Allina Health

The Research Consent Process: A Guide for Researchers

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Allina Health
Institutional Review Boards (IRB)
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Policy Statement

No investigator may involve a human being as a subject in research without obtaining the legally effective consent of the subject or the subject's legally authorized representative unless a waiver of consent has been approved by the IRB.

1. Consent must always be sought under circumstances that . . .
   a. Provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and
   b. Minimize the possibility of coercion or undue influence.

   The IRB will review details of the consent process as well as the qualifications of the individual(s) who will be obtaining consent (e.g., the investigator, sub-investigator, or qualified designee). When the potential subject's understanding of the research may be impaired, the IRB may require an alternative process. (For example, the IRB may require that only the investigator or sub-investigator obtain consent or that consent be obtained prior to entry into the cardiac catheterization waiting area.)
2. There may not be discrepancies between the consent document(s) and the IRB forms, protocol, or investigator's brochure.
3. The information given to the subject or the representative must be in language understandable to the subject or the representative. The IRB asks the investigator to strive for an eighth-grade reading level in all consent forms.
4. The consent form may not contain exculpatory language through which the subject or the representative is made to . . .
   a. Waive or appear to waive any of the subject's legal rights or
   b. Release or appear to release to the investigator, the sponsor, Allina Health, or its employees or agents from liability or negligence.
5. In seeking informed consent, the basic elements of informed consent (as stated in 45 CFR § 46.116(a)(1-8) and 21 CFR § 50.25(a)(1-8) must be provided to each subject unless the IRB has approved an alteration of the basic elements.
6. The IRB may request that one or more of the additional elements of consent (as stated in 45 CFR § 46.116(b)(1-6) and 21 CFR § 50.25(b)(1-6) also be provided to participants.
7. Allina Health IRBs require that investigators include the following information in consent forms for clinical trials:

- Allina Health Research Subject's Bill of Rights
- Conflict of Interest Statement (when applicable)
- Billing Error Statement (when applicable)
- IRB Contact Information

8. Unless the IRB has approved a waiver of documentation of informed consent, all subjects or their legally authorized representatives must sign and date a current, Allina Health IRB-approved consent document. Current IRB approval will be documented by a stamp on the signature page of the consent form and/or assent form that indicates the date of approval. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator must give either the subject or the representative adequate time to read the consent document before signing.
9. A copy of the consent form must be given to the person signing the form.
10. Researchers must document consent for research in the subjects' medical records when protocol-directed interventions take place.
11. A copy of the signed consent form must be available on short notice for audit or regulatory review.

The Research Consent Process

Summary

The goal of the consent process is to provide information about the purposes for participation in a research study, including such things as risks, benefits, alternatives, and procedures and to educate the potential subject so that he or she can make an informed decision about whether or not to participate in the study.

Consent is an ongoing process that should be revisited often throughout the study. The process is a continuous interaction between investigator and research subject that begins at the time of subject recruitment and ends only after the study has been completed.

At the time of recruitment, the research subject's understanding of the risks, benefits, procedures, and purposes is usually documented in an agreement—the consent form—and signed by the subject (or a legally authorized representative) before the research begins.

When obtaining consent from a research subject, it is the investigator's (or the person responsible for obtaining consent) responsibility to present all information (both verbal and written) in a clear and comprehensive manner in order to maximize the potential subject's understanding.

This section contains some tips for talking with potential subjects and for writing a clear consent form.

Talking with Potential Subjects

Recruitment of potential subjects begins with a conversation between a study representative (usually the principal investigator or the study coordinator) and the potential subject. The suggestions below provide some ways to gauge if the potential subject understands what is being asked of him or her.

Prior to an Invitation to Participate in Your Research Study

Find out whether the potential subject is familiar with or has experience with research studies. If he or she is not, educate the potential subject about research studies, the differences between research participation and standard care, and their rights as a research subject.

During the Presentation of the Research Study and the Consent Form

- Ask the potential subject questions about the material you are presenting, including questions about the risks, benefits, and purpose of the study.
- Instead of "yes" or "no" questions, ask open-ended questions. For example, ask the potential subject to explain in his or her own words the risks, benefits, and purpose of the study as he or she understands them.
- Encourage the potential subject to ask questions in response to the information provided and allow enough time during the conversation to answer the questions.

After the Presentation, but Before the Potential Subject Signs the Consent Form

- Allow time for the potential subject to discuss his or her participation in the study with family members and/or friends.
- Provide outside resources (e.g. websites or medical journal articles), if the potential subject would like to do additional research about the study or his or her condition.
- Provide a copy of the consent form for the potential subject to review with family members, friends, or the primary care provider.
- Some potential subjects benefit from talking to other research subjects. Consider whether this is a feasible option, and maintain a list of subjects who are willing to talk about their experiences.

Creating Clear Consent Forms

Carefully formatted and well-organized consent forms are easier for potential subjects to read and understand. A form that is difficult to read because it uses complicated words or because the type is too small reduces the chance that the potential subject will read the entire form and understand what is involved in this study.

To create a form that is understood by potential subjects, Allina Health recommends that you follow these tips for writing consent forms.

