



Instructions for Submitting Research Proposals to the Altru Health System Institutional Review Board

Submit application of **Human Subject Review Form; HIPAA Form; IRB training certification; Student Consent Release as well as Application to Conduct Research and Data Request Form** to:

Marie-Laure Reese, IRB Reliance Specialist
IRB Office - Altru Hospital
1200 S. Columbia Rd,
Grand Forks, ND 58201

Telephone: (701) 780-6161
e-mail: mreese@altru.org

Introduction

At Altru Health System (AHS), any research that involves humans as subjects must be reviewed and approved by the Altru Health System Institutional Review Board (IRB) or a cooperative external IRB before the research begins. The Altru Health System IRB is authorized to approve research projects involving human subjects which are conducted in any Altru Health System facility. The establishment of the IRB at health care institutions such as those at Altru Health System has been mandated by the federal government in order to protect human subjects.

In evaluating a research proposal, the IRB employs a risk-benefit analysis, in which the risks of the research (e.g., physical, emotional, or psychological dangers to the subjects) are weighed against the actual or potential benefits resulting from the study (e.g., advances in scientific knowledge or improvement of subjects' well-being). This approach requires that as the risks to the subjects increase, so should the benefits from the research. When subjects are going to be experiencing high levels of "risk" in a study, it is important to explain why less intrusive or stressful procedures are not being used. Adequate justification for research that contains risks to the subjects must be provided.

The IRB also needs to know what the human subjects will be required to do in the study, how subjects will be recruited, how risks will be minimized or prevented, how confidentiality will be protected, and the process by which fully informed consent from the subjects will be obtained. The consent document to be used must be submitted to be reviewed by the Board. It is essential that the consent document be in lay language, with any abbreviations or technical terms adequately explained.

Process

The process which follows applies to all studies in which human subjects are to be used (includes retrospective chart reviews).

1. Complete a Human Subjects Review Form and submit the original to the Institutional Review Board office for review. Include any supporting document (such as consent form, questionnaire...) with the form.
2. Complete a HIPAA Form (see pages 3 & 4 for explanation how to complete the HIPAA form)

3. If a Researcher is part of Altru Health System as well as the University of North Dakota, their project will have to be reviewed by the Altru Health System IRB and the University of North Dakota IRB.
4. Decide whether expedited, exempt, or full board review is appropriate for your project and include, if possible, the category under which it qualifies for exempt or expedited reviews. (See definitions below) If you are undecided as to which category is appropriate for your project, the Altru Health System IRB chairperson will make the decision.
5. All proposals that will require full board review must be submitted to the Altru Health System IRB office 14 days prior to the scheduled meeting – You can call or email the IRB office to find out the deadline.
6. Approval to conduct the project at Altru must be obtained prior to be review by the IRB. Please fill out the “Application to conduct research at Altru Health System”. Also, if needed data build from the IS depart., fill out the “AHS Data Request Form. For any assistance, please call the IRB office.
7. The number of copies of completed forms to be submitted and the subsequent process steps depend on the nature of the project and the type of review required (see below).
8. Make sure to include an IRB training such as CITI or other for the entire research team. (certification less than 3 years old).

Types of Review

FULL BOARD REVIEW:

Definition: Projects where there is a physical risk or potential for injury or harm to the subject’s dignity or well being required a FULL BOARD review before the entire Institutional Review Board.

Requirements: Submit the original (wet ink signature) with (3) copies and an electronic copy of the Human Subjects Review Form along with consent form, questionnaire, and supporting documentation to the IRB office for distribution to the members. Only the original (wet ink signature) is needed for the HIPAA form as well as the “Application to conduct Research” form.

EXEMPT REVIEW: (see pages 5 and 6 with complete description of Exempt categories)

Definition: Federal regulations classify certain types of projects as EXEMPT from the requirements of the Common Rules. The project still must receive initial approval from the IRB.

Projects in these classifications are not exempt from review – only from FULL BOARD review and subsequent continuing review.

Requirements: Projects qualifying for exempt review can be approved by a single authorized reviewer. Submit the original Human Subjects Review Form along with any supporting documentation to the IRB office. The project will be reviewed by a designated member of the IRB. Research projects qualifying for Exempt Review can be submitted at any time.

EXPEDITED REVIEW: (see pages 6, 7 & 8 with complete description of Expedited categories)

Definition: Federal regulations allow certain types of projects to receive EXPEDITED review.

