

Documentation of verified exemptions consists of the reviewer's citation of a specific exemption category and written concurrence that the activity described in the investigator's request for exemption satisfies the conditions of the cited exemption category.

4.5 DOCUMENTATION OF EXPEDITED REVIEWS

IRB records for initial and continuing review by the expedited procedure must include: the specific permissible category, a description of action taken, if any, by the reviewer, and any determinations required by the regulations and study-specific findings supporting those determinations.

4.6 RECORD RETENTION

The above detailed records must be stored securely by the HRCO and must be retained for at least three years after final close-out of the research. IRB records not associated with research or for studies closed without participant enrollment will be retained at the facility for at least three years after closure.

After that time, those records may be securely destroyed. All records must be accessible for inspection and copying by authorized representatives of the OHRP, sponsors, and other authorized entities at reasonable times and in a reasonable manner.

Records are primarily maintained electronically on secure servers and are available only to IRB members, HRCO staff, and senior leadership, as necessary. Some historical documents are maintained in paper format.

5. OBTAINING AND DOCUMENTING INFORMED CONSENT FROM RESEARCH PARTICIPANTS

5.1 PURPOSE

The following procedures describe the requirements for obtaining and documenting consent from participants in research conducted under the auspices of New York University.

5.2 DEFINITIONS

Legally Authorized Representative (LAR):

A LAR is 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 procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

Legal guardian:

A person appointed by a court of appropriate jurisdiction.

Clinical trial:

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

5.3 INFORMED CONSENT PROCESS

Informed consent must be obtained under the following circumstances:

1. Informed consent may only be obtained from participants who have the legal and decisional capacity to give consent. For participants without that capacity, consent must be obtained from a legal guardian or a legally authorized representative.
2. The informed consent process shall be sought under circumstances that provide the participant or LAR with sufficient opportunity to consider whether to participate.
3. The informed consent process shall be sought under circumstances that minimize the possibility of coercion or undue influence.
4. The informed consent information must be presented in language that is understandable to the participant or LAR given the target participant population and context of the research. Layman's terms shall be used in the description of the research.
5. The informed consent process must give prospective subjects the information that a reasonable person would want to have in order to make an informed decision about whether to participate.
6. The information needs to be presented in sufficient detail and organized and presented in a way that facilitates an understanding of why one might, or might not, want to participate. The key information about the study must be provided at the beginning. This should include information about the purpose, the risks,

the benefits, and the alternatives, and explain to the person how to think about these pieces of information in terms of making a decision. It should be presented in a concise and focused manner.

7. For participants who are not competent to provide consent in English, informed consent must be obtained in a language that is understandable to the participant or the participant's LAR. The IRB requires that informed consent conferences include a reliable translator when the prospective participant does not understand the language of the person who is obtaining consent.
8. The informed consent process may not include any exculpatory language through which the participant is made to waive, or appear to waive, any of the participant's legal rights or through which the investigator, the sponsor, the University, or University employees or agents are released from liability for negligence, or appear to be so released.
9. The PI is responsible for ensuring that each prospective participant is adequately informed about all aspects of the research and understands the information provided.

5.3.1 BASIC ELEMENTS OF INFORMED CONSENT

The basic elements of consent are:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the participant's participation, a description of the procedures to be followed, and identification of any procedures which are experimental; a description of any reasonably foreseeable risks or discomforts to the participant;
2. A description of any benefits to the participant or to others which may reasonably be expected from the research;
3. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant
4. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;
5. For research involving more than minimal risk, an explanation as to the availability of medical treatment in the case of research-related injury, including who will pay for the treatment and whether other financial compensation is available;
6. An explanation of whom to contact on the research team for answers to pertinent questions about the research or to voice concerns or complaints about the research, and whom to contact in the event of a research-related injury to the participant
7. Contact information for the IRB to obtain answers to questions about the research; to voice concerns or complaints about the research; to obtain answers to questions about their rights as a research participant; in the event the research staff could not

be reached; and in the event the participant wishes to talk to someone other than the research staff;

8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled;
9. If the study involves the collection of identifiable private information or identifiable biospecimens, notice about whether participants' information or biospecimens collected as part of the current research might be stripped of identifiers and used for other research in the future. Consent forms must indicate either that information or biospecimens collected for the research might be stripped of identifiers and used in other research in the future, or that this will not occur. Note that this is only about future research use of information and biospecimens that will be stripped of identifiers.