Formatting Tips

1. **Typeface**

   Use reasonable type sizes (no less than 11 or 12-point font). If an investigator knows that the study population may have difficulty reading small print, the investigator should use a larger font and type size. When revising an existing consent form, make sure that the font size is consistent throughout. (Inconsistent font sizes are often noted as stipulations.)

Tip

Readability studies have shown that serif fonts are easier to read. Serif fonts have little embellishments on the tip and base of each letter, making them more distinct and recognizable. The idea is that the serifs actually make the letters flow together and, consequently, are easier on the eyes. For this reason, nearly all books, newspapers, and magazines use a serif font. (Popular serif fonts include Times New Roman, Palatino, Georgia, Bookman, and Garamond.)

2. First Page

Place the title of the study and the name of the investigator at the top of the first page of the consent form. Do not use the term, "Informed Consent." The title on the consent form should be the same as the study title submitted to the IRB unless the investigator seeks and receives approval from the IRB to alter the title.

3. Page Numbering

a. Number all pages so that missing pages can be easily identified. (Using "Page X of Y" is the best way to ensure that all pages are copied for each subject.)

b. If there are different versions of the consent form, note the version number and/or date in the footer or header on each page.

4. Section Headings

Use section titles to break up the text and make it easier for the reader to find information on a particular topic.

Tips for Writing Headings

- Write sub-headings that describe, summarize, or clearly label each part of the page or article.
- Avoid jargon, acronyms, and other shortened forms unless they are familiar to your target audience
- Start headings and labels with distinguishing information, so those who only look at the first few words can distinguish it from earlier and later headings.
- Avoid using questions as headings as they can push distinguishing words away from the start of a heading.
- Be concise. Headings that wrap to a second line may be harder for some readers to understand.
- Write in title case (i.e., capitalize key words only). Uppercase is harder for people to read.

5. Bullet Points

Whenever possible, use bullet points to set off lists of information. They are especially helpful in the following sections:

- Sequential procedures
- Risks
- Benefits
- Alternatives
- Study Contacts

6. Dating

When revising or updating the consent form, enter the date of the revision in the header or footer.

Content and Language Tips

1. Use appropriate language.

- Use language that is easily understood by the average person with an eighth grade reading ability, the generally accepted standard for newspapers and popular magazines. Simplify complicated sentences as much as possible. Use action words, strong verbs, short sentences, and personal pronouns.
- Keep paragraphs short (two or three sentences) to improve the readability of the form.
- Any technical language or jargon should be defined. See the "Alternatives and Definitions" in Appendix A for further guidance.
- Avoid referring to the intervention as a "treatment" unless you include a modifier such as "study" treatment or "experimental" treatment. Most likely, the purpose of the study is to determine whether the intervention can someday be used as a treatment, but to refer to it as a "treatment" in the context of a research consent form is misleading.
- Refer to measurements in terms understandable to a lay person. For example, convert "10ccs" to teaspoons or tablespoons, or convert the amount of radiation exposure into how much radiation a person is exposed to during a typical day spent out of doors. Convey the information in the simplest manner possible.
- Consider using pictures or diagrams to illustrate sizes or certain procedures.
- Use flowcharts to illustrate complicated study procedures.

2. Tailor the consent form to meet the needs of your potential subjects.

- Develop appropriate foreign-language forms for subjects who are not proficient in English and have a qualified interpreter present to verify the potential subjects' understanding of consent.
- A translated consent form should be back translated to verify the appropriateness of the language.

3. Make sure the consent form makes sense to the average person.

Prior to submitting the consent form to the IRB for review, the investigator should ask a layperson unaffiliated with the study to read the consent form. Often a reader with no vested interest in the study can identify unclear language or information in the consent form that the author might have missed due to their familiarity with the form.

4. Avoid exculpatory language.

- If the subjects agree to waive or appear to agree to waive any of their legal rights or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence, the language is exculpatory.
- Subjects in research studies do not give up any of their legal rights when they agree to participate in a study and sign the consent form. To avoid this possible misunderstanding, do not use exculpatory language.
- Use of legalese is not appropriate in a consent form. Think of the consent document primarily as a teaching tool, not as a legal instrument.
- Avoid using words or phrases such as "relinquish," "give up the rights to," "donate," or "waive the right to."

  Example of exculpatory language:

  "I voluntarily and freely donate any and all blood, urine, and tissue samples to the U.S. Government and hereby relinquish all right, title, and interest to said items."

  Example of acceptable language:

  "By consenting to participate, you authorize the use of your bodily fluids and tissue samples for the research described above."

5. Avoid using statements that begin with "I understand."

Do not use the statement "I understand" to introduce sections in the consent form because its use might be interpreted as coercive or as a poor substitute for sufficient factual information.

6. Write in second person ("you will") rather than first person ("I will"), and avoid shifting from one person to another.

Elements of a Research Consent Form

Summary

Several elements are required in consent forms so that the potential subject has all the information available to make an informed decision about whether or not to participate in a research study. These elements fall into three different categories:

- Federal required elements: Federal regulations require that these elements be included in the consent form.[1]
- Additional federal required elements: Depending on the type of study that is being conducted, certain other elements may be required or their addition to the consent form is highly recommended.[2]
- Allina Health required elements: Allina Health requires that certain elements be included in consent forms submitted to Allina Health IRBs when they are relevant to a study.

