

Guidelines for Documentation of the Informed Consent Process for Capable Adult Subjects

Informed consent is more than just a signature on a form. The consent document should be the basis for a meaningful exchange between the investigator and the prospective subject. The consent form should be written in language that is clear, non-technical and can be understood by the subject.

Consent documents are more understandable if they are written just as the investigator would give an oral explanation to the subject. That is, the subject is addressed as "you" and the investigator as "I/we." This second person writing style also helps to communicate that there is a choice to be made by the prospective subject. Use of the first person may be interpreted as-presumption of subject consent. (FDA guidance).

When a research subject is also an OMH patient a note should be placed in the progress notes of the patient's chart documenting the consent process.

During, or at the conclusion of a consent interview, the person obtaining consent should ask open ended questions to determine whether the prospective subject understands the research and his/her potential involvement in the research.

If someone other than the principal investigator will obtain consent, this person(s) name(s) and credentials must be listed in the IRB Application.

The following guidelines are based upon federal and state regulatory requirements and OMH/OMRDD/RFMH policies and procedures. The informed consent process and documentation must be tailored to individual protocols and subject populations. Therefore, some deviations from the guidelines, that nonetheless comply with applicable regulatory requirements, may be appropriate.

These guidelines do not address research involving children or incapable adults, waivers of consent or waivers of consent documentation.

BASIC ELEMENTS OF INFORMED CONSENT

CONTENTS OF CONSENT FORM

NAME OF FACILITY

TITLE OF PROTOCOL (and number, if applicable)

NAME OF PRINCIPAL INVESTIGATOR

PURPOSE OF STUDY

1. Provide a statement that the activity involves research.
2. Explain the purpose of the research:
 - Provide a general description of the purpose of the research.
 - If drugs are used, give generic and trade names.
 - If you are using an investigational drug or device, explain that it is not marketed in the United States but is used in research studies, and state that the purpose of the study includes an evaluation of the safety of the drug or device.
 - If you are using a marketed drug for a condition other than that for which it was approved, explain this here.
 - Number of subjects participating in study.

STUDY PROCEDURES

1. Describe the actual events in which the subject will take part. Include the following:
 - The expected duration of the subject's involvement: the number of sessions, where they will take place, their frequency and duration (e.g., two three-hour sessions) or, when appropriate, the length of the protocol (e.g. six weeks of treatment)
 - A description of the procedures to be followed. Include all screening tests and blood tests (give amount either in familiar terms -- e.g. teaspoons -- or in comparison to the amount drawn when one donates blood).
 - If either washout/placebo are involved, explain clearly, including the chances of receiving a placebo and the duration. Explain what a placebo is. Describe general areas to be covered in interviews.
 - If audio/videotaping is required, explain for what purpose the tapes will be used, who will see or hear the tapes, that the tapes can be erased at any time either during or after the session, and how long tapes will be kept. Identify any procedures which are experimental.
 - Provide information on any follow-up care or treatment.
 - Describe any use of medical records or other sources of private information.

RISKS

Provide a description of any foreseeable risks or discomforts to the subject and the precautions that will be taken to minimize risks. (The IRB must weigh the severity of a risk and its probability when determining whether it is a 'reasonably foreseeable risk or discomfort'.) Risks include:

- breach of confidentiality
- injury
- risk associated with taking placebo
- discomfort (e.g. diet restriction, restriction of movement, potentially distressing questions)

BENEFITS

Provide a description of any benefits to the subject or to others that may reasonably be expected. The significance of knowledge that will be obtained should be briefly explained.

If no benefits to the subject are expected, this should be stated, e.g., "This study is not designed for (your) benefit."

REIMBURSEMENT

If the subjects are receiving payment for their participation, the amount and anticipated schedule of payment should be stated, together with effects on payment of premature study withdrawal. Explain if payment will be in cash, check or voucher, and if mailed, provide a time frame for receipt.

ALTERNATIVE TREATMENT

Provide a disclosure of alternative procedures or courses of treatment, if any, that might be advantageous to the subject. If there are no standard alternative treatments, this should be stated.

For studies which do not involve treatment and subjects are not patients, the following statement may be used: "This is not a treatment study. Information is being collected for research purposes only."

CONFIDENTIALITY

Include a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. You are obliged to tell the subject what you intend to do with respect to confidentiality. Include the following:

- Where records will be kept, who will have access to them, how privacy will be protected (e.g. by the use of codes, reporting only about aggregate data, etc.).
- If this is a drug company sponsored study, its staff members may also review the research records.
- If the study is FDA regulated (investigational drug or device or some studies of marketed drugs for unlabeled indications) a statement that the FDA may inspect the records.
- When applicable, all records will be kept confidential to the extent permitted by law.
- Add the following statement:

"There are legal advocacy organizations (groups that support patient's rights) that are authorized under state law to access otherwise confidential records, although they cannot re-disclose this information without your consent."

