National Institute of Mental Health

# Human Subjects Research Protections Toolkit


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- Monitoring Examples
- Assessment Practice Exercises
- Monitoring Practice Exercises

NIH National Institute of Mental Health

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# Introduction

A human research protection program (HRPP), in part, aims to protect human research subjects. The National Institute of Mental Health (NIMH) protects potentially vulnerable **SUBJECTS** with **ADVOCATES** who support the individual subject as well as educate and advise **RESEARCHERS**.

This NIMH Toolkit for Human Subjects Research Protections is based on the NIMH's experience conducting research with potentially vulnerable subjects. Our aim is to help research organizations assess, implement, and refine appropriate levels of human subjects protections during all phases of research (submission of the initial protocol to the Institutional Review Board [IRB] through subject transition out of the protocol). Research organizations need to tailor these practices to suit their own standards and legal and policy requirements.

**SUBJECTS**
**ADVOCATES**
**RESEARCHERS**

**Section 3: Training Tools** provides examples and practice exercises to develop advocate skills in specific consent processes. Assessment and monitoring outcomes are nuanced and complex. Outcomes presented in this section are possible conclusions based on a particular interpretation of the facts presented. It is possible to come to a different conclusion based on a different interpretation of the facts and application of organizational policy.

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***Disclaimer:*** *This NIMH Toolkit does not incorporate state or local law or organizational policies, nor does it address possible applicable federal law or speak to regulatory interpretation of 45 C.F.R. § 46. It does not address specifics for a particular type of protocol or IRB requirements. This Toolkit is the opinion of the NIMH intramural program and is subject to change.*

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# Capacity Assessment



**A 21-year-old female** diagnosed with recent onset schizophrenia plans to enroll in an inpatient double-blind, placebo-controlled protocol. The Institutional Review Board (IRB) determined that the protocol

- Is more than minimal risk
- Has no prospect of direct benefit
- Requires an advocate to administer a capacity assessment to all potential subjects before participation

The potential subject has not received any treatment in the community and, by participating in this protocol, will not receive standard treatment until her participation in the protocol is complete.

During the capacity assessment held prior to the consent process, the potential subject clearly is not aware of alternative treatments available to her in the community. The advocate discusses the difference between research and clinical care with the potential subject. The potential subject continues to have difficulty appreciating the difference between the two.

**Points to consider**

- The potential subject does not understand that alternative standard treatments are available in the community.
- The potential subject does not understand the difference between research and clinical care.
- This scenario does not incorporate applicable organizational policy.

**Possible outcome**

The potential subject is determined not to have consent capacity for this protocol at this time. The advocate discusses the result with the potential subject and the researcher. The researcher recommends pursuing treatment in the community. The advocate documents the outcome according to organizational policy.

# Ability to Assign a Surrogate Decision-Maker Assessment

Training Tools

Examples



**A 39-year-old male** with frontal lobe epilepsy is invited to participate in a protocol. The IRB determined that the protocol

- Is more than minimal risk
- Has a prospect of direct benefit
- Allows surrogate decision-maker consent

The advocate determined the potential subject does not have consent capacity at this time.

The potential subject is accompanied by his mother. His mother is not his legal guardian, and he does not have an advance directive (AD). The advocate recommends and administers an assessment of the potential subject's ability to assign a surrogate decision-maker for research.

**Points to consider**

- A potential subject without consent capacity may be able to assign a surrogate decision-maker.
- The protocol allows designation of a surrogate decision-maker.
- There is a difference between a legal guardian and an agent named in an AD.
- This scenario does not incorporate applicable organizational policy.

**Possible outcome**

The potential subject is determined able to assign a surrogate decision-maker. He selects his mother. The advocate helps him complete an AD form for research. The advocate assesses the appropriateness of the surrogate decision-maker. The advocate documents the outcome according to organizational policy.

# Surrogate Decision-Maker Assessment



**A 79-year-old female** with symptoms of dementia plans to enroll in a 2-year protocol requiring multiple visits. The IRB determined the protocol

- Is minimal risk
- Has no prospect of direct benefit
- Allows for surrogate decision-maker consent with subject assent
- Requires an advocate to administer a capacity assessment at each visit

Using a protocol-specific capacity assessment, the advocate determines the potential subject does not have consent capacity at this visit. The potential subject has a pre-existing durable power of attorney (DPA) for healthcare identifying her husband as her surrogate decision-maker. Legal counsel reviews the document and determines the surrogate decision-maker can authorize consent for research participation.