Federal Required Elements

At a minimum, federal regulations require that the research consent form contain the following information.

WHAT	WHY	SAMPLE TEXT
Purpose	Informs the subject that the study involves research. Explains why the research is being done and what the researcher is hoping to prove or disprove.	The purpose of the study is to <explain what the study is attempting to prove or find out>.

[1] These elements are spelled out in the federal regulations "Elements of informed consent," section 21 CFR 50.25 and/or "General requirements for informed consent," section 45 CFR 46.116.
[2] These elements are spelled out in the federal regulations "Elements of informed consent," section 21 CFR 50.25 and/or "General requirements for informed consent," section 45 CFR 46.116.

WHAT	WHY	SAMPLE TEXT
Procedures	Describes the procedures to be followed during the study, the expected duration of the study, and identifies any procedures and/or products that are experimental.	If you agree to participate in this study, you will be asked to do the following: <insert information about what will happen at each visit, which tests and procedures the subject is required to participate in, which drugs/devices the subject will be expected to take or use, etc.>
Risks	Describes any reasonably foreseeable risks or discomforts to the subject.	*Insert if the study has risks:* The study has the following risks: List the known risks and/or discomforts the subject may experience. OR *Insert if the study has no known risks:* There are no known risks. But there may be unforeseeable risks that have not yet been identified.
Benefits	Describes any benefits to the subject or to others which may reasonably be expected from the research.	• *Insert the following statement when there are no direct benefits to the participant:* There are no direct benefits to you for participating in this study. • *Insert the following statement when information learned in this study may lead to possible benefits to others in the future:* There may or may not be direct medical benefit to you. We hope the information learned from this study will benefit other patients with your condition in the future. • *Insert the following statement when there are possible benefits to the participant:* Possible benefits you may experience include <list and describe the possible benefits>.

WHAT	WHY	SAMPLE TEXT
Alternatives	Informs the subject about any appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.	• Alternative treatments for patients with <insert the condition or symptom> include the following: <insert a list or description of alternative procedures>. **OR** • *If there is no alternative treatment, include this statement:* There is no alternative treatment for<insert condition or symptom>. **AND/OR** • Your alternative is not to participate in this study.
Costs	Explains what costs the subjects (and/or their insurance providers) may incur as a result of their participation in the study.	*If the sponsor will pay all of the study costs:* There is no cost to you to participate in this research study. *If the sponsor will pay for research costs, and the research subject or insurance will be billed for routine care:* You will be charged for all tests and procedures required for the treatment of your medical condition. If your health insurance or Medicare requires any co-payment, co-insurance or deductible, you will be responsible for the making the payment. The sponsor <insert name> will pay for tests or procedures needed for this study that are not considered routine care for your medical condition.

WHAT	WHY	SAMPLE TEXT
Compensation	Explains what, if any compensation is provided to the subject.	*Insert when there is no compensation:* You will not be paid for participating in this study. **OR** *Insert when there is compensation:* In return for your time, effort and travel expenses, you will be paid <insert amount> for each visit – a total of <insert amount> if you complete the whole study. If you do not complete this study, you will be paid <insert amount> for each visit you complete.
Compensation for Research Related Injury **(Not required for minimal risk studies)**	Informs the subject what to do if they experience any research-related injuries and what their financial responsibilities will be. Make sure that the language that is used in the consent form agrees with the language that exists in the sponsor's contract. Do not use exculpatory language.	If your participation in this research study results in an injury, treatment will be available, including first aid, emergency treatment, and follow-up care, as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company. **AND** *Insert the following statement when the sponsor has NO funds to pay for a research-related injury:* No funds have been set aside to pay for care for injuries resulting from your participation in this study. If you believe you have suffered a research-related injury, notify the researcher immediately at ___. **OR** *Insert when the sponsor has SOME funds available:* The sponsor of the study has set aside some funds to pay for the care of injuries directly related to participating in the study. If you believe you have suffered a research-related injury, immediately notify the researcher at ___. You may be eligible for reimbursement of medical care costs related to the injury.

WHAT	WHY	SAMPLE TEXT
Confidentiality	States the extent, if any, to which confidentiality of records identifying the subject will be maintained. It should include a statement that the Food and Drug Administration may review the records, if the study involves an investigational drug, device, or biologic. This requirement is in addition to requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). If the study involves videotaping of subjects, describe how the videotape will be used, with whom it will be shared, how the subject's identity will be masked, and whether or not the videotapes will be destroyed. Occasionally, videotapes may be saved after the completion of the study for teaching or training purposes. If this is the case, the consent form should state this intended use.	Every effort will be made to be sure that your participation in this study and all records of your participation will remain confidential. But absolute confidentiality cannot be guaranteed. Due to the nature of clinical trial oversight, some funding and regulatory agencies may have the right to review the records of this study. These include the following agencies or groups: <insert funding or regulatory agencies>. **AND IF APPLICABLE:** • *Insert the following statement if you plan to publish or present the study:* No information that could identify you, such as names or addresses, will be used when the results of this study are published or presented. • *Insert the following statement if you are using photos:* Every attempt will be made to disguise identifying features in photographs. • *Insert the following statement if you are using the Internet to transmit data:* Patient data transmitted over the Internet will be encrypted. (This means that it is very difficult for an unauthorized person to see this information.) The utmost care will be taken to make sure all patient data contained in the study is secure.