Note: there are two exceptions to this requirement:

If no identifiable information is retained the notification is not necessary

If a certificate of confidentiality has been obtained, the notification is not necessary. Use the required federal language, e.g., "A Federal Certificate of Confidentiality has been obtained for this study. This Certificate protects the investigators from having to release the names or other identifying characteristics of research subjects. Investigators so authorized may not be compelled in any Federal, State, or local, civil, criminal, administrative, legislative or other proceedings to provide identifying information about research participants even if subpoenaed."

MEDICAL TREATMENT AND COMPENSATION

For research involving more than minimal risk (or determined by the NKI/IPC IRB), an explanation of whether any treatment and/or compensation is available. The subject must be told what it consists of or who to contact for further information.

The following paragraphs are **required** for all more than minimal risk studies

"In the event that you experience an injury at (facility name) as a direct result of participating in this research, the facility will provide emergency medical care within its capabilities, arrange for such other emergency medical care as may be necessary and assist you in arranging follow up care. Neither the facility nor RFMH makes any commitment to pay for medical care, nor do they have programs to provide you with financial compensation for such injury."

"By agreeing to participate in this research and signing this consent form, you do not waive any legal rights nor do you release the research staff of (facility name), (the sponsor), nor the Research Foundation for Mental Hygiene, Inc. from liability for negligence."

For studies where a sponsor has agreed to provide treatment and/or compensation, add a paragraph that explains what the sponsor has agreed to pay for. The language must be consistent with the language in the contract and must not include any exculpatory language through which the subject or representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

ADDITIONAL REQUIRED INFORMATION

- A statement that the investigator has answered to the best of his/her ability all questions posed by the subject and that he/she will answer to the best of his/her ability any questions that the subject may have in the future about the procedures or about the subject's response to the procedures (list principal investigator's name and telephone number).
- An explanation of who to contact in the event of a research-related injury and how to contact them (required only if the research involves more than minimal risk).
- A statement of who to contact if the subject has questions about their rights as a research subject. This should be the chairperson of the IRB or another appropriate person who is not affiliated with the research.
- A statement that the subject will be given a copy of the Consent Form and that a copy may also be sent to the Director of Quality Assurance and Rockland Psychiatric Center for monitoring purposes.
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

ADDITIONAL ELEMENTS TO CONSIDER

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus if the subject is, or may become pregnant) which are currently unforeseeable.
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
- Any additional costs to the subject that may result from participation in the research.
- A statement subjects will be notified of significant new findings that may relate to the subject's willingness to continue to participate.

- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
- Notification of a friend or relative: Involvement of family members or a friend is strongly encouraged. Suggested language:

You are entitled to keep your research participation confidential, but you might like to notify a friend or relative about it. If so, please provide us with the information needed and we will do our best to notify that person.

I want someone notified

Yes _____

No _____

Person to be notified _____

Telephone number _____

Address _____

SIGNATURE REQUIREMENTS

PATIENT CONSENT TO RESEARCH PARTICIPATION:

I voluntarily consent to participate in this research study described above. I may choose not to participate, or to discontinue participation at any time, without any penalty or loss of benefits to which I am otherwise entitled.

Patient's Name

Patient's Signature

Date

PERSON OBTAINING CONSENT:

I believe that this consent is freely given, by a subject with sufficient capacity to consent. The subject has been given all of the information deemed necessary by the IRB or requested by the subject.

Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date

CAPACITY ASSESSMENT: (should be a separate page from subject.signature)

When an independent assessment of capacity is conducted:

I have examined (name) _____ on (date) _____ for the purpose of determining whether he/she is capable of understanding the purpose, nature, risks, benefits and alternatives (including non-participation) of the research, making a decision about participation, and understanding that the decision about participation in the research will involve no penalty or loss of benefits to which the patient is otherwise entitled for Dr.- (name) 's research project, (name of project) . On the basis of this examination, I have arrived at the conclusion that:

- A. This patient has capacity at this time.
- B. There is a question about this patient's capacity at this time.
- C. This patient clearly lacks this capacity.

Date _____ Signature _____

Print Name _____

TREATMENT TEAM APPROVAL:

For all studies that involve more than minimal risk:

Participation in the research project described above will not come into substantial conflict with _____ name of subject _____'s treatment plan and is approved by the treatment plan.

Print Name

Signature

Date

Print Name

Title