Before obtaining consent, the advocate assesses the appropriateness of the surrogate decision-maker. The husband states, "This study is important. I want her to get better." The advocate clarifies that participating in this protocol will not cure or treat the potential subject's dementia. The husband confirms his understanding and says, "I know these scans will not help her directly, but I think it will help science. She has told me before that she wants to help others in the future, even if there is no cure for her."

**Points to consider**

- The protocol allows surrogate decision-maker consent with subject assent.
- The surrogate decision-maker may not understand "no prospect of direct benefit."
- The surrogate decision-maker is able to express the potential subject's wishes as opposed to his own.
- This scenario does not incorporate applicable organizational policy.

**Possible outcome**

The advocate determines that the husband has sufficient understanding to provide surrogate consent and can appropriately represent the subject's wishes concerning research participation. The advocate documents the outcome according to organizational policy.

# Consent Monitoring



**A 41-year-old female** with depression plans to enroll in an inpatient mood disorder protocol. The IRB determined the protocol

- Is more than minimal risk
- Has a prospect of direct benefit
- Requires consent monitoring by an advocate

The researcher obtaining consent asks the potential subject, with the trainees present, if they may observe the consent process. She agrees, but the advocate observes that the potential subject's tone of voice, demeanor, and body language indicate discomfort. The advocate pauses the consent process and speaks individually with the potential subject to confirm whether these observations are accurate. The advocate emphasizes that, if the potential subject is not comfortable with additional people attending the consent process, the observers do not have to be present. The potential subject states, "I would prefer fewer people in the room." The advocate conveys the potential subject's preference to the researcher.

**Points to consider**

- Determine the number of people necessary for the consent process.
- Be sensitive, reasonable, and flexible about additional observers.
- Obtain the potential subject's permission and honor refusal.
- Avoid asking the potential subject's permission with observers present. It may place undue pressure on the potential subject's decision.
- This scenario does not incorporate applicable organizational policy.

**Possible outcome**

Per the potential subject's request, the researcher communicates to the trainees that they will not observe this consent process.

# Assent Monitoring



## Pediatric Assent

**A 12-year-old female** plans to enroll in an inpatient pediatric mental health protocol. The IRB determined the protocol

- Is a minor increment over minimal risk
- Has no prospect of direct benefit
- Requires consent and assent monitoring by an advocate

The researcher conducts the consent and assent process with the potential subject and her parents with the advocate present. The researcher discusses each element of the consent with the potential subject and answers her questions. The potential subject verbally demonstrates throughout the process that she is thoroughly informed regarding her condition, the protocol procedures, and possible risks. The potential subject is enthusiastic that she may help others by participating in the protocol. She is aware she can change her mind about participation.

**Points to consider**

- Engage the potential subject in conversation rather than read the consent form.
- Clarify protocol terms and concepts as needed.
- Address the potential subject's questions and concerns.
- Understand the potential subject's motivation for participation.
- This scenario does not incorporate applicable organizational or local policies.

**Possible outcome**

The potential subject gives her assent and her parents provide consent. The advocate documents the outcome according to local organizational policies.

## Pediatric Dissent

**An 11-year-old male** comes with his parents to enroll in an outpatient protocol. The IRB determined that the protocol

- Is minimal risk
- Has no prospect of direct benefit
- Requires subject assent
- Requires consent and assent monitoring by an advocate

During the consent and assent process, the researcher describes the voluntary nature of research and explains that all procedures are for research purposes and not for clinical care. The parents are eager for their son to participate in this protocol. However, the potential subject begins shaking his head when reviewing the protocol procedures. He states, "I've told my parents over and over that I'm not interested in written tests, and I'm afraid of small spaces and do not want to do the MRI."

The advocate pauses the process. The researcher discusses the potential subject's concerns to determine if they can be mitigated. The advocate speaks with the parents about assent and respecting dissent.

