "Do you have a sixth sense? Do you have ESP? Have you experienced telepathy? Are you psychic?" "Do you experience anxiety or discomfort around new people?" In this instance, it may be somewhat more surprising to discover that this study is about prodromal stages of psychosis, schizophrenia or schizotypal personality disorder. Two features of this study complicate the use of deception. First, as noted, psychotic disorders often carry a stigma in many societies (Rosen, 2006). Second, if a study on prodromal psychosis uses this recruitment strategy, i.e., does not disclose that the study is on prodromal psychosis, and also involves the collection of genetic samples, this use of deception arguably impairs consent regarding all aspects of the collection and use of those samples. These two features, together, present serious ethical challenges for the use of deception in research.

Issues regarding social factors, cognition, and stigma can arise in certain kinds of neuroscience research, which may make it a particularly challenging enterprise. In general, research on the brain carries with it particular hazards and responsibilities (Miller and Fins, 2006). In the research context, the brain is also the "tool" that we use to evaluate the research, ascertain risks and benefits, and make decisions about whether to participate in research at all. Beyond the research context, there are many who regard the brain as the "seat of the soul" (Churchland, 1995). Thus recruitment for neuroscience research will necessarily invoke issues that are not implicated in other kinds of research, precisely because the brain is the locus of cognitive processes and because of the aspects of personhood and identity that are associated with the brain. In the case of research on psychiatric illness, the issues and challenges may be even more complex (see Shamoo, 1994; Shamoo et al. 1997; for discussion on autonomy and informed consent in research involving the mentally ill).

### Situational and Social Factors

Certain social circumstances, e.g., low income, low education levels, or mistrust based on past discriminatory practices, may make some individuals particularly vulnerable in the research context. Individuals with less education, for example, may apply less scrutiny to the terms of participation than others who are well educated (Taylor et al., 2005; Young et al., 1990). Erosion of public trust (Benham, 2008) may become even more problematic for groups who have had negative experiences with the biomedical research community (see, e.g., Freimuth et al., 2001; Harris et al., 1996 regarding impact of Tuskegee study). In view of the importance of research regarding health disparities, further erosion of trust in the research enterprise by members of groups with historically negative experiences could be highly detrimental to future research efforts.

Recruitment from a general vs. a clinical population may also present special concerns in the context of prodromal psychosis research. Conducting psychosis research with a nonclinically derived sample could raise concerns about unattended vulnerabilities, i.e., vulnerabilities for which no special protections have been put in place because the fact of the vulnerability (prodromal psychosis) has not been identified. Absent a clear indication to the contrary, capacity to consent may be presumed by the researchers, since no clinical screening by way of referral has occurred, for example.

Additionally, since the source of the vulnerability, psychosis, is the basis on which participants are recruited, the vulnerable population is the one that is targeted. This targeting of the vulnerable from the general population may be different from recruiting from the clinic in several ways.

A particularly salient distinction is that a clinical population is “help-seeking,” while undiagnosed individuals in the general population are not. This “help-seeking” implies two significant differences between the two recruitment populations: 1) recognition of a problem; and 2) possible active treatment or care. Unlike a person who has recognized the need for clinical help, a person recruited from the general population on the basis of “paranormal experience” may object strenuously to participating in research on a condition with which he or she does not identify. Thus, members of a clinical population have already accepted association with a stigmatizing condition, which may make debriefing a more viable option, and may, at least in part, eliminate the need for deception. Furthermore, the clinically derived participant may be receiving treatment for his or her condition, which could make both returning research results and debriefing less problematic. That participants may be receiving treatment should have little or no bearing on the scientific integrity of the study, particularly if the treatment is nonpharmacologic, depending, of course, on the nature of the study inquiry. If the clinically derived participant is receiving medication, then the issue of washout and relapse must be carefully addressed (Shamoo, 1994). Perhaps most importantly, the clinically derived participant is likely to have a physician looking after his or her welfare and monitoring the participant’s need for follow-up care (Shamoo, 1994). Thus, careful evaluation of the need for recruitment from a general vs. clinical population is necessary, which, in turn, may affect whether there is a need for deception.

