COLUMBIA UNIVERSITY INSTITUTIONAL REVIEW BOARD
POLICY ON INFORMED CONSENT

TABLE OF CONTENTS

I. BACKGROUND

The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects (the **Belmont Report)**, first published in 1979, provides the ethical underpinnings of the current laws governing research with human subjects. The Belmont Report establishes three fundamental ethical principles for research with human subjects: respect for persons, beneficence and justice. The principle of "respect for persons" acknowledges the dignity and autonomy of individuals and requires that subjects give voluntary informed consent to participation in research. The U.S. Department of Health and Human Services (**DHHS)** regulations (45 CFR 46, Subpart A, which is also known as the Common Rule), establish the core procedures for human subjects research protection, which include informed consent and review by an Institutional Review Board (**IRB).** Food and Drug Administration (**FDA**) regulations (21 CFR 50) also set forth similar, but not identical, rules for informed consent when conducting research with investigational drugs, biologics and medical devices. All of the foregoing principles, laws and regulations apply to research involving human subjects conducted by Columbia University (**Columbia** or the **University)** faculty, staff and student researchers.

In general, both the DHHS and FDA regulations and guidances hold that subjects may not be enrolled or involved in any non-exempt research activities until legally effective informed consent has been obtained. Informed consent involves providing a prospective subject, or their legally authorized representative, with adequate information to allow for an informed decision about participation in a research study prior to enrollment. Informed consent also involves facilitating the prospective subject's understanding of the information, providing adequate opportunity for the prospective subject to ask questions and to consider whether to participate, obtaining the prospective subject's voluntary agreement to participate prior to enrollment, and continuing to provide information as the study progresses or as the enrolled subject or situation requires. Of note, informed consent is an ongoing process rather than occurring at a single point in time. Reconsent is required to be obtained and documented when additional information becomes available that may affect subjects' willingness to continue participation, such as information that affects the real or perceived risks (e.g., identification of a new drug toxicity), benefits (e.g., data on efficacy of an intervention), alternatives, and/or rationale for participating in the research).

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

II. EFFECTIVE DATE

[Table of Contents]

The Effective Date of this Policy is February 1, 2026 and supersedes the University's Institutional Review Board Policy on Informed Consent, dated May 8, 2007 and revised as of November 19, 2009, April 1, 2010, and October 26, 2010, and, to the extent provided herein, supersedes all other University informed consent policies.

III. DEFINITIONS

[Table of Contents]

Certain terms used in this Policy are defined as follows:

CUIMC: Columbia University Irving Medical Center.

DHHS: U.S. Department of Health and Human Services

Epic: The electronic medical record system shared by CUIMC, WCMC and NYP**.**

Identifiable Biospecimen or **IB:** A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Identifiable Private Information or **IPI:** Private Information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Legally Authorized Representative or **LAR:** an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the research. For purposes of this policy, if there is no applicable law addressing the issue, "legally authorized representative" means an individual recognized by institutional policy as acceptable for providing consent in the non-research context (e.g., a named health care proxy or a legal surrogate) on behalf of a prospective subject to the subject's participation in the research.

NIH: The National Institutes of Health of DHHS.

NYP: NewYork-Presbyterian Hospital.

OHRP: Office for Human Research Protections of DHHS.

Private Information: Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

Rascal: Research Compliance and Administration IT System used at Columbia.

Surrogate: an individual listed in the hierarchy described in Section VII(I)(3) below, including a LAR, who is authorized by the IRB to provide consent for subjects who have impaired capacity.

WCMC: Weill Cornell Medical Center.

NOTE: In this Policy, the terms "participant" and "subject" are used interchangeably.

IV. GENERAL REQUIREMENTS FOR INFORMED CONSENT

[Table of Contents]

Informed consent must meet the regulatory requirements of DHHS under 45 CFR 46 and, if applicable, the FDA under 21 CFR 50. Under these regulations (21 CFR 46.116; 21 CFR 50.20), the following requirements for informed consent must be met:

- **Consent Required.** Before involving a human subject in research, an investigator shall obtain the legally effective informed consent of the subject or their LAR, unless the requirement has been waived by the IRB or the research is exempt from the requirements of the applicable regulations.

- **Voluntary Participation.** An investigator may seek informed consent only under circumstances that provide the prospective subject or their LAR sufficient opportunity to discuss and consider whether to participate or not and that minimize the possibility of coercion or undue influence.