**Points to consider**

- The potential subject's assent is required for enrollment in protocol.
- Dissent is respected.
- This scenario does not incorporate applicable organizational policy.

**Possible outcome**

The potential subject is consistent in stating he does not want to participate. This protocol will not benefit him and provides no clinical care. He does not enroll at this time but has the option to enroll at a later date should he change his mind. The advocate documents the outcome according to organizational policy.

# Assent Monitoring

Training Tools

Examples



## Adult Assent

**A 50-year-old female** with a traumatic brain injury is eligible to enroll in an outpatient brain imaging protocol. The IRB determined that the protocol

- Is more than minimal risk
- Has a prospect of direct benefit
- Requires a capacity assessment
- Allows surrogate decision-maker consent with subject assent as appropriate
- Requires consent and assent monitoring by an advocate

The potential subject is assessed and determined to have consent capacity at the first visit. The researcher conducts the consent process, and the subject provides her own consent.

One month later, the subject returns to participate in another protocol with the same IRB requirements. She is assessed and is determined not to have consent capacity but able to assign a surrogate decision-maker. The subject chooses her spouse, who is assessed to be an appropriate surrogate decision-maker. The surrogate decision-maker provides consent, and the subject provides assent. The advocate monitoring the assent process observes that the subject is engaged in the conversation, asks questions, and states her intention to participate in the protocol.

**Points to consider**

- The protocol requires potential subject assent as appropriate.
- The subject's choice to participate does not change even if her consent capacity fluctuates.
- This scenario does not incorporate applicable organizational policy.

**Possible outcome**

Over a one-month period, the subject's decision-making capacity to give consent fluctuates, but the advocate observes the potential subject's expressed choice to participate in research generally and the protocol specifically does not. The advocate documents the outcome according to organizational policy.

# Assent Monitoring

Training Tools

Examples



## Adult Dissent

**A 21-year-old male** with Fragile X syndrome is eligible to enroll in an outpatient brain imaging protocol. The IRB determined that the protocol

- Is minimal risk
- Has no prospect of direct benefit
- Requires an advocate to administer a capacity assessment to all potential subjects
- Allows surrogate decision-maker consent with subject assent

The potential subject's mother is his legal guardian. Legal counsel confirms the guardianship order allows the mother to provide consent for this research. A capacity assessment by the advocate is not required since the court has already determined the potential subject cannot provide his own consent. The potential subject's mother understands the parameters of the protocol and provides consent. The potential subject indicates his willingness to participate in the protocol and gives assent.

Technical difficulties occur during a procedure, and the procedure is stopped before gathering usable data. The IRB approves the repetition of the procedure but requires re-consent and assent.

During the re-consent process, the advocate notes a change in the subject's non-verbal behavior (e.g., lack of eye contact, grimacing, folding his arms over his body). The advocate consults with the mother who states his behavior indicates he does not wish to undergo a second attempt at the procedure.

**Points to consider**

- Guardianship papers should be reviewed (e.g., by legal counsel).
- Use the surrogate decision-maker's familiarity with the potential subject's behavior as a resource.
- Both verbal and behavioral dissent are respected.
- This scenario does not incorporate applicable organizational policy.

**Possible outcome**

The subject's dissent is respected, and the repeat procedure does not occur. The advocate documents the outcome according to organizational policy.

# Subject Monitoring



**A 32-year-old female** enrolls in an inpatient schizophrenia protocol. The IRB determined that the protocol

- Is more than minimal risk
- Has no prospect of direct benefit
- Requires subject monitoring by an advocate

During their weekly meeting, the subject shares with the advocate her increasing doubts about continuing in the protocol. Specifically, being off medications is harder than she expected, but she feels guilty about disappointing the researcher.

**Points to consider**

- Informed consent is an ongoing process, not a one-time signing of a document.
- The subject's circumstances, symptoms, and willingness to continue participation in the protocol may fluctuate over time.
- This scenario does not incorporate applicable organizational policy.

**Possible outcome**

With the advocate's support, the subject conveys her concerns to the researcher and withdraws from the protocol. The researcher meets with the subject and designs an appropriate discharge plan. The advocate documents the outcome according to organizational policy.

