

# **Author's Commentary on "Music Therapy: Research on Human Subjects with Mental Disorders"**

Commentary On

Music Therapy: Research on Human Subjects with Mental Disorders

This case raises several important dilemmas that confront clinical scientists who conduct research with individuals who have mental disorders. A dilemma can be defined as a situation in which rights or obligations of interested parties are in conflict. In this case, the interested parties include Miriana, Duncan, Duncan's advisers and others who may require the use of the data, health care workers involved in Miriana's care, and the agencies and Internal Review Boards of the hospital, university and funding source. Whichever course of action Duncan chooses, consequences will ensue for each of these parties. For this reason, Duncan must consider both participant protection and methodological factors as he seeks to resolve his dilemma.

In deciding upon an appropriate course of action, Duncan could take solace in the fact that the IRBs of the hospital, university, and granting agency have approved the research protocol, including the consent procedure. Or can he? There is a potential conflict of interest inherent in approval of research protocols by the granting agency, in that the agency has a vested interest in the success of the research project.[\(1\)](#) Furthermore, Bonnie reported that a 1966 *New England Journal of Medicine* article provided evidence of twenty-two studies, published in prestigious peer-reviewed journals, in which procedures were retrospectively assessed as unethical.[\(2\)](#) Finally, IRBs can themselves be judged in need of improvement, as occurred following an investigation of the informed consent procedure in a study at UCLA that included medication withdrawal from schizophrenia patients.[\(3\)](#) Indeed, the inspector general of the Department of Health and Human Services recently concluded that both local and national IRBs require modifications of their review procedures.[\(4\)](#) Although these conclusions may be debatable, they do suggest that individual researchers cannot rely on the mere fact of IRB approval to justify their

procedures and protocols. Thus, Duncan must reason through a response to his predicament and consider how similar situations could be avoided in the future.

## Informed Consent

Informed consent is at the core of Duncan's dilemma, and in particular, informed consent with individuals who may exhibit impaired capacity to fulfill the requirements of informed consent. Informed consent becomes a dilemma in this case because of the potential conflict between the rights and interests of the research participant and those of the individuals who have a stake in the outcome of the research. The Belmont Report described three elements of informed consent: information, comprehension, and voluntariness.[\(5\)](#) That is, informed consent minimally requires that an individual make a voluntary and informed decision to participate in a research study based on his/her accurate comprehension of the information necessary to make such a decision.

When Duncan initially reviewed the consent form with Miriana, he asked her whether she understood each component of the study, including the component that she was to complete today, and she stated that she did. This procedure is described as relatively intensive. Yet, at least one study has demonstrated that, in some cases, objective assessments of schizophrenia patients' comprehension of informed consent are discrepant with the patients' self-report of understanding.[\(6\)](#) Duncan relied on Miriana's self-assessment of comprehension (i.e., affirmative responses to closed-ended questions); it is possible that she did not understand the nature of the study or provide truly informed consent at the outset. Furthermore, her cognitive status appears to have changed between the time that she signed the form and today. Thus, even if she did provide informed consent to participate at the beginning of the study, it is unclear whether she currently has the capacity to comprehend the situation. Indeed, her behavior and words today clearly indicate that she does not understand that she is participating in a research project, and instead appears to believe that the procedure is part of her treatment. Her limited understanding is likely to impact on her ability to evaluate, recall and reason through various aspects of the procedures she previously consented to, such as the fact that she is free to withdraw from participation at any time. In short, Duncan has reason to question her current decision-making capacity.

The capacity of patients with mental disorders to engage in decision making related

to participation in research and treatment has been the subject of increased attention and debate. Current conceptualizations of decision-making capacity have evolved from operational definitions of legal competence and generally include four standards for determining whether individuals have the capacity to make autonomous decisions. These standards are: 1) the ability to express a choice, 2) the ability to understand relevant information, 3) the ability to appreciate the situation and its likely consequences, and 4) the ability to manipulate information rationally or to reason.<sup>(7)</sup> Although these standards are arranged in a hierarchy, such that the last appears to subsume the first three, recent evidence suggests that some individuals may fulfill only some of these standards in a nonhierarchical manner.<sup>(8)</sup> Thus, in applying these standards, it has been argued that "investigators must consider how much of each relevant ability subjects will be required to manifest."<sup>(9)</sup>