- **Understandable Language.** The information given to the subject or their LAR must be in language understandable to the subject or the LAR. See also the Columbia University Institutional Review Board Policy on Enrollment of Non-English Speaking Subjects in Research.

- **Sufficient Information.** The subject or their LAR must be provided with information that a reasonable person would want to have to make an informed decision about whether to participate in the research.

- **Key Information.** Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or their LAR in understanding the reason why one might or might not want to participate in the research, presented in sufficient detail and in a way that facilitates comprehension.

- **Exculpatory Language.** The consent form may not include language that waives the participant's or their LAR's legal rights or releases the investigator, the sponsor, the University or its agents from liability for negligence.

NOTE: While 45 CFR 46.116(a) permits broad consent, which may be obtained with respect to the storage, maintenance and secondary research uses of IPI and IBs, the Columbia IRB has not approved use of the broad consent process for access to IPI or IBs stored as a result of clinical care at Columbia or NYP, and such broad consent is disallowed.

V. ELEMENTS OF INFORMED CONSENT

[Table of Contents]

Both DHHS (45 CFR 46.116) and FDA regulations (21 CFR 50.25) require that there be an appropriate informed consent by or on behalf of each research subject or their LAR in a process that provides an understanding of certain elements of consent. Although some of the elements listed below are not currently referred to in the FDA regulations, the following basic elements, and additional elements as applicable, are required for informed consent in non-exempt studies conducted by Columbia researchers, including FDA-regulated studies.

A. Basic Elements

[Table of Contents]

The following elements shall be provided to each prospective subject or their LAR:

- **Purpose and Procedures.** A statement that the study involves research, the purpose of the research and the expected duration of the subject's participation, a description of the procedures to be followed and identification of any procedures that are experimental.

- **Risks.** A description of any reasonably foreseeable risks or discomforts to the subject.

- **Benefits.** A description of any benefits to the subject or others that may reasonably be expected.

- **Alternative Procedures.** A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

- **Confidentiality.** A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained, the possibility that OHRP may inspect the research records and, for those studies regulated by the FDA, the possibility that the FDA may inspect the research records.

- **Compensation and Treatments.** For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained. Compensation must not be coercive.

- **Contact Information.** An explanation of whom to contact for questions regarding the research and research subjects' rights and whom to contact in the event of a research-related injury to the subject.

- **Participation is Voluntary.** A statement that participation is voluntary, refusal to participate will not involve any penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without any such penalty or loss of benefits.

- **Identifiable Private Information or Biospecimens.** One of the following statements, if the research involves the collection of IPI or IBs:

    - A statement that identifiers might be removed from the IPI or IBs and that, after such removal, the IPI or IBs could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject; or
    - A statement that the subject's IPI or IBs collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

B. Additional Elements [Table of Contents]

One or more of the following elements, if appropriate, shall also be provided to each subject or their LAR:

- **Unforeseeable Risks.** 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) that are currently unforeseeable.

- **Termination of Participation.** Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

- **Additional Costs.** Any additional costs to the subject that may result from participation in the research.

    - If the human subjects research involves an experimental drug or device with therapeutic intent, in general, all medical evaluations that are reasonably justifiable to monitor the efficacy of the intervention ((e.g., physician visits, imaging studies), or the safety of the intervention (e.g., blood tests), other than the supply of the experimental drug/device itself, are not considered research and must be billed to the subject and/or insurance. Investigators should consult with the University's Clinical Trials Office for appropriate language to address this issue in informed consent documents.
    - Further information is available here: https://www.cms.gov/medicare/coverage/clinicaltrialpolicies/downloads/finalnationalcoverage.pdf

- **Withdrawal.** The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

- **New Findings.** A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject.

- **Number of Subjects.** The approximate number of subjects involved in the study.

- **Biospecimens.** A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in the commercial profit.

- **Disclosure of Results.** A statement regarding whether clinical research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.

- **Genome Sequencing.** For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Further details of the elements of consent can be found at: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html

Note that pursuant to FDA regulations (21 CFR 50.25(c)), relating to "applicable clinical trials" (as defined in 42 U.S.C.282(j)(1)(A)), the following statement must be provided to each subject in informed consent documents and processes:

"A description of this clinical trial will be available on https://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."