WHAT	WHY	SAMPLE TEXT
Voluntary Participation	States that participation is voluntary and that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled. It also states that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.[3]	Participation in this study is voluntary. Your decision to participate or not participate in this study will not affect your current or future care with <insert researcher's name> or at <insert hospital/ clinic/ organization>.
Contact Information (Often titled "Contacts and Questions" on the consent form)	States whom to contact for answers to pertinent questions about the research and whom to contact in the event of a research-related injury to the subject	The researcher conducting this study is <list investigator(s) name(s)>. You may ask any questions you have now. If you have questions later, you can contact <him or her> at <insert telephone number>. If you have any questions about your rights as a research subject or complaints about this research study, please direct them to the Allina Health Institutional Review Board Administrative Office at 612-262-4920.

Additional Federal Required Elements

When appropriate for the study, the additional elements in the table below must also be included in the consent form.

WHAT	WHY	SAMPLE TEXT
Unforeseeable risks	States 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.	The drug or procedures may involve risks that are as yet unknown.

[3] 45 CFR § 46.116(a)

WHAT	WHY	SAMPLE TEXT
Termination of a Subject's Participation	States the anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.	The <investigator/sponsor/FDA or other governmental agency> may discontinue your participation in the study without your consent if they feel that it is in your best interest or if you fail to comply with the study procedures, experience a study-related injury or unacceptable side effects. They may also remove you for administrative reasons.
Costs	Explains what costs the subjects (and/or their insurance providers) may incur as a result of their participation in the study.	*If the sponsor will pay all of the study costs:* There is no cost to you to participate in this research study. *If the sponsor will pay for research costs, and the research subject or insurance will be billed for routine care:* You will be charged for all tests and procedures required for the treatment of your medical condition. If your health insurance or Medicare requires any co-payment, co-insurance, or deductible, you will be responsible for the making the payment. The sponsor <insert name> will pay for tests or procedures needed for this study that are not considered routine care for your medical condition.
Withdrawal	Informs the subject of the consequences of withdrawing from the research and explains how the subject may terminate his or her participation in the study.	**Right to Withdraw:** You may withdraw from the study at any time. Your decision not to take part in or to withdraw from this study will not involve any penalty or lost benefits to which you are entitled. Your withdrawal will not affect your access to health care at <insert hospital/clinic>. If you do decide to withdraw, we ask that you contact <insert principal investigator's name and address> to let <him or her> know that you are withdrawing from the study.

WHAT	WHY	SAMPLE TEXT
New Findings	Informs the subject 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.	If we find out new information during the course of the study that may change your willingness to continue (for example, a new, serious side effect), we will contact you.
Size of the Study	Discloses the approximate number of subjects involved in the study.[4]	<*Insert number*> subjects will be enrolled in the study.

Allina Health Required Elements

In addition to the federal requirements, Allina Health's IRB requires that investigators include the following information in all consent forms.

WHAT	WHY	SAMPLE TEXT
Conflict of Interest Statement	Informs the subject if the researcher and/or other study staff member has an actual or perceived conflict of interest in conducting a research study. Conflicts of interest can be defined as any situation in which financial or personal obligations may compromise or present the appearance of compromising an individual's or group's professional judgment in conducting, reviewing, or reporting research.	This study will receive funding from <insert sponsor> for costs related to conducting the study. Include a statement that reflects the researcher's relationship with the sponsor, such as one of the following: • The principal investigator and/or other study personnel do not have a financial interest in the company. • The principal investigator is a consultant for the company. • A spouse/partner/relative of the principal investigator is employed by the sponsor.
Research Subject's Bill of Rights	Informs the subject of his or her rights as a research subject.	See the list of rights online. Please cut and paste this text directly onto the first page of your consent form.
Billing Error Statement	Informs the subject what to do if there is a billing error.	If you believe that you have received a bill in error, contact <insert investigator or study coordinator's name and number>.

[4] 45 CFR § 46.116(b)

WHAT	WHY	SAMPLE TEXT
Contact Information for the IRB **(Found in the Contacts and Questions section on the consent form)**	Investigators conducting research at Allina Health must provide research subjects with contact information for the IRB Administrative Office.	If you have any questions about your rights as a research subject or complaints about this research study, please direct them to the Allina Health Institutional Review Board Administrative Office at 612-262-4920.
HIPAA Privacy Language **Please note Allina Health IRBs prefer that the HIPAA authorization be a separate form.**	If the consent form includes HIPAA Authorization required text, the form must include the correct signature lines.	• Signature of Study Participant & Date of Signature • Signature of Legally Authorized Representative & Date of Signature (if applicable) • Description of Representative's Authority to Act for Subject

Waiving the Research Consent Requirement

The Office of Human Research Protection (OHRP) has granted Institutional Review Boards the authority to waive the entire consent process or to alter or waive some of the required federal elements of consent in some circumstances. (A detailed list of these elements appears in this guide).

