

COLUMBIA UNIVERSITY INSTITUTIONAL REVIEW BOARD POLICY

INFORMED CONSENT

I. SCOPE:

This Policy applies to all research involving human subjects, including behavioral, social science, epidemiological, and biomedical research, and sets forth Columbia University's requirements for obtaining informed consent from living individuals involved in human subjects research.

II. EFFECTIVE DATE: May 8, 2007; revised November 19, 2009; revised April 1, 2010; revised October 26, 2010

To the extent provided herein, this Policy supersedes all prior Columbia University informed consent policies.

III. BACKGROUND:

Legally effective informed consent must be obtained from every subject in human subjects research or the subject's legally authorized representative unless the requirement has been waived by the IRB in accordance with 45 CFR 46.116(c) or (d) or 21 CFR 50.24 or the research is exempt from IRB review pursuant to 45 CFR 46.101(b). Legally effective informed consent is not fully defined by federal regulations and, therefore, state law must also be considered. Hence, Columbia's policy for obtaining legally effective informed consent for participation in human subjects research is based on Department of Health and Human Services (DHHS) regulations (45 CFR 46), Food and Drug Administration (FDA) regulations (21 CFR 50), New York State law (Article 24A, Sections 2440 & 2442, Article 29-C and Article 29-CC), and the ethical principles articulated in the Belmont Report.

Both the DHHS and FDA regulations require that there be an appropriate informed consent by or on behalf of each research subject in a process that provides an understanding of the following eight elements of consent:

- 1) the purpose of the research and expected duration of the subject's participation, the procedures that will be followed and identification of any procedures which are experimental;
- 2) any reasonably foreseeable risks or discomforts;
- 3) benefits to subjects or others which may reasonably be expected;
- 4) appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- 5) the extent, if any, to which confidentiality of records identifying the subject

- will be maintained;
- 6) whether any compensation (including amount and schedule of payments) and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained (for research greater than minimal risk);
 - 7) whom to contact for questions regarding the research, research-related injuries, and rights as a research subject; and
 - 8) that participation is voluntary, refusal to participate will not involve any penalty or loss of benefits to which the subject is otherwise entitled and participation may be discontinued at any time without any such penalty or loss.

The federal regulations also provide additional elements of informed consent that should be considered. When appropriate, one or more of the following elements of information should also be provided to each subject:

- 1) 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;
- 2) anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- 3) any additional costs to the subject that may result from participation in the research;
- 4) the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- 5) a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
- 6) the approximate number of subjects involved in the study.

Further details of the elements of consent can be found at:

<http://www.cumc.columbia.edu/dept/irb/regulations/index.html>.

The federal regulations require that an investigator seek consent only under circumstances that provide the prospective participant or his/her legally authorized representative with sufficient opportunity to consider whether or not to participate in the research and that minimize the possibility of coercion or undue influence. The information that is given to the participant or such representative shall be in a language understandable to the participant or such representative. Further details about enrollment of non-English speaking subjects can be found at:

http://www.cumc.columbia.edu/dept/irb/policies/Nonenglish_Speaking_Subjects.rtf

New York State law defines human research differently than the federal regulations and as a result only research that involves medical experimentation, medical procedures, or therapeutic intervention on human individuals is covered. Behavioral, social science, and epidemiological research in general are not regulated by New York State law unless such research involves medical experimentation, medical procedures, or therapeutic

intervention. New York State law, like the federal regulations, also requires that written informed consent must be obtained prospectively from every participant involved in research to the extent that such consent is required. The federal regulations may still require that consent be obtained, even if New York State law does not.

Note that the terms “participant” and “subject” are used interchangeably in this policy.

IV. POLICY:

Columbia University policy with respect to informed consent incorporates all of the requirements stated above in Section III and will be applied in a manner that is consistent with both federal and state regulations. Legally effective informed consent for all human subjects research conducted domestically or internationally by Columbia faculty, employees, or students is defined as the process of the investigator or designee explaining, and the prospective participant understanding, all of the elements of informed consent as provided in the federal regulations, except when one or more of the element(s) have been appropriately waived. For international research, one should also consult the IRB Policies and Procedures at

<http://www.cumc.columbia.edu/dept/irb/policies/documents/SOP.FINAL.060906.doc>

A. CONSENT PROCESS

The process of obtaining legally effective informed consent from a prospective participant must be free from coercion or undue influence, and the individual must have both the capacity to make decisions, and appropriate opportunity to consider all information related to participation in the research study. The Principal Investigator is responsible for ensuring that legally effective consent is obtained from each participant prior to the enrollment of the individual in the study. Furthermore, legally effective consent must be obtained prior to procedures and assessments (e.g., screening or diagnostic tests, surveys, etc. required by the study) that are conducted to determine eligibility for enrollment in the study. The current IRB-approved consent document(s) must be used for the consent process (the consent document may be a signed consent form or an information sheet that will be used for verbal consent).