Interventional clinical trials involving drugs and devices and clinical research studies (i.e., any clinical test, procedure or service at NYP or CUIMC) conducted at clinical facilities of CUIMC or NYP are required to be entered into Epic (regardless of whether the activity is billed to the patient or to the sponsor), and the following statement must be provided to each subject in the informed consent documents:

"Your participation in this research study will be documented in your electronic medical record. This record can be viewed by authorized personnel from Columbia University Irving Medical Center, Weill Cornell Medical Center and NewYork-Presbyterian Hospital and its affiliated institutions because these institutions share the electronic medical record system. Study monitors and others who provide oversight of the study may also need to access this record."

The following sections contain links to examples of language that has been suggested by either a federal regulatory agency or the University, and should be considered for inclusion in informed consent documents when applicable:

- **Certificates of Confidentiality (CoC)**

NIH has issued sample consent form language for studies for which a CoC has been obtained to protect personally identifiable, sensitive research information from forced disclosure. Effective October 1, 2017, CoCs are automatically deemed to be issued for any NIH-funded research that is ongoing on or after December 31, 2016 and that collects or uses identifiable, sensitive information,

- **Audio/Video/Photographic Recording**

Although not required by federal regulations, the University has its own requirements as to additional elements of consent that must be included in the consent form for review and approval by the IRB. For further information, see the Columbia University/Columbia University Medical Center Institutional Review Board Policy/Procedure Audio/Video/Photographic Recording of Human Subjects

- **NIH-funded Research with Data and Biospecimens**

NIH's 2023 Data Management and Sharing Policy strongly encourages that information about data management and sharing be addressed in the informed consent process, including communicating with prospective participants as to how their scientific data are expected to be used and shared. The NIH has provided guidance on consent for secondary research with data and biospecimens and has provided sample language for future use and sharing of such data to be included in the informed consent documents for the primary research study. The use of the sample language is voluntary. For further information, see Informed Consent for Secondary Research with Data and Biospecimens: Points to Consider and Sample Language for Future Use and Sharing and the Columbia University Institutional Review Board Guidance and Sample Language for Informed Consent to Address Requirements of the NIH Data Management and Sharing Policy.

- **Genomic Data Sharing**

Under the NIH Genomic Data Sharing Policy, for studies initiated after January 25, 2015, the effective date of such Policy, NIH expects investigators to obtain participants' consent for their genomic and phenotypic data to be used for future research purposes and to be shared broadly. The informed consent documents should include an explanation about whether participants' individual-level data will be shared through unrestricted or controlled-access repositories. In addition, NIH expects that informed consent for future research use and broad data sharing will have been obtained even if the cell lines or clinical specimens are de-identified. For further information, see the NIH Genomic Data Sharing Policy.

VI. THE CONSENT PROCESS [Table of Contents]

The Principal Investigator **(PI)** of the study is responsible for ensuring that legally effective consent is obtained from each participant prior to the enrollment of the individual in the study, and for documenting the informed consent process. 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, provided that the IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of such subject or their LAR, if either of the following conditions are met:

- The investigator will obtain information through oral or written communication with the prospective subject or LAR, or
- The investigator will obtain IPI or IBs by accessing records or stored identifiable biospecimens (45 CFR 46.116(g)).

The federal regulations provide two possible mechanisms for obtaining informed consent from a research participant:

- A process involving the documentation of consent by the subject or their LAR signing a written IRB-approved consent document, or
- A process involving a waiver of documentation of consent that has been approved by the IRB.

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

In most situations, the investigator or IRB-approved delegate must have a documented conversation with the participant to ensure that the participant really understands the study and its risks and benefits. The conversation must allow adequate time for the participant to ask questions. It must take place in a setting that affords a sufficient level of privacy for the participant.

Before beginning the conversation, the PI should discuss with the participant whether any special provisions will be needed for the consent process to take place. For example, hearing impaired individuals may want to have a sign language interpreter present. The process should be specific to each participant population and must take into consideration the participant's native language, level of education and maturity.