Requirements: Expedited projects can be approved by a single authorized reviewer. Submit the original Human Subjects Review Form with any supporting documentation (such as consent form, questionnaire...) to the IRB office to be reviewed by the designated member of the IRB. Research projects qualifying for Expedited Review can be submitted at any time.

- The study must present no more than minimal risk to subjects
- Involve only procedures listed in one or more of the expedited categories (*see below*) for the listing categories
- If the IRB designee determines that the study involves more than minimal risk, the reviewer can override that presumption, but the reviewer must document it and the study will have to go for a full board review at the next IRB meeting.
- Although continuing review is no longer a requirement of the new Common Rule, Altru Health System IRB has made a determination at a convened meeting that all expedited research at AHS will continue to be subjected to the pre-2019 Common Rule continuing review process.
- The expedited review procedure will be used to conduct Limited IRB Review.
- When the study is finished the IRB requests that the researchers fill out the “Research Project Termination Form” found in the Altru.org under “IRB”; “Forms” or under Altrulink.org, under “IRB”; “Form”.

Notification of IRB Decision

Written notice of the IRB decision regarding the project will be sent to the research with the approval to conduct research at Altru Health System. The following actions may be taken based on the IRB decision:

Full Board Approval with minor modifications required: Do not initiate project until modifications have been made and reviewed by the IRB and final approval has been granted.

Final Approval: Initiate project upon receiving final approval from the Altru Health System IRB and of the participating institution (if applicable).

Approval Denied: Do not initiate project. The researcher may request to appear before the IRB to appeal the decision. Projects submitted as Exempt or Expedited Review may be determined by the reviewer to require full IRB review.

Subsequent Reviews: Full Board Review projects are reviewed annually, unless it has progress to the point where it only includes data analysis or follow-up clinical data as part of clinical care, or when deemed appropriate by the IRB. The Investigator will be notified two months prior to the review date. Exempt and Expedited projects are not subject to annual review, unless the IRB determine otherwise.

Protocol Changes and Amendments: Changes and amendments in research projects/protocols must be submitted as they occur. Use the “Human Subject Review Form (one page)”.

Adverse Events: Serious adverse/unexpected events and deaths must be reported to the IRB within 24 hours of learning of the event. Less serious adverse events must be reported to the IRB as soon as possible. Use the “Adverse Event Report” form.

HIPAA Form - Explanation to help you complete the HIPAA form:

- ❖ Check box A1 and sign page 1 only if you are not using any patient records (paper or electronic) or other health information that can be traced back to the patient by any means, including a code, MR # or date of procedures. **If you check box A1, you do not need to complete the rest of the form.**
- ❖ If you are planning on asking for the patients’ consent prior to accessing or using their medical record, check box A3.

- ❖ Check Box A4 if it is not practical or necessary to (and you don't plan to) obtain patients' consent to access or use their medical record. This typically applies to minimal risk, retrospective chart, review studies.
- ❖ Check Box A5, if you are going to review some charts only to see if these patients would qualify for your study.
- ❖ Boxes A6 + A2 should only be checked if your research is limited to deceased patients or you sign a Data Use Agreement to receive a limited data set (this rarely applies).
- ❖ B- List the health data you are seeking, i.e. procedures, outcomes, labs, side effects, medications, signs/symptoms.
- ❖ C1- Check off all applicable sources of the data listed in B.
- ❖ C2- This question applies to the records you will review. If you are reviewing the patients' complete paper or electronic chart (most chart review research) check unrestricted identifiers.
- ❖ C3- This question applies to how you will record your data.
 - If your data has no identifiers (e.g. MR#, dates of procedure, or code), check first box
 - If your data includes only the identifiers listed after box 2, check box 2
 - If you code the data to allow you to go back and identify the patient (useful if you want to collect more data later), check box 3
 - If your data contains MR#, or other identifiers (beyond limited identifiers above) listed in A1, check box 4
- ❖ D- For student/residents doing chart review research for example, you may want to state "medical records will be used to collect (list data you will record) which will be analyzed to (list purpose of the study) and will be shared with my/our research advisor.
- ❖ E- For Students/Residents doing chart review research, check #6 and state that patients will be identified by ICD-9 codes related to the diagnosis/condition of interest. If Physicians/Residents are studying their own patients only, check box 1. If other physicians' patients are to be studied as well, check all boxes (2-4) applicable.
- ❖ F1- For Students/Residents doing chart review research, check colleagues/collaborators if advisor will also see your data, statistician if you use one and publication if planned.
- ❖ F2- In what format will you share your data – Potentially same as C3 (how you will record your data), except if data is coded and you do not need to share the code, then check without any identifiers.
- ❖ G1- Check all that applies. If coded data is on a laptop best to keep the code and master list in separate files. Another level of protection could include encryption of the data for example.
- ❖ G2- Hardcopy data should be in a secure location. Specify if locked file cabinet, office or both. If C3 was coded data, check data coded box. If C3 was de-identified check data de-identified box.
- ❖ H – Complete only if A4 or A5 checked
 - 1- List same information given in B + C1
 - 2A- For chart review research on non sensitive topics, state that the study will utilize only limited non sensitive information
 - B- If data is de-identified, state N.A. If data is coded, state where master list and code is kept and how it is secured and who will have access to it. If data has identifiers, state how data is secured (see G1 + G2) and who has access.
 - C- Describe how/when identifiers will be destroyed. For example, data files will be deleted using file removing software at the completion of the study.
 - D- For chart review studies, state that identifying and contacting subjects to get their permission to review their medical records would not be feasible.
 - E- For chart review studies, state that the information needed to answer the research question can only be found in the patients' medical record.