As noted in the case, schizophrenia is a disorder that can affect multiple areas of cognitive functioning. In one investigation of the four decision-making standards, one-fourth to one-third of patients with schizophrenia exhibited impaired understanding, reasoning, or appreciation. The investigators reported a significantly lower percentage of healthy comparison participants, patients with depression, and patients with angina who exhibited impairment in these capacities.<sup>(10)</sup> A more recent investigation of these standards in outpatients diagnosed with depression suggests that their decision-making faculties are largely within the average range.<sup>(11)</sup> Taken together, these studies suggest that patients with schizophrenia may be particularly vulnerable to impairment in decision-making abilities.

Duncan wonders whether the controversy over informed consent is relevant to his situation with Miriana, because she may not have schizophrenia. Although it may be true that much of the current controversy concerns patients with schizophrenia, and that they are at a greater risk of impairment, Miriana's diagnosis would appear to be irrelevant. In the individual case, the diagnosis in and of itself cannot indicate whether decision-making capacity is impaired. (Indeed Grisso and Appelbaum suggest that as many as 75 percent of patients with schizophrenia are unimpaired in at least one of these capacities.<sup>(12)</sup> )

Rather, the relevant question is whether the individual prospective research participant has sufficient decision-making capacity to engage in the consent process. Indeed, there has been considerable discussion regarding whether the decision-making capacity of *all* prospective research participants should be

evaluated, regardless of psychiatric status. Some commentators suggest that the capacity of all hospitalized psychotic patients, whether or not they have schizophrenia, should be evaluated, but concede that this practice might lead to an overestimation of incapacity among such patients.[\(13\)](#) Although the parameters vary to some degree, it appears that prevailing opinion contends that capacity should be evaluated in anyone for whom there is some reason to suggest that it is compromised. In this case, in which Miriana mistakenly believes that she is engaged in a treatment study, Duncan clearly has reason to think that her capacity is compromised. Therefore, it would be decidedly inappropriate to ignore her requests for music therapy and simply attempt to continue with the interview. Rather, if Duncan seeks to continue the study, he must evaluate Miriana's decision-making capacity.

However, one aspect of Duncan's problem is that he did not initially employ, and does not seem to have at his disposal, an effective means of identifying impairments in Miriana's decision-making capacity as they relate to informed consent. Duncan appears to have unwittingly contributed to the development of this dilemma by not reminding her that he was from the research project when he approached her today. At this point, Duncan could review the informed consent form with Miriana and obtain consent again, using the approved protocol. Such re-consent procedures have been suggested in cases in which experimentation occurs over an extended period of time.[\(14\)](#) As Moreno points out, such procedures "conform with the spirit of informed consent as a process rather than a single event."[\(15\)](#) However, using this protocol, in which she would simply respond to yes or no questions, could he really be assured that Miriana was providing true informed consent? Could he be certain that she comprehended the questions?

A further problem arises when one must rely on the subjective judgments of a participant's capacity by researchers who have a potential conflict of interest between the need to gather data and the need to protect their human subjects.[\(16\)](#)

Duncan illustrates this conflict when he considers pressure from his advisers to gather more data each week and worries that the data Miriana has already contributed may be unusable without the interview. As a result of this conflict, he may encounter difficulty in his attempts to make a beneficent judgment about Miriana's capacity. Objective tools for the assessment of decision-making competency, such as the MacArthur Capacity Instruments, have been developed for treatment of serious illnesses and are potentially modifiable for use in research.[\(17\)](#)

The use of such objective tools combined with predetermined criteria could minimize reliance on fallible -- and potentially biased -- researcher judgment.

In determining criteria for acceptable levels of capacity, the American Psychiatric Association guidelines state "As a general rule, the less favorable the risk/benefit ratio of participation in a research project, especially as the absolute level of risk increases, the higher the level of capacity that should be required."[\(18\)](#) The concept of risk typically refers to "the combination of the probability and magnitude of some future harm."[\(19\)](#) Duncan's study is described as involving minimal risk, and there are no immediate benefits of participation. However, minimal risk is not clearly delineated, and definitions depend on multiple factors, possibly including the characteristics of the population under investigation.[\(20\)](#) In this case, Miriana is misconstruing the study as treatment. Her misunderstanding potentially increases her risk in several ways. For example, believing that she has received music therapy, she may refuse to take her medications or to participate in other legitimate treatments. Thus, the flexible criteria including risk/benefit ratios will likely require development for use with objective assessment tools.