# Subject Monitoring

Training Tools

Examples



**A 14-year-old male** diagnosed with childhood onset schizophrenia enrolls in an inpatient pediatric protocol. The IRB determined that the protocol

- Is greater than minimal risk
- Has a prospect of direct benefit
- Requires subject assent

The subject begins to refuse protocol-related tasks. The researcher, unit staff, and the advocate meet with him over several days to discuss his willingness to remain in the protocol. The subject continues to state he wants to participate. However, despite this statement, he routinely declines protocol tasks.

After several discussions with his advocate, the subject admits he no longer wants to be in the protocol and is concerned his parents will be upset with him. The subject communicates clearly and consistently his wish to withdraw from the protocol. He and his advocate meet with the researcher who assures him his reasons for wanting to stop are valid and will be discussed with his parents.

**Points to consider**

- Subject dissent is consistent.
- Both verbal and behavioral dissent are considered.
- Tasks refused by the subject are protocol-related, not clinical.
- Alternative treatments are available in the community.
- This scenario does not incorporate applicable organizational policy.

**Possible outcome**

The researcher meets with the parents to discuss the subject's withdrawal of assent, and the subject ends his research participation. The advocate documents the outcome according to organizational policy.

# Capacity Assessment

Training Tools

Practice Exercises



**A 26-year-old female** with a diagnosis of schizophrenia is invited to participate in a protocol. The IRB determined that the protocol

- Is more than minimal risk
- Has no prospect of direct benefit
- Requires an advocate to administer a capacity assessment to all potential subjects

The advocate administers a protocol-specific capacity assessment and determines the potential subject has a clear understanding of the purpose and procedures involved in the protocol. The potential subject states that her most significant risk is a worsening of symptoms associated with the tapering of her anti-psychotic medications.

Toward the end of the assessment, the advocate asks the potential subject about her choice to participate in the protocol. She states, "I don't really want to be in the study, but my husband says I have to. He is getting ready to travel for work and will be gone a long time. He doesn't want me to be home alone."

***What is your determination of the potential subject's capacity to provide informed consent?***

**Write the points you will consider:**

**Write your outcome:**

Prompts and possible outcome on next page

# Capacity Assessment



## PROMPTS

- How can the advocate help the potential subject identify her choices and preferences regarding protocol participation?
- What are the alternatives to protocol participation?
- In what ways can the advocate help the potential subject identify and discuss her right to autonomy versus her husband's suggestion about protocol participation?
- Should the advocate speak with the spouse?
- What organizational policies may apply?

## POSSIBLE OUTCOME

The potential subject has capacity to provide informed consent. She understands the purpose, procedures, and risks of the protocol. The potential subject chooses not to participate in the protocol at this time but is open to participation in future protocols. After a discussion with the advocate and the researchers, the husband arranges for her clinical care in the community. The advocate documents the outcome according to organizational policy.

# Ability to Assign a Surrogate Decision-Maker Assessment

Training Tools

Practice Exercises



**A 21-year-old female** with Down syndrome plans to enroll in a protocol. The IRB determined that the protocol

- Is minimal risk
- Has no prospect of direct benefit
- Allows surrogate decision-maker consent with subject assent

The researcher determines the potential subject has cognitive limitations and is unable to provide her own consent for research at this time. The researcher contacts the advocate to assess the potential subject's ability to assign a surrogate decision-maker.

The advocate explains the purpose of the assessment to the potential subject. The potential subject shares that her father usually takes her to her medical appointments in the community. She states, "Sometimes I get shy about speaking up, and sometimes I am confused by what the doctor is saying. My father understands and knows what I like and don't like to do." She further states she trusts him to speak for her and help her make decisions. She says she does volunteer work in the community and likes helping others.

***Does the potential subject have the ability to assign a surrogate decision-maker?***

**Write the points you will consider:**

**Write your outcome:**

Prompts and possible outcome on next page

# Ability to Assign a Surrogate Decision-Maker Assessment



## PROMPTS

- Whom does the potential subject trust to speak on her behalf about medical care and preferences?
- Has the potential subject discussed medical care issues with this person?
- How would the potential subject inform researchers if she does not agree to procedures or tests?
- What organizational policies may apply?