Whenthe consent process does not include a conversation with the prospective participant, such as when recruitment is online and participants will provide consent through an electronic mechanism, the information presented to the prospective participant

must include a statement as to how questions about the research can be asked and include contact information for the study team.
For FDA-regulated research, as indicated in the FDA Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors, dated August 2023, methods other than a face-to-face consent discussion may be acceptable if those methods allow for an adequate exchange of information and documentation and ensure that the signer of the consent form is the person who plans to enroll as a subject or is the LAR of the subject. For instance, the consent form may be sent to the subject or their LAR by fax or email, with the consent discussion conducted by telephone or videoconference and the manually or electronically signed consent form returned to the investigator through a secure electronic method, by mail or in person. In situations in which the signed document cannot be retrieved for filing in the study records (e.g., because the subject is in strict isolation due to a highly transmissible infectious disease, and electronic consent is not available), it is acceptable to retain in the study records a photographic image of the signed consent form, along with an attestation by the person entering the photograph into the study records that states how the photograph was obtained and that it is a photograph of the informed consent form signed by the subject.

For research studies involving a medical intervention that is conducted with a patient in a hospital, the physician of record for care of the patient during the hospitalization must be informed of the patient's enrollment in the study, and the process of informing the physician of record must be documented.

When patients are identified as potentially eligible for a study through review of information in their medical record, the introduction of the patient to the research study should be from an individual who has legitimate access to the patient's medical information for healthcare purposes, generally the treating physician. The introduction may also come from or be provided on behalf of the medical director of a clinical department or unit under the following conditions:

- The providers in the unit are informed of details of the study;
- The providers are offered the opportunity to identify patients who should **not** be approached; and
- The introduction includes a letter or other form of documentation provided to the patient from the medical director, either directly or communicated through the researchers, indicating awareness of the study and acknowledging identification of potential eligibility through review of information in the patient's medical record. If the initial outreach is remote and documents are not able to be provided in advance, the introductory script should include an explanation of the medical director's awareness and acknowledgement as described above.

In all cases, the process by which consent will be obtained (e.g., written, electronic, use of LAR, other), including the members of the research team delegated with authority by the PI to obtain informed consent, must be submitted for approval by the IRB in Rascal.

A. WRITTEN DOCUMENTATION OF INFORMED CONSENT

[Table of Contents]

Generally, the IRB requires consent to be documented by a written consent form that includes all of the required elements and all appropriate optional elements, is written in lay language at a 6-8th grade reading level, and is approved by the IRB prior to use. This is consistent with the requirements of 45 CFR 46 and 21 CFR 50. The consent form must be reviewed with the participant or their LAR and the investigator must give the subject or their LAR adequate opportunity to read the consent form or to have the form read to the subject or the subject's LAR. The form should be signed and dated by the participant or LAR and the individual who obtains the consent. A copy of the signed consent document should be given to the participant.

The HRPO has prepared helpful templates, sample language and other aids to assist investigators in preparing consent forms.

For minimal risk research, the signed IRB-approved informed consent document generally serves as adequate documentation of the consent process unless otherwise stipulated by the IRB for a specific research activity. Documenting the process itself in the research records is not required, but is recommended if there are any unusual circumstances. If a waiver of documentation has been approved by the IRB, the research team should include a note in the research records to confirm that consent was obtained and summarize the conditions under which it was obtained.

For all research that is greater than minimal risk, documentation of the informed consent process must be provided in the research records and, when appropriate, in Epic. The presence of a participant's (or LAR etc.) signature on the informed consent form itself is NOT adequate documentation of the informed consent process, which should take the form of an independent note. Such documentation, should also include other relevant information such as the individuals present during the consent discussion, resolution of substantive questions raised by the participant, assessment of the capacity to provide consent, how undue influence was effectively managed and eliminated, and the subject's decision. Templates to document the informed consent process are also available from the CTO website.

The University permits the use of electronic or digital systems and processes, including electronic consent (**e-Consent)** and electronic signatures (**e-Signatures),** whether in person or remotely, to convey information relating to a research study and to document informed consent of subjects. The e-Consent process must contain all of the elements of informed consent required by DHHS (45 CFR 46) and, if applicable, the FDA (21 CFR 11, 50 and 56) regulations, unless waived by the IRB.

For further information, see the Columbia University Institutional Review Board Guidance on Electronic Informed Consent for Research, including a description of available systems at Columbia that may be used for e-Consenting.

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. This is a requirement for FDA-regulated research. A copy of the signed consent document must 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. Of note, many e-Consent and e-Signature systems automatically provide the required date and time stamp.

If informed consent will be obtained from a hospitalized patient with an IRB-approved waiver of documentation of consent, documentation of the discussion with the patient and a copy of the IRB-approved information sheet or verbal script must be included in the hospital medical records.