5.3.2 ADDITIONAL ELEMENTS OF INFORMED CONSENT

When appropriate, the following elements may be applied:

1. A statement that the particular procedure or treatment may involve risks to the participant which are currently unforeseeable.
2. A statement that if the participant is or becomes pregnant, the particular procedure or treatment may involve risks to the embryo or fetus, which are currently unforeseeable.
3. Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent.
4. Any additional costs to the participant that may result from participation in the research.
5. The consequences of a participant's decision to withdraw from the research.
6. Procedures for orderly termination of participation by the participant.
7. A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant.
8. The approximate number of participants involved in the study.
9. Notice to participants that their biospecimens (even if identifiers are removed) may be used for commercial profit and whether they will or will not share in this commercial profit, whether clinically relevant research results will be returned to the participants, and whether research activities will or might include whole genome sequencing.

5.3.3 DOCUMENTATION OF INFORMED CONSENT

Informed consent must be documented by a written consent form (either in paper or in an electronic format) approved by the IRB unless a waiver of documentation of consent is approved.

1. Informed consent is documented by a written consent form approved by the IRB and signed and dated by the participant or the participant's LAR at the time of consent.
2. A copy of the signed and dated consent form shall be given to the person signing the form.
3. The consent form may be either of the following:
4. A written consent document that embodies the basic and required additional elements of informed consent. The consent form may be read to the participant or the participant's LAR, but the participant or representative must be given adequate opportunity to read it before it is signed; or
5. A short form written consent document stating that the elements of informed consent have been presented orally to the participant or the participant's LAR.

When this method is used:

- there must be a witness to the oral presentation; and
- the IRB must approve a written summary of what is to be signed by the participant or representative; and
- the witness must sign both the short form and a copy of the summary; and
- the person obtaining consent must sign a copy of the summary; and
- a copy of the summary must be given to the participant or representative, in addition to a copy of the short form.

5.4 WAIVER OF INFORMED CONSENT

The IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent, provided the IRB finds and documents that:

1. The research involves no more than minimal tangible or intangible risk to the participants;
2. The waiver or alteration will not adversely affect the rights and welfare of the participants;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the participants must be provided with additional pertinent information after participation.
5. For research with identifiable private information or identifiable biospecimens, the IRB must determine that the research could not practicably be carried out without using the information or biospecimens in an identifiable form.
6. In addition, an IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent, or waives the requirements to obtain informed consent, provided the IRB finds and documents that:
7. The research or demonstration project is to 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.
8. The research could not practicably be carried out without the waiver or alteration.

5.5 WAIVER OF DOCUMENTATION OF INFORMED CONSENT

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all participants if it finds that:

1. The only record linking the participant and the research would be the consent document and the principle risk would be potential harm resulting from a breach of confidentiality, and the research is not FDA-regulated. Each subject (or LAR) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

2. The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context; or
3. The participants or LAR 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 provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

In cases in which the documentation requirement is waived, the IRB requires the investigator to provide in the application materials a written summary of the information to be communicated to the participant, and the IRB will consider whether to require the investigator to provide participants with a written statement regarding the research.

5.6 SCREENING, RECRUITING, OR DETERMINING ELIGIBILITY

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 participants without the informed consent of the prospective participant or the LAR, if either of the following conditions are met:

(1) The investigator will obtain information through oral or written communication with the prospective participant or LAR or

(2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

5.7 POSTING OF THE CLINICAL TRIAL CONSENT FORM

(1) For each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll participants must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal Web site that will be established as a repository for such informed consent forms.

(2) If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal Web site (e.g. confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.

(3) The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any participant, as required by the protocol.

6. QUALITY ASSURANCE: POST-APPROVAL MONITORING OF APPROVED HUMAN SUBJECT RESEARCH

This Standard Operating Procedure describes the policies and procedures for the post-approval monitoring of human subjects research under the NYU HRPP Post Approval Monitoring Program (PAM).

6.1 PURPOSE

The purpose of post-approval monitoring of studies involving human subject research is to confirm by observation, interviews with study staff and the PI, and documentation comparison, an accurate and consistent protocol performance, conducted in accordance with the IRB-approved protocol. Through its evaluation process, the program educates investigators on best practices for conducting their human subject research to maintain compliance with their IRB-approved protocol, NYU HRPP, and IRB policies and guidelines, and Federal regulations. The program helps investigators, their teams, and the University prepare for external audits by granting, regulatory, and accreditation agencies.

6.2 ROLES

The purpose of the IRB is to help researchers ensure that the rights and safety of human participants in their research are protected and that they conduct their research in compliance with applicable regulations. To achieve this, the IRB:

1. advises investigators in the design of research projects that minimize potential harm to participants,
2. reviews all planned research involving human participants before initiation of the research,
3. only approves research that meets established criteria for protection of human participants, and
4. monitors approved research to ensure the protection of the research participants.