In order for the IRB to consider waiving all or part of the consent process, the researcher must prove and document that the request falls under one of two categories.

1. Studies considered minimal risk that meet the criteria listed below under "Minimal Risk Studies."
2. Studies that are considered emergency research that meet the criteria listed below under "Consent Requirements in Emergency Research." These criteria are stringent, and the review process is lengthy, involving discussions with not only the IRB, but also representatives of the communities in which the research will be carried out.

Minimal Risk Studies

1. The research has met all of the following requirements:

    a. The research is to be conducted by or subject to approval of a state or local government official and is designed to study or evaluate or otherwise examine:

    - Public benefit or service programs
    - Procedures for obtaining benefits or services under these programs
    - Possible changes in or alternatives to these programs or procedures or
    - Possible changes in methods or levels of payment for benefits or services under those programs.

    b. The research could not practicably be carried out without the waiver or alteration.[5]

OR

2. The research has met all of the following requirements:

    a. The research involves no more than minimal risk to the subjects.

[5] 45CFR46.116 (c)

b. The waiver or alternation will not adversely affect the rights and welfare of the subjects.

c. The research could not practicably be carried out without the waiver or alteration.

d. Whenever appropriate, the subject will be provided with additional pertinent information after participation.[6]

Consent Requirements in Emergency Research

This waiver is not to be confused with an individual emergency treatment situation, for which informed consent is required.

Please note that *studies that meet all the requirements for this waiver are extremely rare*. The studies are designed to address research questions where ALL of the following are true:

1. The intended study population is unable to give consent as a result of their medical condition.
2. The intervention involved in the research must be administered before consent from the subject's legally authorized representatives is feasible.

AND

3. There is no reasonable way to prospectively identify the individuals likely to become eligible for participation in the research.

If this research is subject to FDA regulations, the following requirements must be met:

1. The research will be carried out under an FDA investigational new drug application (IND) or an FDA investigational device exemption (IDE), the application for which has clearly identified the protocols that would include subjects who are unable to consent.

   AND

2. The requirements for exception from informed consent for emergency research using an investigational device exemption (as detailed in 21 CFR 50.24) have been met relative to those protocols.

If this research is not subject to FDA regulations, the researcher must apply to an Allina Health IRB for an "Emergency Research Consent Waiver" and prove that the research is not subject to regulations codified by the FDA at 21 CFR Part 50 and document and report to the OHRP that the following conditions have been met related to the research:

1. The human subject is in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include

[6] 45CFR46.116(d)

evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.

2. Obtaining consent is not feasible because the subjects will not be able to give their informed consent as a result of their medical condition; the intervention involved in the research must be administered before consent from the subjects' legally authorized representatives is feasible; and there is no reasonable way to prospectively identify the individuals likely to become eligible for participation in the research.
3. Participation in the research holds out the proposed of direct benefit to the subjects because:
    a) Subjects are facing a life-threatening situation that necessitates intervention.
    b) Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual subjects.
    c) Risks associated with the research are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.
4. The research could not practicably be carried out without the waiver.
5. The proposed research defines the length of the potential therapeutic window based on scientific evidence, and the investigator has committed to attempting to contact a legally authorized representative for each subject within that window of time and, if feasible, to asking the legally authorized representative contacted for consent within that window rather than proceeding without consent. The investigator will summarize efforts made to contact representatives and make this information available to the IRB at the time of continuing review.
6. An Allina Health IRB-reviewed and approved informed consent process and document in accord with sections 46.116 and 46.117 of 45 CFR Part 46 are to be presented to the subject or his or her legally authorized representatives in situations where use of such procedures and documents is feasible. The Allina Health IRB has reviewed and approved procedures and information to be used when providing an opportunity for a family member to object to a subject's participation in the research study consistent with the information found in section 7 (e) of this document.
7. The following protections of the rights and welfare will be provided by the investigator to the subject:
    a) Consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the research will be conducted and from which the subjects will be drawn.
    b) Public disclosure to the communities in which the research will be conducted and from which the subject will be drawn, prior to initiation of research, of plans for the research and its risks and expected benefits.

c) Public disclosure of sufficient information following completion of the research to apprise the community and the participants of the study, including the demographic characteristics of the research population, and its results.

d) Establishment of an independent data monitoring committee to exercise oversight of the research.

AND

e) If obtaining consent is not feasible and a legally authorized representative is not reasonably available, the investigator has committed, if feasible, to attempting to contact within the therapeutic window the subject's family member who is not a legally authorized representative, and asking whether he or she objects to the subject's participation in the research. The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.

Consenting Minors

Summary

The consent process for studies that include minors must ensure that both the minors and their parents have been given all the information regarding the risks, benefits, alternatives, procedures, and purposes of the research study so both the potential study participant and the parent(s) or legal guardian(s) can make the best decision about whether or not to participate in the research study.