For research studies conducted in a hospital with inpatients, the physician of record for care of the patient during the hospitalization must approve the enrollment of his/her patient in the study. In addition, the first information that an inpatient receives for the purpose of enrollment in a research study should be from an individual who has legitimate access to the patient’s medical information.

The above requirement includes patients in the emergency department (ED). The IRB may consider an exception to the requirement to obtain permission from the physician of record for minimal risk research in the ED when the all of the following conditions apply: 1) the research is non-interventional, 2) researchers do not access the medical records of the subjects without the authorization of the subject, 3) the potential subject has been

evaluated by a health care provider in the ED, 4) the research could not practicably be conducted without such an exception, and 5) the study is approved by the Chief of Emergency Medicine or a designee.

The responsibility to obtain legally effective consent extends to the Principal Investigator's selection of designees who are authorized to obtain consent. In selecting an appropriate designee to obtain informed consent, the Principal Investigator should consider the nature of the research study and the expertise of the designee, as well as institutional and regulatory requirements to ensure that informed consent will be obtained appropriately from each participant.

B. DOCUMENTATION

The consent process must be documented by: 1) obtaining the signature of the prospective participant on the IRB-approved informed consent document(s), unless this requirement has been waived by the IRB, and 2) documenting the process itself in the research records as noted below. The name of the person obtaining consent and the date that consent was obtained should be documented on the consent form. When written consent is required a copy of the consent document will be given to the participant. If documentation of consent is waived by the IRB and an information sheet is being used for the verbal consent process, a copy of the information sheet will generally be given to the participant unless otherwise not required by the IRB.

For minimal risk research, the signed IRB-approved informed consent document(s) generally serves as adequate documentation of the consent process unless otherwise stipulated by the IRB for a specific research activity. For research activities approved by the IRB with the requirement of only obtaining verbal consent (i.e., waiver of the documentation of informed consent, that is, waiver of a signed consent form), the research records should document that verbal consent was obtained in accordance with IRB requirements.

For all research that is greater than minimal risk, documentation of the informed consent process should be provided in the research records. Such documentation, when appropriate, should also include other relevant information such as resolution of substantive questions raised by the participant, assessment of the capacity to provide consent, or how undue influence was effectively managed and eliminated.

For clinical research studies that enroll patients who are hospitalized at the time of enrollment, the time that consent was obtained should also be documented on the consent form and in the medical records; in addition, a copy of the signed consent document(s) must also be included in the medical records. Clinical research in this context refers to research in which the research protocol determines the treatment or management of the subject, regardless of whether the treatment, drug, or device is investigational in status.

If verbal consent is obtained from a hospitalized patient, documentation of the discussion with the patient and a copy of the IRB form approving verbal consent must be included in the hospital medical records.

C. INFORMED CONSENT FOR EXEMPT RESEARCH

Exempt research is not subject to the federal regulations and therefore informed consent is not required for such research. However, in the spirit of the principles of the Belmont Report, in which autonomy of the individual and the voluntariness of participating in research are fundamental ethical principles, the IRB strongly recommends that informed consent also be obtained for certain exempt studies. For exempt studies that allow for direct interaction between the investigator and human subjects, participants should minimally be informed of the following: that the activity is research, the procedures that are involved in the study, the nature of the risks (e.g., little, if any expected inconvenience or harm), that participation is voluntary and that they may withdraw from the study at any time. Benefits to the participant or others, plans for ensuring confidentiality, and contact information for the investigator should also be provided when relevant. The information may be communicated orally and when possible should be supported with an information sheet.

D. WAIVER OF CONSENT

The IRB may approve a consent procedure which does not include or alters some or all of the elements of informed consent, or may waive the requirement to obtain informed consent if all of the following criteria can be appropriately satisfied:

- 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.

For consideration of a waiver or alteration of the requirement to obtain informed consent, the investigator should include in the submission to the IRB justification for each of the above criteria.

Waiver of the requirement to obtain informed consent may also be requested by the investigator for a research or demonstration project if:

- 1) such project will be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

(a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs; and

2) the research could not practicably be carried out without the waiver or alteration.

E. WAIVER OF WRITTEN DOCUMENTATION OF INFORMED CONSENT

The IRB may waive the requirement for the investigator to obtain a signed consent form, for some or all subjects in a study, if it finds either:

1) that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

2) that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

For consideration of a waiver of the requirement to obtain written documentation of informed consent (e.g., a signed consent form), the investigator should include in the submission to the IRB justification for the relevant criterion found above.