## POSSIBLE OUTCOME

The advocate determines the potential subject has the ability to assign a surrogate decision-maker. Her father already serves as her surrogate decision-maker for medical care in the community, and she relies on him to communicate for her. While she may not fully understand the protocol, she values helping others. The advocate documents the outcome according to organizational policy.

# Surrogate Decision-Maker Assessment

Training Tools

Practice Exercises



**A 70-year-old female** with Alzheimer's disease enrolls in an outpatient protocol. The IRB determined that the protocol

- Is minimal risk
- Has no prospect of direct benefit
- Allows surrogate decision-maker consent with subject assent
- Requires a surrogate decision-maker assessment by an advocate

The potential subject was determined not to have consent capacity at this time. The potential subject previously named her spouse as the agent of her AD.

The potential subject's husband accompanies her to the visit and is authorized to provide consent. The advocate assesses the appropriateness of the surrogate. During the assessment, the husband confirms he and his wife have discussed research participation prior to her dementia worsening. "My wife's motivation for participating is the knowledge that Alzheimer's disease runs in her family. She is concerned for our children and grandchildren and wants to contribute to finding a future treatment or cure."

The husband understands the protocol procedures and potential risks and confirms he knows the protocol will not directly benefit his wife. He states that, although he gives consent, he feels comfortable stopping her participation if she no longer wants to continue. He explains she will communicate her dissent by scowling, shaking her head, or leaving the room if she does not want to do something.

***Is the husband an appropriate surrogate decision-maker?***

**Write the points you will consider:**

**Write your outcome:**

Prompts and possible outcome on next page

# Surrogate Decision-Maker Assessment



## PROMPTS

- Does the protocol allow for surrogate decision-maker consent?
- Has an appropriate surrogate decision-maker been identified?
- Is the potential surrogate decision-maker willing to serve in this capacity?
- What conversations have the potential surrogate decision-maker and the potential subject had about research participation? Did they discuss non-beneficial research?
- During the protocol, how will the surrogate decision-maker know if the subject withdraws assent?
- What organizational policies may apply?

## POSSIBLE OUTCOME

The advocate determines the husband is an appropriate surrogate decision-maker. The researcher may now invoke the AD and obtain consent from the husband and assent from the wife. The advocate documents the outcome according to organizational policy.

# Consent Monitoring

Training Tools

Practice Exercises





**A 35-year-old male** plans to enroll in an inpatient bone marrow transplant protocol. The IRB determined that the protocol

- Is more than minimal risk
- Has a prospect of direct benefit
- Requires identification of a surrogate decision-maker in case the subject's capacity fluctuates
- Requires consent monitoring by an advocate

Prior to the consent process, the potential subject identified his wife as his surrogate decision-maker. His wife requests that the researcher conduct the discussion with her alone. She is aware of the procedures and risks and feels anxious about the treatment protocol. In addition, she wants her husband to remain optimistic and fears the possibility of needing a surrogate decision-maker will have a negative impact. She insists, "Please don't talk to him about these complications. This will get into his head, and he will feel worse. I can sign the informed consent for him. I want him to have the right mind set and be optimistic about the treatment."

***What do you tell the potential subject's wife?***

**Write the points you will consider:**

**Write your outcome:**

Prompts and possible outcome on next page

# Consent Monitoring



## PROMPTS

- Is it allowable for the potential subject's wife to provide research consent? Why or why not?
- What is the role of self-determination and autonomy in research participation?
- How can the advocate help educate the wife about the consent process?
- What organizational policies may apply?

## POSSIBLE OUTCOME

Potential subjects provide their own consent unless unable to do so.* The advocate provides education about the voluntary nature of research and reassures the wife the discussion will be more helpful than harmful to her husband. The wife understands and is willing to include her husband in the consent process. The researcher discusses all the consent elements with both the potential subject and his wife. The advocate documents the outcome according to organizational policy.

*National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, Bethesda, MD: U.S. Govt. Print. Off., 1978, Part B: Basic Ethical Principles, Section 1, Respect for Persons.