Because of their varying levels of maturity, adults and minors will approach an invitation to participate in a research study and comprehend the information presented differently. In order to account for these differences, two consent forms are required:

- A parental permission form allowing the child to participate

  AND

- An assent form obtaining the minor's agreement to participate.

Both forms are tailored to the persons who will be reading and signing them and should take into account the maturity level and comprehension abilities of the intended audiences.

Parental permission is documented in a form similar to an adult subject consent form. The language of the form is tailored to invite "your child" to participate. Once parental permission has been obtained, the agreement of the child is required.

The child's agreement is documented with an "assent form." This is a child-friendly document that outlines the essential information about the research. All children eight years through 17 years old should be given an opportunity to assent to participation in a study since most eight-year-olds have the cognitive and emotional maturity to understand a research project and to decide whether they want to participate. Some children under age eight may also be capable of granting and withholding assent, and the IRB asks researchers to be sensitive to the needs of these children on an individual basis.

Researchers should draft a form that is age-appropriate and study-specific, taking into account the typical child's experience and level of understanding and composing a document that treats the child respectfully and conveys the essential information about the study. The form should . . .

- Be written in a child friendly font, such as Comic Sans MS or Verdana.

- Tell why the study is being conducted.
- Describe what will happen and for how long or how often.
- Say it is up the child to participate in the study.
- Tell the child that it is okay to say no or to withdraw from the study at any time.
- Explain whether things that happen in the study will hurt them and for how long or how often.
- List the child's other choices.
- Describe good things that might happen.
- Say whether there is any payment for participating.
- Ask for questions.

Re-consenting Minors Who Become Adults

The Office for Human Research Protections (OHRP) notes that informed consent should be viewed as an ongoing process throughout the duration of a research project. When a child who was enrolled in research with parental or guardian permission subsequently reaches the legal age of consent in ongoing research, the subject's participation in the research is no longer regulated by the requirements of 45 CFR Part 46.408 regarding parental or guardian permission and subject assent.

The investigators should seek and obtain the legally effective informed consent, as described in 45 CFR 46.116, for the now-adult subject for any ongoing interactions or interventions with him or her because the prior parental permission and child assent are not equivalent to legally effective informed consent for the now-adult subject. However, the IRB could approve a waiver of informed consent under 45 CFR 46.116(d), if the IRB finds and documents that the required conditions are met.

Sample Assent Form

A sample assent form for a fictitious cough medicine study appears below. The sample paragraphs were written for children ages 8 to 12. The underlined phrases describe the information to include.

A section describing why the study is being done, why the child is being invited to participate and what the study is trying to find out:

Your doctors know that when you get sick, you cough a lot. We are asking you if you would like to be in an experiment to try a new medicine to help you stop coughing. We will not know if the medicine works unless we try it in an experiment first.

A section describing the procedure and the duration of the study:

If you would like to be in this experiment, you will need to take the medicine only one time. You will take some of this medicine when you start coughing. Then you will tell your parents when you stop coughing and if the medicine made you feel sick or funny in any way. Your parents will write down your answers and give them to the people working on the experiment.

A section telling the child about the risks and benefits:

The medicine might help you stop coughing or might not help at all. It might make you feel sick. You might get a stomach ache or feel tired. You might feel funny in other ways.

A section informing the child of other options and letting the child know that they do not have to participate in study:

You make the choice if you want to be in this experiment. There are other medicines that you can take to help you stop coughing. If you don't want to be in this experiment and take this medicine, you don't have to. Nobody will be mad at you if you don't. Nobody will be mad at you if you decide to be in the experiment and then want to quit later.

A section encouraging the child to ask questions:

You may ask questions about this medicine or experiment now. If you think of a question later, you can call us on the phone *(insert phone number)* or ask the next time you visit your doctor.

A section explaining what signing this form means:

Being in this experiment is your choice. If you want to be in this experiment, write your name at the bottom of this paper. This tells us that you have read this paper, or that somebody has read it to you. It also means that you want to be in the experiment. If you do not want to be in the experiment, do not write your name on the line.

Child's Signature _____ Date _____

Signature of person explaining study _____

Special Situations

Humanitarian Use Devices

A Humanitarian Use Device (HUD) is a device that is intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect or are manifested in less than 4,000 individuals in the United States per year.[7] In an effort to encourage the discovery and use of devices intended to benefit these small populations of patients, federal regulations allow device manufacturers to seek pre-market approval for such devices through the Humanitarian Device Exception (HDE) process. An approved HDE provides an exemption from the requirement that a device be shown to be effective before pre-marketing approval is granted.

Once approved by the Food and Drug Administration (FDA), a physician must obtain IRB approval for the proposed use of the device. The physician must submit an IRB Application, a protocol for the use of the HUD, a consent form, and FDA documentation of HUD status to the IRB. Although the FDA does not require the use of a consent form for an HUD, Allina Health's IRBs do.

Because the use of an HUD is not research, certain required elements do not apply to the consent form for an HUD. For assistance in creating an appropriate consent form for an HUD, consult the sample HUD consent document in Appendix B.