### Cognitive Capacity

Vulnerabilities of a cognitive nature may directly affect judgment and discernment (Bass et al., 2008), particularly regarding decisions about participating in a study (Carpenter et al., 2000; Shamoo and Keay, 1996). Yet, it is important to stress that psychosis does not necessarily involve cognitive impairment. While the prevalence of cognitive impairment may be greater in this population than in the general population (see Carpenter et al., 2000), the extent to which any individual with prodromal symptoms is cognitively impaired must be

assessed on a case-by-case basis. Because of this higher prevalence and the impact on voluntariness and autonomy with regard to consent, careful attention should be given to the possible presence of this vulnerability.

### Stigmatizing Nature of the Condition

The breach of autonomy by the use of deception about the study purpose is further compounded because the fact of stigma itself could be sufficient to deter someone from participating in a study. Of course, research on stigmatized conditions is conducted openly and responsibly, as in the case of AIDS research, for example (see, e.g., Hillman, 2007; Leurcht et al., 2007). Indeed, some challenges presented by research on stigmatized conditions can be resolved by providing adequately for privacy and confidentiality concerns. In the case of deception about the study purpose, however, the participant has not consented to the special risk of a privacy breach regarding a stigmatized condition like psychiatric illness, thus escalating the intrusion on autonomy. The presence of stigma has several ramifications. First, it could raise the degree of risk such that participation involves greater than minimal risk. This would violate one of the requirements for a waiver or alteration of informed consent requirements (45 CFR 46.116(d)(1). Second, the fact of stigma constitutes both a material fact and a risk. Regardless of whether deception is used in the research, according to federal regulations, all risks must be disclosed to participants (45 CFR 46 116(a)(2)).

Consequently, when deception has been used in research involving stigmatized conditions, debriefing should be strongly encouraged, given that the fact of stigma could elevate the risk of harm. In such cases, the participant should have the opportunity to withdraw from participation after being fully informed of the true nature of the study (see, e.g., Miller and Kaptchuk, 2008). Furthermore, both researchers and ethics review committees should work to ensure that the risk of privacy breach is minimized, in view of the fact that where deception is necessary, the exact nature of the risk cannot be disclosed.

### Collection of Genetic Samples

Among the most difficult aspects of the use of deception in human subject research are the downstream effects — the consequences of not fully informing a human subject about the true nature of the study at the outset. To begin with, an unorthodox consent to participation in a study in which key aspects of the consent process are absent potentially renders virtually all aspects of the study problematic. The initial deception is compounded when additional components of participation are added to the study, e.g., the taking of genetic samples. Similar to the concept in criminal law, “fruit of the poisonous tree,” which prohibits the admission of evidence that was not legally obtained, consent for genetic samples obtained after deceiving the participant about the study purpose is also tainted and, consent, arguably, vitiated.

Increasingly, studies seek genetic samples of human subjects as part of the protocol even when the study of those samples is not anticipated in connection with the study for which the participant is enrolled (Pullman and Latus, 2003). Whether intended for use in the study in which the sample is collected or for later use, deception regarding the study purpose complicates the acquisition, use and storage of these samples. Again, consider the example of the recruitment of persons based on “paranormal experiences” to a study on psychosis. Such a study may describe its purpose in the consent form as “to investigate aspects of brain health.” While this is true, it also obscures the true study purpose by its broad and opaque description of an investigation into psychosis.

Even if the study provides detailed information in the consent form on the acquisition of genetic samples and provides distinct opportunities to specifically consent to or deny the taking of these samples, the consent is arguably tainted by the initial deception. In this case, it is not unreasonable to think that someone who consents to the use of her genetic sample in a study on persons with psychic ability may not consent to the use of that same sample in a study on psychiatric illness. Arguably, the consent would not be valid as to the genetic sample, since it was specific to a study on people with paranormal experience. That the perception of having paranormal experiences may overlap with psychotic symptoms is irrelevant since principles of informed consent demand that the analysis be made from the perspective of the participant and her understanding and expectations (Daugherty et al., 1997).

A description of the study purpose in the informed consent process as "brain health" and not "psychic abilities" still does not eliminate the deception problem. Rather, this seems a stark case of misrepresentation by omission. To a potential participant, a study on brain health is probably very different from one on psychosis. Thus, a vague and overly broad description that allows a participant to easily and reasonably misperceive the exact nature of the study falls within the category of deception, as it induces and knowingly allows a participant to have a false belief. As a result, consent for genetic samples obtained in such circumstances is arguably invalid, absent a debriefing.