- F- State that only the patients' medical record contains all the data needed to answer the research question.
- ❖ Sign the bottom of page 5.

EXEMPT CATEGORIES

45 CFR 46.101(b)

Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from Full Board review and may be approved by a single member of the Board.

- (1) Research in Established or Commonly Accepted Educational Settings where Students' opportunity to learn required educational content, or the assessment of educators who provide instruction is not adversely impact.
- (2) Educational Tests, Surveys, Interviews, Observations of Public Behavior Research that only includes interactions involving educational tests, surveys, interviews, and observations of public behavior, only if at least one of the following is met:
 - a. Information recorded cannot be readily linked back to subjects, or
 - b. Any information disclosure would not place subjects at risk of harm.
(Risk of harm refers to the risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation)
 - c. Identifiable information is recorded with limited IRB review for privacy and confidentiality protection under 46.111(a)(7).
- (3) Research involving benign behavioral interventions with adults who prospectively agree and when information collection is limited to verbal or written responses (including data entry) or audiovisual recording, and:
 - a. Information recorded cannot be readily linked back to subjects, or
 - b. Any information disclosure would not place subjects at risk of harm, or
 - c. Identifiable information is recorded with limited IRB review for privacy and confidentiality protection under 46.111(a)(7).
- (4) Secondary Research for Which Consent is Not Required
Category 4 does not require informed consent if at least one of the criteria listed below is met:
 - a. Use involves publicly available identifiable private information or identifiable biospecimens
 - b. Information, which may include information about biospecimens, is recorded by the investigator in such a way that the identity of the subjects cannot be readily ascertained, and the investigator will neither contact the subjects nor re-identify subjects
 - c. Research use of identifiable health information when that use is regulated by HIPAA as health care operations, research, or public health activities and purposes as those terms are defined in HIPAA
 - d. Analysis of data on behalf of a federal agency department – as opposed to an investigator-initiated analysis of federally supplied data – if the requirements of certain federal laws are met. Please note: data do not need to be existing (“on the shelf”) at the time of the research study. That data can be collected prospectively and still be used for exempt research under Category 4 in the Final Rule.
- (5) Research and Demonstration Projects that Are Conducted or Supported by a Federal Department or Agency

This category allows research supported by a federal agency (not just conducted) to qualify for this exemption.

- (6) Taste and food quality evaluation and consumer acceptance studies:
 - a. If wholesome foods without additives are consumed or
 - b. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
- (7) Storage or Maintenance for Secondary Research for which Broad Consent is Required
Note: This category is for the storage of identifiable biospecimens and identifiable private information, prior to secondary analysis. The storage or maintenance may be exempt if the IRB conducts a Limited IRB Review to determine if appropriate documented (or documentation) and if a change is made in the storage process that there are adequate provisions to protect the privacy of subjects and confidentiality of data and if broad consent is obtained.
- (8) Secondary Research for Which Broad Consent is Required
Category 8 allows the secondary analysis of existing private identifiable data and identifiable biospecimens provided broad consent was secured and the documentation of consent was either secured or waived. The IRB will also conduct a Limited IRB Review to determine that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data as noted in 46.111(a)(7), and that the use is within the scope of the broad consent. Finally, category 8 also requires that the investigator does not include returning individual research results to subjects as part of the study plan; however, the exemption does not prevent investigators from returning results if required by law.