Non-English Speakers

Federal regulations permit the oral presentation of consent information in conjunction with a "short form" consent document and a written summary of what is presented orally. The short form lists the elements of consent that have been presented orally and provides signature lines. These forms may be used as an alternative to translated consent forms to obtain consent from non-English speaking subjects for studies in which the majority of subjects are English speakers (see 45 CFR 46.117(b)(2)). A short form can be used in these instances to ensure equal access for potential participants. (NOTE: The IRB must approve these materials prior to their use.)

A witness to the oral presentation is required, and the subject must be given copies of the short form document and the summary. (A sample short form appears in Appendix C.) In general, the signature witnesses should not be relatives of the potential subject.

[7] FDA Information Sheet: "Humanitarian Device Exemption (HDE) Regulation: Questions and Answers."

NOTE: Short forms cannot be used as a substitute for a translated consent form when the primary population of a study will be non-English speakers. In such situations, fully translated consent forms should be provided for IRB review with an English Language Version.

Changing an Approved Consent Form

If a consent form requires alterations, the investigator must submit the new form to the IRB for approval prior to its use. Please consult the Allina Health Human Research Protections Program web site for instructions.

Upon approval of the revised consent form, the IRB will provide the investigator with a new, stamped, approved copy of the form.

Appendix A: Alternatives and Definitions for Common Medical and Research Terms

Avoid using technical language and jargon that may be familiar to those in your profession, but not to the average person. The following chart lists common medical terms and their lay explanation.[8]

TERM	LAY EXPLANATION
Absorption	The way that a body takes in a substance
Acute	New, sudden onset of an illness
Adhesion	Two or more tissues sticking to each other
Adverse effect, adverse reaction	A harmful or abnormal result
Adverse event	Any unexpected or dangerous reaction
Aggressive	Quickly growing, tending to spread rapidly
Albuminuria	More than a normal amount of a certain protein in the urine
Allergy	A reaction by the immune system to a particular substance
Amelioration	Improvement in the patient's condition
Amniocentesis	A procedure used to obtain fluid from the liquid surrounding an unborn baby in order to conduct certain tests
Analgesic	A drug that relieves pain
Anaphylaxis	An allergic reaction that can be dangerous or deadly
Anemia	A below average number of red blood cells
Anesthesia	Loss of feeling or awareness
Anesthetic	A substance that causes lack of feeling or awareness
Anoxia	Lack of oxygen
Anterior	Front
Antibiotic	A drug used to treat infections caused by bacteria or germs
Antibody	A protein substance that helps protect the body against another substance
Anticoagulant	A substance used to prevent blood clots
Antihistamine	A drug used to treat an allergic reaction

[8] Source: MedicineNet at www.medterms.com

Antiseptic	Something that prevents the growth of germs
Aphasia	Inability to speak, write, or understand what others are saying or read
Arrhythmia	An abnormal heart rhythm
Artery	A blood vessel that carries oxygen from the heart to the other parts of the body
Arthritis	Inflammation of joints
Asphyxia	Inability to breathe; suffocation
Assay	A lab test
Asymptomatic	Without symptoms
Atrophy	Wasting away
Bacteria	Germs or small organisms
Benign	Not malignant, usually without serious consequences
Beta blocker	Medicine used to slow down or regulate the beating of the heart
Bilateral	Having two sides
Biopsy	The removal of a sample of tissue for testing and diagnosis
Bolus	An amount given all at once
Bone marrow	The soft tissue inside bones that contains fat and blood cells
Capillary	Small blood vessels
Carcinogenic	Causing cancer or contributing to the cause of cancer
Cardiac	Having to do with the heart
Cataract	A clouding of the lens of the eye
Catheter	A thin, flexible tube that can be used to remove fluids or put fluids into the body
Cephalalgia	Headache
Cerebellum	The portion of the brain that controls balance
Chemotherapy	A drug therapy usually used for the treatment of cancers
Chronic	Lasting a long time
Clinical trial	An experiment involving people
Cohort	A group of study subjects or patients
Contraindications	Medical reasons that make it unwise or unsafe for a person to take a particular medicine or have a certain procedure
Control group	A group of subjects used as a standard of comparison in a controlled trial
Controlled trial	A study in which the experimental treatment procedures are compared to a standard treatment procedure

Contusion	A bruise
Cornea	The clear front window of the eye that transmits and focuses light into the eye
Culture	A test for infection or certain substances that may cause infection
Deoxyribonucleic acid (DNA)	Genetic material
Dermatitis	Inflammation of the skin, either due to direct contact with an irritating substance, or to an allergic reaction
Dialysis	The process of cleansing the blood when the kidneys can no longer filter it, by passing it through a special machine
Double-blind trial	A study in which at least two separate groups receive treatment, and neither the investigators or participants know what drug the participant is receiving
Duct	A tube that allows for the flow of air or liquids
Dysphagia	Difficulty in swallowing
Dysphoria	Anxiety
Dysplasia	Abnormal cells
Dyspnea	Shortness of breath
Edema	Swelling due to increased fluid
Efficacy	Effectiveness
Electrocardiogram (EKG/ECG)	A recording of the electrical activity of the heart
Electroencephalogram (EEG)	A study of electrical current within the brain
Embolus	Something that travels through the bloodstream, lodges in a blood vessel and blocks it—usually a blood clot
Emesis	Vomiting
Endorphin	A substance made by the body to kill pain
Epidermal	Having to do with the outer layer of the skin
Epidermis	The outer layer of the skin
Erythema	A redness of the skin resulting from inflammation
Extravasate	To leak outside of a blood vessel
Gastric	Having to do with the stomach
Gland	A group of cells that release substances for use in the body, or remove substances from circulation in the body
Glucose	A sugar that acts as the main source of energy for the body
Hematoma	A bruise, usually caused by a break in the wall of a blood vessel
Hemoglobin	An oxygen-carrying protein in red blood cells