# Assent Monitoring

Training Tools

Practice Exercises





**A 32-year-old male** with an intellectual disability whose parents are his legal guardians is eligible to participate in a protocol. The IRB determined that the protocol

- Is minimal risk
- Has no prospect of direct benefit
- Allows surrogate decision-maker consent with subject assent
- Requires consent and assent monitoring by an advocate

Legal counsel determined the guardianship order authorizes the parents to consent for this research, and the advocate found the parents to be appropriate surrogate decision-makers.

As part of the consent and assent process, the researcher describes protocol procedures which include an IV, an MRI, and computer tasks. The potential subject states, "I'm afraid the MRI will hurt. No, I don't want to do this." The researcher talks with the potential subject about the potential subject's concerns. He further clarifies that this procedure is for research and not for clinical care. The parents would like their son to participate. However, the potential subject continues to say, "No."

***Can the potential subject dissent independently?***

**Write the points you will consider:**

**Write your outcome:**

Prompts and possible outcome on next page

# Assent Monitoring



## PROMPTS

- Is assent by the potential subject required when the legal guardians are providing consent?
- Is the MRI for research or clinical care?
- Is the MRI required for protocol participation?
- What organizational policies may apply?

## POSSIBLE OUTCOME

If the MRI is not required, the potential subject could assent to the other procedures. If the MRI is required, even though his legal guardians could provide consent, dissent by the subject is respected and research does not proceed. The advocate documents the outcome according to organizational policy.

# Assent Monitoring

Training Tools

Practice Exercises



**A 75-year-old female** diagnosed with moderate dementia is eligible to enroll in a protocol. The IRB determined that the protocol

- Is more than minimal risk
- Has a prospect of direct benefit
- Requires an advocate to administer a protocol-specific capacity assessment
- Allows surrogate decision-maker consent with subject assent

The potential subject previously executed an AD which included research and designated her husband as her surrogate decision-maker. Over the years, they have discussed her desire to contribute to science for the benefit of others who may suffer with a similar diagnosis.

The advocate determined that the subject is unable to provide her own consent at this time and that her husband is an appropriate surrogate decision-maker.

During the assent discussion, the potential subject tells the advocate and the researcher that she does not want to participate in the brain scan for fear it would make her symptoms worse, but if her husband thinks it's a good idea, then she will do the scan.

***Is the potential subject providing assent?***

**Write the points you will consider:**

**Write your outcome:**

Prompts and possible outcome on next page

# Assent Monitoring



## PROMPTS

- What is the impact of the couple's earlier conversation about research participation?
- Is it possible to address the potential subject's concern?
- Should the surrogate decision-maker's wishes override the potential subject's concern?
- What organizational policies may apply?

## POSSIBLE OUTCOME

The researcher explains to the potential subject that the brain scan will not make her symptoms worse. The subject could respond in two ways:

- She states she now understands the scan will not hurt her. Earlier conversations with her husband confirm her willingness to participate in this protocol. The potential subject is providing assent at this time.
- She becomes agitated, insisting the scan will hurt her. Due to the nature of her illness, she gets frustrated and confused when feeling frightened. The potential subject is not providing assent at this time.

The advocate documents the outcome according to organizational policy.

# Assent Monitoring

Training Tools

Practice Exercises



**An 8-year-old male** comes with his parents for enrollment in an inpatient protocol. The IRB determined that the protocol

- Is greater than minimal risk
- Has a prospect of direct benefit
- Requires consent and assent monitoring by an advocate

During the consent process, the potential subject states he is worried about the blood draw. The researcher explains that the nurse will numb the skin first so that it will feel more like a pinch. The potential subject states, "OK." He asks questions about what it will be like on the inpatient unit. He then excitedly states, "My parents said I'll be helping kids like me by being here."

## *Is the potential subject giving assent?*

**Write the points you will consider:**

**Write your outcome:**

Prompts and possible outcome on next page

# Assent Monitoring



## PROMPTS

- Is the potential subject engaged in the conversation?
- Does he have concerns? If so, were they addressed?
- Have he and his parents discussed what it means to be in research?
- What organizational policies may apply?

## POSSIBLE OUTCOME

The potential subject is giving assent. His concern about the blood draw is addressed, and he expresses a desire to help others with a similar condition. The advocate documents the outcome according to organizational policy.