### Blanket Consent

An interesting argument could be made that the use of deception does not necessarily result in impermissible taking and use of genetic samples if the study seeks blanket consent. Under blanket consent, a person gives consent to any and all uses, known and unknown, of her sample (see Caulfield, 2003). Thus, if a participant to a study that recruited persons with "paranormal experiences" gave blanket consent, then the argument could be made that any and all uses of that sample, including use in a study on psychosis, would be permissible.

This argument, though logical, is flawed because the initial consent to participate in the study in which blanket consent was sought was given based on misleading disclosure. Given that people may feel more generous about making their samples available when they have been told the truth than when they were deceived, the use of blanket consent to collect and use samples within the context of unresolved deception (i.e., prior to debriefing) would inappropriately take advantage of this greater generosity and further mislead subjects. Consequently, even blanket consent given in the context of deception cannot authorize the use of genetic samples of a participant who has not been informed about the true nature of the study.

### Secondary and Future Uses

Secondary use of human biological material generally refers to uses other than for the original purpose for which the sample was taken (see Hull et al., 2004; Pierce, 2008). Secondary use may occur, for example, when researchers wish to use samples obtained in a study on psychosis in a different study on a different disorder. Again, applying the concept of "fruit of the poisonous tree," it would follow that failure to inform the participant of a material fact about the original study purpose taints the permissibility of the use of this sample for the life of the stored sample. Given the invalid consent to its acquisition, no secondary studies could be performed using these samples. Likewise, unknown future uses would also be prohibited for the same reasons, as would transfers to third parties for other studies. Thus, the taint placed on the sample by the use of deception at the outset considerably limits the potential benefit that could be derived from the use of a sample in

important studies on psychosis and related disorders. Therefore, when researchers have used deception in recruitment to a study, genetic samples should not be taken until the patient has been debriefed and has consented anew after being told the true study purpose.

### The Debrief: A Satisfactory Solution?

Once a researcher has initiated a study that deceives the participant about a significant fact about the study, virtually every other aspect of the study to which the participant has given consent may be affected. Importantly, one of the requirements for the use of deception in human subjects research is that participants be debriefed after the study is over, if appropriate (45 CFR 46.116(d)(4)). Although federal regulations require a debriefing of the participant, where appropriate, two questions immediately arise: 1) when is it "inappropriate" to debrief; and 2) what should be done to restore autonomy when debriefing is not deemed appropriate. In the case of psychosis, disclosure of the true nature of the study to one who is undiagnosed could actually prove to be more harmful than beneficial, and the risk of such disclosure may outweigh the value of restoring autonomy. In such a case, debriefing may be "inappropriate" and, therefore, according to 45 CFR 46.116(d)(4), not required. However, as suggested earlier, this should effectively prohibit the taking of genetic samples, since this activity requires informed consent (45 CFR 46.101(b) (4)). In the case of recruitment to psychosis studies on the basis of paranormal experiences, it is particularly important to recognize that someone who considers herself to be psychic may readily offer a genetic sample for a study on extrasensory abilities but emphatically refuse to allow her sample to be used in a study on schizotypal personality disorder, for example. The restoration of autonomy in such circumstances seems especially important.

Therefore, to restore autonomy with regard to the provision of genetic samples, there should be a debriefing that affords the participant the opportunity to withdraw from the study and to withdraw her sample (although retrieval of individual information from any aggregation of data is not required).

### Alternatives to Deception?

Several suggestions have been offered in an effort to resolve the deception dilemma (the dilemma that arises from the need to deceive participants in order to ensure scientific integrity of the study, and the need to respect the autonomy of potential participants). I argue, however, that none of them sufficiently address the research situation in which a stigmatizing condition is studied and the collection of genetic samples is contemplated. Two alternatives have been suggested 1) "consent to incomplete disclosure" (Levine, 1982); and 2) "authorized deception" (Wendler and Miller, 2004). These concepts recommend that a potential human subject be told that some aspect of the study will not be disclosed to him, but that he not be told specifically which aspect that is. The human subject would thus be consenting to be deceived.