If Duncan were able to use such an instrument, and if he determined that Miriana evidenced a level of impairment in decision-making capacities that was not acceptable, given the risks in the study, he could discontinue with Miriana for the day, running the risk that she will be discharged, and approach her again tomorrow. If she were discharged, or if she still exhibited impairment, the data he has already collected apparently would be unusable. But, even if a research participant such as Miriana demonstrated impaired capacity when assessed objectively, should she necessarily be ineligible for participation? As Appelbaum points out, "Impairments exist on a spectrum and some degree of dysfunction is not incompatible with competent decision-making."[\(21\)](#) Furthermore, he states, "merely identifying individuals as having decisional impairments does not mean that they are incompetent to consent to research. . . . They are at a high risk of lacking competence, but that risk may be mitigated by such additional efforts as offering education, providing congenial settings, and enlisting support from family and friends."[\(22\)](#) Could Duncan re-educate Miriana about the study and then accurately determine the extent to which her decision-making capacities are compromised following the re-education?

Such questions frequently have been explored from the armchair; more recently, several investigators have begun to address these issues as empirical questions. In

one investigation, Wirshing et al. designed a consent procedure that involved an explanation of the study protocol, brief survey, re-explanation of information pertaining to missed items, and a re-testing. In their sample, schizophrenia patients obtained a median score of 80 percent on the first testing; 37 percent of the remaining individuals required three or more trials to answer all items correctly.[\(23\)](#)

Stephenson reports on investigations conducted at the Maryland Psychiatric Research Center. This work, which involved a similar education component, included a longitudinal follow-up. When re-tested one and three months later, many participants performed well on a test that posed questions about vital study details such as how to withdraw as a participant.[\(24\)](#) Other researchers have suggested creative approaches to enhance participants' decision-making capacities.[\(25\)](#)

Despite such promising results, there are potential drawbacks to the use of assessment tools to evaluate capacity. Results may be influenced by other factors including performance anxiety, psychometric properties of the instrument, and current context.[\(26\)](#) Continued development and refinement of such instruments is clearly warranted and would assist researchers in determining whether educational efforts have been beneficial. In this case, Duncan appears to consider the pressure he has been experiencing from his advisers while pondering his course of action. Stephenson suggests that principal investigators could suggest to research staff that they can expect to exclude a certain number of prospective participants who will not have the capacity to consent.[\(27\)](#) In this way, the assistants like Duncan may experience less stress over the potential "loss" of a participant.

If educational efforts and objective testing are not successful in eliciting a satisfactory level of decision-making capacity, then state laws may allow an alternative individual to consent for the patient. The American Psychological Association's guidelines stipulate, "For persons who are legally incapable of giving informed consent, psychologists nevertheless 1) provide an appropriate explanation, 2) obtain the participant's assent, and 3) obtain appropriate permission from a legally authorized person, if such substitute is permitted by law."[\(28\)](#) In this case, Duncan noticed that Miriana did not have a legally authorized representative. She may lack a representative because she has fallen through the bureaucratic cracks or because representatives are not designated in her home state, or she may generally be able to engage in decision making appropriately. The fact that she has a chronic mental illness does not necessarily mean that she cannot function autonomously. Carpenter and others warned against stigmatization of individuals

who receive psychiatric diagnoses, which can come about by implying that individuals with mental disorders are necessarily impaired in their decision-making abilities (rather than simply at risk for impairment). He recommends, "Include significant others as the patient considers participation, but do not compromise the patient's autonomy and dignity rights if decision-making capacity is adequate."[\(29\)](#) Development of more refined psychometric assessments of capacity may assist in maintaining an appropriate balance between autonomy and paternalism.[\(30\)](#)

Keeping in mind these issues, including the facts that Duncan does not appear to have a readily available means of assessing Miriana's current decision-making capacity and that she does not have a legally authorized representative, there may be no way in which Duncan can "set things straight with Miriana" and continue with the interview. Instead, the most appropriate course of action is likely to be to terminate Miriana's participation, despite the risk of being unable to use her data. The loss of one patient's data is a small price to pay if it spurs Duncan and his advisers to design an approach to address these important issues that would better accommodate the conflicting demands of protection of participants and research outcome.