B. WAIVER OF WRITTEN DOCUMENTATION OF INFORMED CONSENT [Table of Contents]

A waiver of documentation of consent, i.e., eliminating the requirement for a signature on a written consent document, must meet the regulatory requirements of DHHS (45 CFR 46.117) and, when applicable, the FDA (21 CFR 56.109). The IRB may approve a request for a waiver of documentation of consent under the following circumstances, provided that if the study is a clinical investigation subject to FDA regulations, the waiver of documentation is only permitted in the situation described in the first bullet point below:

- 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; or
- 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 they want documentation linking them with the research, and the subject's wishes will govern; or
- If the subjects are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

If the IRB waives the requirement for documentation of consent, it is recommended that the elements of informed consent be reviewed verbally with the subject or their LAR.

For consideration of a waiver of the requirement to obtain written documentation of informed consent, the PI should include in the submission to the IRB justification for the waiver in light of the above criteria. In addition, the research records should document that verbal consent was obtained in accordance with IRB requirements and summarize the conditions under which consent was obtained.

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

VII. WAIVER OR ALTERATION OF INFORMED CONSENT

[Table of Contents]

Under 46 CFR 117(c) and 21 CFR 50.22, the IRB may approve a consent procedure that 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 are satisfied:

- The research involves no more than minimal risk to subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver or alteration;
- Whenever appropriate, the subjects or their LARs will be provided with additional pertinent information after participation; and
- If the research involves using IPI or IBs, the research could not practicably be carried out without using such IPI or IBs in an identifiable format.

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 the waiver in light of the above criteria.

For non-FDA regulated research, waiver of the requirement to obtain informed consent may also be requested by the investigator for a research or demonstration project if:

- Such project will be conducted by or be 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
- The research could not practicably be carried out without the waiver or alteration.

VIII. RECONSENTING SUBJECTS

[Table of Contents]

An investigator is required to communicate significant new information or findings to participants enrolled in a research study if there are additional or different risks, additional or modified procedures or other factors that may affect subjects' willingness to continue participation. The IRB must consider options for providing such information, such as obtaining signatures on a revised consent form, providing an information sheet or verbally informing subjects by telephone, email or letter, or in person. If there are changes to the consent form, the IRB may specify which subjects (e.g., all or only new subjects) must sign the new form.

Note that the FDA does not believe it is necessary for (a) subjects who have completed their active participation in the study to be informed of new information unless the new information relates to risks that may manifest themselves after such participation or (b) subjects who are still actively participating in the study to be informed when the change will not likely affect their decision to continue in the study.

IX. INFORMED CONSENT FOR EXEMPT RESEARCH

[Table of Contents]

Exempt research is not subject to the federal regulations for the protection of human subjects in research at 45 CFR 46 and therefore informed consent is not required for such research. However, in the spirit of the principles of the Belmont Report, 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: (a) that the activity is research, (b) the procedures that are involved in the study, (c) the nature of the risks (e.g., little, if any, expected inconvenience or harm), (d) that participation is voluntary and (e) 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, the oral communication should be documented when possible and appropriate, and when possible should be supported with an information sheet.

X. ADDITIONAL PROTECTIONS FOR CERTAIN RESEARCH

[Table of Contents]

A. 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 be taken when children will be enrolled in the study depending on the degree of risk involved in the research. In addition, the regulations also set forth requirements for obtaining parental or guardian permission and, where appropriate, assent by the children themselves.

For further information, see the Columbia University Institutional Review Board Policy on Research Involving Children.

B. RESEARCH WITH NON-ENGLISH SPEAKING SUBJECTS

[Table of Contents]

The principle of "respect for persons" articulated in the Belmont Report requires that potential research subjects are provided with sufficient meaningful information to decide whether they want to participate in a research study. When prospective subjects who do not clearly understand English are to be enrolled in a study, the investigator must ensure that the information given to such prospective subjects or their LARs is in a language

understandable to the subjects and their LARs. The University believes that special processes, such as the use of interpreters or translations, are needed to ensure that this principle is followed.

Obtaining consent with the use of a short form informed consent form is acceptable for the enrollment of a non-English speaking participant in certain limited situations.