In cases in which the documentation requirement is waived, the IRB may require that the investigator provide participants with a written statement regarding the research.

F. SURROGATE CONSENT

Obtaining consent for research purposes from a representative of an adult subject rather than directly from the subject ("surrogate consent") requires the prior approval of the IRB. The IRB may allow use of surrogate consent in accordance with Columbia's policy only for subjects who lack the capacity to provide their own consent.

As with all studies, and especially ones involving vulnerable populations such as subjects who lack capacity, the Columbia IRBs consider whether the risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be gained from the research. The IRB will generally consider the use of surrogate consent for research that would: a) provide the prospect of direct benefit to subjects who lack capacity; or, b) study disorders, conditions, or factors that affect individuals who lack capacity when the research is minimal risk, with or without the

prospect of direct benefit, and the research could not otherwise be conducted on subjects who have capacity.

When the IRBs review protocols in category (b) above, they are more likely to favorably consider them if they include only the types of minimal risk procedures that are routinely performed in a clinical setting without specific informed consent for all patients whether they have, or lack, the capacity for consent. The IRBs will also consider other minimal risk protocols.

The submission to the IRB must include details of how the investigator will verify the authority of the individual to serve as the legally authorized representative designated to provide surrogate consent and how the capacity of the subject will be assessed.

Subjects who appear to lack capacity must have the assessment of capacity made by a licensed physician(s) in accordance with standard practice and applicable state law. In general, the determination that the subject lacks capacity may not be made by the study investigators or study staff. For a given study, the IRB may approve an exception to this prohibition. For an exception to be granted by the IRB, the investigator must submit a specific request for such an exception that includes a justification and written plan for assessment of capacity.

For human subjects research conducted in New York State, the following persons are considered legally-authorized representatives who may act as a surrogate:

- 1) a court-appointed legally-authorized representative/guardian, or a guardian authorized to decide about health care pursuant to Article 81 of the Mental Hygiene Law;
- 2) an individual who is designated as a representative/agent through a health care proxy that is appropriately executed. For a health care proxy to be effective, it must have been signed at a time when the subject had decision making capacity. The subject's wishes, if any, with regard to research as expressed in the health care proxy govern (e.g., prohibiting all research or permitting only research which may provide a direct benefit).
- 3) if an individual who satisfies the requirements of either paragraph 1) or 2) above does not exist, surrogate consent may be obtained from a person on the following list from the class highest in priority who is reasonably available and willing and competent to act:
 - a) the spouse (if not legally separated from the subject) or the domestic partner;
 - b) a son or daughter eighteen (18) years of age or older;
 - c) a parent;
 - d) a brother or sister eighteen (18) years of age or older;

- e) a close friend (meaning a person eighteen (18) years of age or older who has maintained such regular contact with the subject as to be familiar with the subject's activities, health and beliefs).

Such a person listed in a) through e) above may designate another person on the list to be a surrogate provided that no one in a class higher in priority than the person designated objects in a timely fashion.

For protocols that may provide direct benefit to subjects in emergent, life-threatening situations, the IRB may approve a hierarchy of succession that permits a surrogate listed in a) through e) above to provide consent if a representative/agent through a health care proxy exists but is not reasonably available.

New York State law sets forth specific requirements with regard to the determination of lack of capacity and its documentation, including the possible need for a concurring opinion.

For human subjects research conducted in other states, requests for the use of surrogate consent will be considered by the IRB in accordance with local state law.

The submission to the IRB should include the circumstances under which re-assessment of capacity, and re-consent when possible, will be conducted in populations where capacity is likely to change over time and what protections (beyond re-consent) will be implemented to address these considerations. If a subject previously determined to lack capacity to consent regains capacity during the study, the investigator must obtain the consent of the individual for the remaining part of the study. The consent process must disclose all research procedures performed to date and allow the individual an opportunity to continue in or withdraw from the study. The subject must sign the IRB-approved consent document and the research record should document what research procedures were already performed or remain to be performed.

The IRB must approve any use of surrogate consent prospectively during review of the protocol or modification of the protocol.

G. INFORMED CONSENT FOR RESEARCH INVOLVING CHILDREN

Children are a vulnerable research population and, as such, require additional protections when they are potential research subjects. At the same time, children should not be denied the benefits of participating in research. Federal regulations require that additional precautions are taken depending on the degree of risk involved in the research. In addition, the regulations also set forth requirements for obtaining parental/guardian permission and, where appropriate, assent by the children themselves.

Columbia's policy for obtaining parental/guardian permission for the enrollment of children in research and for obtaining assent from children can be referenced at:
http://www.cumc.columbia.edu/dept/irb/policies/docs/Research_Involving_Children_Policy.pdf