## Confidentiality

A second major issue raised by the case concerns the confidentiality of diagnoses obtained during the course of the patient's participation. While Duncan does not specifically face this dilemma in his interactions with Miriana, it is an important point that is worthy of consideration by researchers who investigate mental disorders,[\(31\)](#) and it is an issue that does not appear to be directly addressed in the literature or ethical guidelines. Where confidentiality issues are addressed, it is typically in the contexts of 1) limitations on confidentiality in the case in which the patient discloses an intent to harm oneself or others, or in which information pertaining to abuse of a vulnerable individual is divulged, or 2) maintenance of confidentiality when data bases or participant information are to be shared with other scientists.[\(32\)](#)

In this case, the primary question is whether researchers should promise confidentiality as it pertains to diagnosis when that diagnosis might conflict with that of the hospital. The interested parties are the same as those involved with informed consent, but the interests of hospital staff may be more directly involved



in this context. Here, confidentiality and methodological rigor may be on the "same side" of the dilemma, and may conflict with beneficence regarding the patient's care. That is, research participants typically are promised that their results and the information they provide will be confidential, but that could not be promised if there were an agreement that the diagnosis would be shared.

From a methodological standpoint, it could be argued that it is to the researchers' advantage to ensure confidentiality, because it increases the chances that the information given by the patient will be accurate. Some patients may attempt to downplay or deny their symptoms to the hospital staff if they feel that full disclosure will prolong their stay in the hospital or lead them to be transferred to a state hospital. If confidentiality were not ensured, patients may not be motivated to be as truthful, which may compromise the diagnosis and results of the research. Indeed, Nowell and Spruill conducted an investigation of the reporting of symptoms by college students as a function of the level of confidentiality assured; they reported that participants who were promised complete confidentiality were more willing to disclose information about certain kinds of symptoms depending on their nature and severity.[\(33\)](#) Typically, researchers are able to tell all patients that the information is not provided to the hospital; thus, patients who are concerned about confidentiality will have little reason to hide or deny their symptoms.

Inaccurate information can compromise data in other ways. For example, the patients may be asked to be completely truthful about the last time they used drugs and cigarettes. These substances can affect performance on many tasks and it is vital to interpretation of some forms of data that these variables are known. Thus, the integrity of the information, and therefore the accuracy of results, could be compromised in some cases if complete confidentiality is not ensured. In addition, many patients with schizophrenia exhibit suspicion, and some of these patients have adversarial relationships with their health care teams. Sometimes, patients may choose to participate only because they know that the study is not formally affiliated with the system of which they are so wary. These patients are sometimes the most seriously ill and the most difficult to recruit, but it can be very important to obtain their data. Without assurance of independence from the hospital, it might be difficult to obtain their participation.

The research team is not obligated to inform the hospital staff of a new diagnosis or other information relevant to the patient's status (e.g., use of drugs and alcohol). Yet, through their rigorous procedure, the research staff may obtain a more reliable



and accurate diagnosis that, if shared, could benefit patients like Miriana.[\(34\)](#) A more accurate diagnosis, and more complete information about other aspects of patients' behavior obtained during the course of the research, could potentially affect the quality of care that patients receive. Thus, it may be important for hospital staff to have access to the information in order to treat the patient most appropriately, and it may not be in the patient's best interest for the information to be kept confidential.