The short form informed consent form must state that (a) the required elements of informed consent have been presented orally to the subject or their LAR, and (b) the key information was presented first to the subject, before other information, if any, was provided. When this method is used, the IRB is required to approve a written summary of the information that was presented orally, and there should be a witness to the oral presentation. Only the short form itself must be signed by the subject or their LAR. However, the witness must sign both the short form and a copy of the summary of what was said to the subject, and the person actually obtaining consent must sign a copy of the summary. A copy of each of the short form and the summary should be given to the subject or their LAR.

For further information, see the Columbia University Institutional Review Board Policy on Enrollment of Non-English Speaking Subjects in Research.

C. RESEARCH INVOLVING STUDENTS OR AFFILIATES

[Table of Contents]

In order to minimize the possibility of coercion or undue influence when enrolling students or employees of the University (including CUIMC or NYP), a statement should be included in the consent form specifying (1) with respect to such employees that participation in the research, or a decision against participating, will not impact their compensation, promotion, standing, or status with the University or NYP and (2) with respect to students, that participation in the research will not impact their grades or class standing. In general, the IRB will also require documentation from the appropriate department chair or other programmatic leader that they are aware of and supportive of the research. Additional review may also be required by the Federalwide Assurance Institutional Signatory Official to guard against coercion or undue influence.

D. INTERNATIONAL RESEARCH

[Table of Contents]

Research conducted outside of the United States, especially in places where participants do not speak English, may pose problems with obtaining written documentation of consent. If it is impossible to do so, the investigator should provide the IRB with the reasons why it should waive the requirement for written documentation of consent.

For further information, see the Columbia University Institutional Review Board Guidance for International Research: Information and Documents To Be Provided for IRB Review.

For research involving enrollment of subjects located in the European Economic Area, the European Union General Data Protection Regulation (**GDPR)** requires certain information to be provided to subjects in addition to the consent elements listed in Section V. For further information, see the Columbia University Institutional Review Board GDPR Guidelines for Human Subjects Research Studies.

E. RESEARCH WITH PREGNANT WOMEN, FETUSES AND NEONATES

The Columbia IRB recognizes that the vulnerabilities of pregnant women, either in general or in the labor and delivery units in a hospital, require special sensitivities with respect to research, as not only is the pregnant woman involved, but also the fetus and potentially the father of the fetus. The question of whether the person providing consent is cognizant of the impact of the research on both the mother and the fetus, and whether both parents need to consent to the research, are central to the process of obtaining informed consent in these situations.

For further information, see the Columbia University Institutional Review Board Guidance on Clinical Research Involving Pregnant Women.

F. GENETIC TESTING [Table of Contents]

Section 79-L of the New York State Civil Rights Law imposes special requirements as to what information is required to be given to subjects who are undergoing or may undergo genetic testing (as defined in Section 79-L) for their informed consent. In addition, the Columbia IRB recommends that the informed consent form for any research that involves the collection of biological samples to be used currently or stored for use in genetic testing include such information to give researchers the maximum flexibility for use of the samples.

For further information, see the Columbia University Institutional Review Board Policy on Research Involving Genetic Testing under Section 79-L of the New York State Civil Rights Law.

G. SAME DAY ELECTIVE SURGERY OR PROCEDURE

Most patients experience some anxiety or disruption of normal habits if undergoing surgery or surgical procedures, which increases the possibility of coercion or undue influence in the consenting process. As a result, the Columbia IRB imposes certain different or additional requirements with respect to obtaining informed consent in such situations. In general, for studies involving more than minimal risk, same day consent is disallowed with rare exceptions considered on a case by case basis.

For further information, see the Columbia University Institutional Review Board Policy on Seeking Consent for Research Participation on the Day of an Elective Surgery or Procedure.

H. RESEARCH USING INTENTIONAL DECEPTION [Table of Contents]

Deception occurs when subjects are intentionally not made aware of, or are misled about, key information about the research study. Research using deception constitutes an alteration for some of the consent elements and the IRB will approve such research only if it meets the waiver or alteration of consent criteria listed in Section VII above, the research could not be conducted without the deception, and all other IRB review criteria are satisfied. Deception is most often used in minimal risk research. When deception is used, the IRB will usually require a debriefing process at the end of the research project to provide subjects with the information that was previously withheld and an explanation of why deception was used.

I. OTHER VULNERABLE INDIVIDUALS; SURROGATE CONSENT [Table of Contents]

1. Subjects with Low Literacy and Numeracy

These subjects include individuals who have capacity to provide consent, but cannot read or write or work well with numbers. With these subjects, oral presentation of the information that is required to be in the consent document to the subject is the favored approach, with a witness to the oral presentation who also signs the consent document. The witness can be the subject's LAR, if applicable, or another person not involved in the research. Subjects who cannot write can indicate their consent by "making their mark" on the consent document, with an indication in the research record as to the reason for the lack of a signature.