While this solution has some appeal, particularly in that it alerts potential subjects to the use of deception, thus affording them the opportunity to choose not to participate in research involving deception, it does not protect against all hazards of deception. Specifically, in the case of psychosis, it seems a less satisfying solution when one considers that those consenting to the use of some deception may be cognitively impaired (Carpenter, 2000). Their consent to some deceit does not really seem to advance significantly and meaningfully toward autonomy.

## Returning Research Results

The use of deception in a study on psychosis raises the question of what should be done when the illness under investigation or other disorders are discovered in the participant during the course of the research. Bearing some similarities to the dilemma of incidental findings in neuroimaging, issues regarding the right of the human subject to know, the right not to know, and researcher responsibility are all implicated (Illes et al., 2004; Illes et al., 2008). Unlike incidental findings, however, research results regarding the disorder under investigation are not incidental to the study, but are, in fact, the target of the study. Indeed, a study that seeks individuals with prodromal psychosis will, by definition, discover mental disorders in the participants. When deception hides the nature of the disorder under investigation, the question will be whether or not participants should be informed of a need to seek medical attention because of this disorder.

Returning research results in the case of prodromal stages of psychosis is further complicated by challenges relating to diagnosis and available interventions. Many of the interventions for psychosis are pharmacological and are designed to treat symptoms (see Austin, 2005). Therefore, if the prodrome is a retrospective concept (Addington, 2003), and can only be defined after a psychotic illness is established and identified, a case could be made that the prodromal stage is not treatable and therefore should not be disclosed to an undiagnosed participant. However, success is being reported using non-pharmacologic interventions, such as cognitive behavioral therapy (Austin, 2005; Morrison et al., 2004), suggesting that effective intervention for early stage psychosis exists and that being alerted to a possible need to seek help could alleviate the severity of the disorder. It is also important to note, however, that the clinical diagnostic procedure may differ from the research screening. Consequently, the standard may be sufficiently different, such that research results may not reach the level of clinical reliability and thus be inappropriate for disclosure to a research participant. In any event, like a key recommendation for incidental findings (Illes et al., 2008), a plan for returning research results should be in place before beginning the study. Moreover, the additional layer of deception surely makes the case even more problematic, as disclosure of deceit may be devastating to one already psychologically vulnerable.

Finally, the dilemma of how to handle the return of research results may serve as support for recruitment from a clinical population. Knowingly entering a study on psychosis and being informed of the need to seek medical attention is likely to be considerably less distressing than thinking that one is entering a study on psychic ability and being informed of the need to seek attention for a mental disorder. The attendant difficulties of returning potentially significant research results in such instances is likely to deter researchers from doing so with an undiagnosed population. Recruiting from a clinical population could largely eliminate this dilemma, since the return of potentially significant research results presents fewer challenges and, consequently, affords the possibility of early intervention.

## Conclusion

Advances in research on prodromal psychosis are opening up possibilities for significant improvements in the prevention and treatment of psychosis. Given that longer periods of untreated psychosis are associated with worse outcomes, improvements in the ability to diagnose and treat psychosis at an earlier stage can offer substantial benefit. Yet, for many reasons, the use of deception in studies involving a stigmatizing condition or seeking to collect genetic samples, or both, is highly problematic. Researchers may address both of these concerns without necessarily compromising scientific integrity. Heightened attention to the protection of privacy and recruiting from a clinical population can alleviate some concerns about stigma. Furthermore, debriefing participants after the study but before

collecting genetic samples should be mandatory. Adopting this practice affords participants appropriate autonomy and allows researchers to engage in optimal use of the genetic samples with the appropriate and ethical authorization of the participants. Requiring a debriefing of the participant before genetic samples are taken or simply not using deception to recruit participants to studies in which the collection of genetic samples is contemplated constitute ethical and regulatory compliant ways to conduct research.

In essence, while deception in recruitment can be a useful and, in some instances, is a necessary tool, its regulation must be monitored and adapted to deal with new challenges brought about by the introduction of new types of study practices. In neuroscience research, particularly regarding disorders that may involve cognitive impairment, several aspects require greater caution. Here, I have pointed to two elements of any research project that should signal the need for greater scrutiny if deception is used: 1) the underlying condition is stigmatizing, as in the case of psychosis; and 2) the intention to collect genetic samples. The use of deception in recruitment requires deliberate and thorough consideration of these aspects to ensure the ethical and responsible use of deception in clinical research.


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