- If your study falls into a category requiring Limited IRB Review, please document in details how you are maintaining the privacy and confidentiality of the patients and data.

EXPEDITED REVIEW

45 CFR 46.110

21 CFR 56.110

- 1. Research activities that (a) present no more than minimal risk to human subjects, and (b) involve only procedures listed in one or more of the following categories.
- 2. The categories in this list apply regardless of the age of the subjects, except as noted.
- 3. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- 4. The expedited review procedure may not be used for classified research involving human subjects.
- 5. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.

6. Categories one (1) through seven (7) describe the correct types of expedited research.

- (1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- (2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - (a) From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - (b) From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
- (3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples:
 - (a) Hair and nail clippings in a nondisfiguring manner;
 - (b) Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
 - (c) Permanent teeth if routine patient care indicates a need for extraction;
 - (d) Excreta and external secretions (including sweat);
 - (e) Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
 - (f) Placenta removed at delivery;
 - (g) Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
 - (h) Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
 - (i) Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
 - (j) Sputum collected after saline mist nebulization.
- (4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:

- (a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
 - (b) Weighing or testing sensory acuity;
 - (c) Magnetic resonance imaging;
 - (d) Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
 - (e) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
- (5) Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.104(d)(2). This listing refers only to research that is not exempt.)
- (6) Collection of data from voice, video, digital, or image recordings made for research purposes.
- (7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.104(d)(2) and (d)(3). This listing refers only to research that is not exempt.)
- (8) Continuing review of research previously approved by the convened IRB except when research has progressed to the point that it involves only one of the following, which are part of an IRB approved study:
- (a) Data analysis including analysis of identifiable private information or identifiable biospecimen; or
 - (b) Accessing follow-up clinical data from procedures that subjects would undergo as part of their clinical care.
- (9) Continuing review of research not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Note: Children are defined in the HHS regulations as “persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.” 45 CFR 46.402(a).

- If your study required broad consent, then you will need to complete another form and answer the questions from SOP 20 “Expedited, Exempt & Limited IRB Review”, on pages 5, 6 and 7. You can request the form by emailing or calling the IRB Reliance Specialist.

Informed Consent Requirements

Federal regulations require that certain information be included in all consent forms for research studies. The following pages outline the informed consent requirements prescribed by federal regulations.

In addition to the federal requirements relating to confidentiality of records, the following statement needs to be on the consent forms for studies conducted at Altru Health System facilities:

“I understand that my medical records and study records are confidential. However, representatives of the study sponsor, the U.S. Food and Drug Administration (FDA), or the Institutional Review Board (IRB) may need to inspect my medical and/or study records. By signing this consent, I am allowing this inspection.”

REGULATIONS PERTAINING TO INFORMED CONSENT

45 CFR 46.116

21 CFR .20 & 25

45 CFR 46.116 General requirements for informed consent.

Except as provided elsewhere in this or other subparts, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the 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.

- (a) Basic elements of informed consent. Except as provided in paragraph (c) of this section, in seeking informed consent the following information shall be provided to each subject:
- (1) A statement that the study involves research, an explanation of the purposes 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;
 - (2) A description of any reasonably foreseeable risks or discomforts to the subject;
 - (3) A description of any benefits to the subject or to others that may reasonably be expected from the research;
 - (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
 - (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
 - (6) For research involving more than minimal risk, an explanation as to whether any compensation 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;
 - (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
 - (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may

discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

- (9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

- (i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
- (ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

- (b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall 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) that are currently unforeseeable;
- (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative'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 that may relate to the subject's willingness to continue participation will be provided to the subject;
- (6) The approximate number of subjects involved in the study.
- (7) 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 this commercial profit'
- (8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
- (9) 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).

- (c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

- (1) The research is to be conducted for the purpose of demonstrating or evaluating:
 - (i) Federal, state, or local benefit or service programs which are not themselves research programs, (ii) procedures for obtaining benefits or services under these programs, or
 - (iii) possible changes in or alternatives to these programs or procedures; and
- (2) The research could not practicably be carried out without the waiver or alteration.

- (d) An IRB may approve a consent procedure which does not include, or which 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 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.
- (e) The informed consent requirements in these regulations are not intended to pre-empt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.
- (f) Nothing in these regulations is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

45 CFR 46.117 Documentation of informed consent - 21 CFR 50.27

- (a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.
- (b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:
- (1) A written consent document that embodies the elements of informed consent required by 46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or
 - (2) A "short form" written consent document stating that the elements of informed consent required by 46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the "short form."
- (c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects 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.

In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.