2. Subjects with Physical or Sensory Disabilities

Subjects with physical or sensory disabilities (for example, physically unable to talk or write or with hearing or visual loss), can enroll in a study, so long as accommodations are made to meet their disabilities and the study records contain documentation of the informed consent process. It is also recommended that investigators provide reasonable modifications and auxiliary aids and services when necessary. For example, for subjects with vision disabilities, the investigator could use an audio recording of the consent form or a consent form with enlarged font.

3. Subjects with Impaired Capacity to Consent

Potential subjects may have impaired consent capacity, whether partial impairment, impairment that fluctuates over time or complete impairment. For example, this might occur with a wide range of disorders and conditions, such as a brain tumor, dementia, stroke, traumatic brain injury, intellectual and developmental disabilities, serious mental illness, intoxication and delirium (collectively, **Impaired Capacity).** These conditions may require modifications to the process of obtaining informed consent from such individuals.

Where researchers are unable to obtain first-person informed consent from a participant due to Impaired Capacity, researchers may rely on informed consent from a Surrogate in combination with assent from the participant, where the participant is able to provide such assent. Assent should be obtained through written or oral communication where possible. If a participant with Impaired Capacity that is capable of giving assent fails to do so, the participant cannot be enrolled in the study. Further, if signs of dissent are present, the researcher may not enroll the participant.
Federal law clearly contemplates allowing LARs to consent to research involving adults with Impaired Capacity (45 CFR 46.112). As indicated in the definition of LAR in Section III above, the federal government looks to the applicable state law and, if necessary, institutional policy for the definition of who constitutes a LAR. As most of the research at the University is conducted in New York State (**NYS)**, NYS law is typically the governing law for legal questions involving human subjects research at the University. There are two applicable NYS laws that touch on this subject. The 1975 NYS Public Health Law Article 24A unambiguously allows reliance on LARs for human subjects research; however, it does not provide a statutory definition of, or hierarchy for, LARs. On the other hand, the 2010 NYS Family Health Care Decision Act (**FHCDA)** does create a statutory framework for health care decision making and provides a Surrogate consent hierarchy in certain health care settings, but does not deal with research.

To try to harmonize these two laws, a NYS Task Force on Life and the Law (**Task Force)** was established to review the issues relating to research with individuals with Impaired Capacity. The Task Force's 2014 Report and Recommendations for Research with Human Subjects Who Lack Consent Capacity concluded that if the two statutes are taken together, there is sufficient overlap between health care and research to justify the use of the rules established for health care decision-making in the research context without new legislation. It recommended that the IRB establish policies and procedures for approving and overseeing research with individuals with Impaired Capacity.

Therefore, at this time, for human subjects research conducted in NYS, the following persons may act as a Surrogate:

- An individual who is designated as a representative/agent through a health care proxy or research advance directive (RAD) that is appropriately executed. For a health care proxy or RAD 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 or RAD govern (e.g., prohibiting all research or permitting only research which may provide a direct benefit); and
- If an individual who satisfies the requirements of either of the two bullet points 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 spouse (if not legally separated from the subject) or a domestic partner;
    - A son or daughter 18 years of age or older;

- A parent;
- A brother or sister 18 years of age or older; and
- A close friend or relative (meaning a person 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.

At the University, obtaining consent for research purposes from a Surrogate rather than directly from the subject (**Surrogate Consent)** requires the prior approval of the IRB. The IRB may allow use of Surrogate Consent only for subjects with Impaired Capacity to provide their own consent.

The IRB will generally consider the use of Surrogate Consent for research that (a) provides the prospect of direct benefit to subjects who lack capacity; or (b) studies disorders, conditions, or factors that affect individuals witih Impaired 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 IRB reviews a protocol described in clause (b) of the preceding sentence, it is more likely to favorably consider it if it includes 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.

Subjects who appear to lack capacity must have the assessment of capacity made by a licensed physician in accordance with standard practice and applicable state law. In general, the determination that the subject with Impaired 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.

NYS 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 for a research study with subjects having Impaired Capacity must 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 records should document which research procedures were already performed or remain to be performed.

[Table of Contents]