# Assent Monitoring

Training Tools

Practice Exercises



**A 16-year-old female** with depression is referred by her therapist to enroll in an outpatient protocol. The IRB determined that the protocol

- Is minimal risk
- Has no prospect of direct benefit
- Requires consent and assent monitoring by an advocate

During the consent conversation with her mother present, the potential subject crosses her arms, says nothing, looks down, and turns her back to the rest of the people in the room. After the researcher reviews all the consent elements, the advocate asks the potential subject if she wants to participate in the protocol. She replies, "No! But my parents won't let me go to a concert this weekend unless I do this."

## *Is the potential subject giving assent?*

**Write the points you will consider:**

**Write your outcome:**

Prompts and possible outcome on next page

# Assent Monitoring



## PROMPTS

- What is the potential subject conveying verbally and non-verbally?
- Is there alternative treatment available in the community?
- Can the parents insist the potential subject participate?
- What organizational policies may apply?

## POSSIBLE OUTCOME

The potential subject's dissent should be respected. Despite the parents' good intentions, making concert attendance contingent on research participation is coercive. The protocol does not provide a prospect of direct benefit, and the potential subject can continue her treatment in the community. The advocate documents the outcome according to organizational policy.

# Subject Monitoring

Training Tools

Practice Exercises



**A 42-year-old male** is enrolled in an inpatient double-blind, placebo-controlled schizophrenia protocol. The IRB determined that the protocol

- Is more than minimal risk
- Has no prospect of direct benefit
- Requires subject monitoring by an advocate

The subject confides to the advocate that he has had only three hours of sleep for the past three nights. He appears distracted and extremely tense. He shares that he is experiencing increased anxiety and is terrified that "something bad is going to happen." He admits that his auditory hallucinations have increased but is reluctant to divulge their content.

When the advocate asks him if he wants to continue in the protocol, he responds, "I don't want to let the research team down." He further requests the advocate withhold this information from the researchers.

***Has the subject confirmed his consent?***

**Write the points you will consider:**

**Write your outcome:**

Prompts and possible outcome on next page

# Subject Monitoring



## PROMPTS

- What concerns might the advocate have following this interaction?
- Should the advocate honor the subject's request not to share this information with the researcher?
- What organizational policies may apply?

## POSSIBLE OUTCOME

The subject's increasing symptoms may impact his ability to provide ongoing informed consent. In addition, delaying treatment of symptoms by the possibility of being on placebo may not be in his best interest. The advocate addresses the subject's concerns and reminds him that information relevant to his safety cannot be withheld from the researcher. The advocate facilitates a discussion with the researcher about the subject's continued participation. The advocate documents the outcome according to organizational policy.

# Subject Monitoring

Training Tools

Practice Exercises





**A 12-year-old male** is enrolled in a two-month inpatient mood dysregulation protocol. The protocol includes a tapering of the subject's current medications, a double-blind medication trial, and research tasks such as brain imaging and cognitive testing. The IRB determined that the protocol

- Is a minor increment over minimal risk
- Has a prospect of direct benefit

The subject attends an in-hospital school, enthusiastically participates in recreational therapy activities, and completes protocol tasks without complaint. One month into the protocol, the subject abruptly announces to one of the nurses that he no longer wants to participate in the protocol. He states, "I know I can change my mind about being here, and I want to leave!"

The teacher discloses that the subject had difficulty with that morning's lessons and became very upset about not being able to complete them. The advocate is consulted to ascertain if the subject is withdrawing assent.

***Did the subject withdraw his assent?***

**Write the points you will consider:**

**Write your outcome:**

Prompts and possible outcome on next page

# Subject Monitoring



## PROMPTS

- Does this incident occur during the medication taper when mood symptoms may increase?
- Has the subject given previous indication of dissatisfaction with being in the protocol?
- Has the subject been participating in all aspects of therapeutic and protocol activities?
- What organizational policies may apply?

## POSSIBLE OUTCOME

A one-time statement made in momentary frustration is not necessarily a withdrawal of assent although the statements made should be further discussed with the subject and his parents. If the subject's behavior continues over time and he states his desire to leave when calm as well, he has withdrawn assent. The advocate documents the outcome according to organizational policy.