However, in addition to researchers' potential concerns regarding integrity of information, there could be other ramifications if research diagnoses were disclosed to the hospital staff. The first issue relates to the importance of safeguarding the voluntariness of the patient's consent. Consent forms include the statement that the relationship with the hospital will not be affected by the patient's participation in the research; this provision is intended in part to minimize the possibility that a patient will feel pressured to participate. The Belmont Report states, "Unjustifiable pressures usually occur when persons in positions of authority or commanding influence -- especially where possible sanctions are involved -- urge a course of action for a subject."[\(35\)](#) If the hospital staff routinely received better diagnostic information from study, it could lead medical staff to pressure patients to participate in the study, or at least to strongly support their participation (and indeed to rely on the research team to make the diagnosis). This strategy could be construed as coercion, as the doctors/nurses have a significant impact on patients' lives (e.g., in terms of their being discharged to their own homes, which many patients prefer, vs. being discharged to a group home or a state hospital, and so on). Even if the hospital staff did not directly pressure them, some patients might feel compelled to participate because they may be more likely to confuse the study with their treatment or other required hospital activities, or because they might believe that their participation will earn "brownie points" with the hospital staff. Thus the patients' right to voluntary consent could be compromised.[\(36\)](#)

One way of addressing this concern would be to allow participants or their legally authorized representatives to determine whether the research diagnosis is shared with the staff. However, this alternative too would raise important questions. Would patients choose to share the diagnosis with the staff only if they "liked" the research team's diagnosis? If they didn't "like" it and didn't want it shared, what responsibilities would the research team have? If patients had to decide at the beginning of the study whether the research team's diagnosis would be shared

regardless of the outcome, might some of those electing to share the diagnosis purposefully manipulate the information given to the research team?

Further questions are raised by uncertainty about the way in which discrepant diagnoses would be handled by hospital staff. Not all practitioners would agree that the diagnosis achieved through use of a semi-structured interview leads to a more valid diagnosis. In addition, a prevailing hierarchy in many hospitals ranks psychiatrists higher than psychologists in certain areas of expertise, and psychiatrists frequently have administrative superiority over psychologists. Thus, it is possible that the psychiatric staff would choose not to accept the diagnoses provided by a psychologist-staffed research team. How far would the research team be obligated to go if a psychiatrist insisted on one diagnosis and the research team another? In this situation, what responsibilities would the researchers have to the patients? Would the researchers be required to inform patients or their legally authorized representatives about the discrepant diagnosis? How could patients or representatives ensure that the research diagnosis was taken into consideration? Could this practice lead to legal ramifications for the hospital? What if the hospital diagnosed and treated a patient for bipolar illness, but the research diagnosis was schizophrenia? The patient or family could see legitimate grounds for a suit against the hospital for misdiagnosis and treatment. To avoid this problem, would the hospital pressure the research team to reconsider the diagnosis in discrepant cases? How would that affect patient care, the ability to conduct research, and the results of the investigation? Would some level of irreconcilable differences affect hospitals' willingness to allow research? How might that affect the progress of knowledge about the etiology and treatment of disorders like schizophrenia?

In order to weigh the costs and benefits of compromising voluntariness by disclosing diagnoses and contending with the ensuing issues, it is important to consider the likelihood of benefits to the patients from sharing diagnoses with the hospital staff. An important point is that psychiatric treatment is not currently so specific that well-supported and distinct treatments exist for specific psychotic disorders. For example, most treatment of patients with psychotic disorders includes antipsychotic medications regardless of the specific disorder. Thus, in studies that include patients with different types of psychotic disorders, such as Duncan's, all participants may already be receiving similar treatments and the actual diagnosis may be irrelevant. Although this fact perhaps begs the major question, and will likely change as treatments become more refined, it raises

questions about the extent to which psychiatric patients would actually benefit from disclosure of their diagnoses.

Just as researchers have begun to empirically address issues surrounding consent, the issues surrounding confidentiality of diagnoses could be framed as empirical questions. To determine the scope of the problem, studies could be designed that would quantify the frequency with which hospital and research diagnoses are discrepant. These investigations could include whether the prescribed medications varied as a function of the patient's diagnosis, to address the relevance of conflicting diagnoses. By posing hypothetical cases to hospital staff, investigators could examine the ways in which staff members are likely to handle discrepant information. Such empirical studies are likely to contribute to a better understanding of the extent of the problem and potentially lead to modifications in confidentiality agreements where they are warranted. As Bonnie states, "Current controversies regarding research with cognitively impaired subjects should be seen, in historical context, as a reminder of unfinished business."[\(37\)](#)

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- (20) Ibid., Chapter 4.
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