Hemophilia	A type of bleeding disorder that reduces the ability to clot blood
Heparin lock	A needle placed in the arm with a blood thinner to keep the blood from clotting
Hepatic	Having to do with the liver
Hypercholesterolemia	High cholesterol
Hyperglycemia	High blood sugar
Hyperopia	Farsightedness
Hypertension	High blood pressure
Hyperthermia	Overheating of the body
Hypodermic	Under the skin
Hypoglycemia	Low blood sugar
Hypotension	Low blood pressure
Hypothermia	Abnormally low body temperature
Incontinent	Inability to control certain bodily functions, such as urination
Inflammation	A basic way in which the body reacts to infection, irritation or other injury, the key feature being redness, warmth, swelling and pain
Influenza	The flu
Insomnia	Inability to sleep or poor quality sleep
Intramuscular (IM)	Medication given by needle into the muscle
Intraocular	In the eye
Intravenous (IV)	Medication given by needle into a vein
Investigational	Not part of accepted standard of care, experimental, unproven
Lactating	Producing breast milk
Lateral	The side of the body or a body part that is farther from the middle or center of the body
Lesion	An abnormality involving any tissue or organ due to any disease or any injury
Lipid	Fat
Local	Affecting only a small area of the body
Lymphoma	Tumor of the lymphoid tissue
Macro-	Large or long
Magnetic Resonance Imaging (MRI)	A special radiology technique designed to image internal structures of the body using magnetism, radio waves, and a computer to produce the images of body structures
Mastectomy	Removal of the breast
Metastasis	The process by which cancer spreads from one part of the body to another

Micro-	Small
Microscopic	So small it cannot be seen without the aid of microscope
Monitor	To check on, keep track of, watch closely
Morbidity	An undesired result or complication
Mortality	Death or death rate
Mutation	A permanent change or structural alteration
Myopia	Nearsightedness
Nasogastric tube	A tube that is passed through the nose and into the stomach
Necrosis	The death of cells or tissues
Nephritis	Inflammation of the kidney
Nyctalopia	Night blindness
Oncology	The study of cancer
Oral administration	A drug given by mouth
Pap test	A screening test for cervical cancer
Pathogenic	Causing disease or capable of causing disease
Percutaneous	Through the skin
Placebo	A substance of no medical value; an inactive substance
Post- market	A drug, device or treatment that is FDA approved and available to the public
Posterior	The back or behind
Postpartum	The period just after delivery
Potentiation	Increase in drug action from using two drugs together instead of using each drug separately
PRN	As needed
Prognosis	The probable outcome or course of a disease; the patient's chance of recovery
Prospective Study	A study that looks forward in time
Protocol	A plan of study
Proximal	Nearest
Pruritus	Itching
Psychosis	A mental illness that markedly interferes with a person's capacity to meet life's everyday demands
Psychosomatic	A connection between the mind and body
Pulmonary	Having to do with lungs
Radiotherapy	Treatment of disease through radiation
Random	The process by which an outcome is determined completely by chance
Relapse	The return of signs and symptoms of a disease after a patient has enjoyed a period of remission

Remission	Disappearance of symptoms or signs of illness
Renal	Having to do with the kidney
Retrospective	Looking backward on the past, on what has already taken place
Retrospective study	A study that looks backward in time, usually using existing records
Sepsis	A blood stream infection
Septic	Infected
Serum	A clear liquid part of blood
Shunt	A tube that moves fluid from one place to another
Single-blind trial	A test or experiment in which the investigator knows which treatment a participant is receiving, but the participant does not
Sleep apnea	Temporary stoppage of breathing during sleep
Sternum	The breast bone
Steroid	Drugs used to reduce pain, swelling, and other symptoms of inflammation
Subcutaneous	Under the skin
Sublingual	Under the tongue
Syndrome	A set of signs and symptoms that tend to occur together and which reflect the presence of a particular disease or an increased chance of developing a particular disease
Thorax	The area of the body between the neck and the abdomen that is home to the heart and lungs
Titrate	To slowly increase the dosage of a medication based on the needs of the patient
Tolerance	A decrease in response to a particular dose of a drug, requiring continually increasing doses to achieve the proper effect
Topical application	Applied to the skin
Toxicity	A harmful or poisonous effect of a drug
Trachea	A tube that connects the lungs to the voice box; the windpipe
Tranquilizer	A drug that calms and relieves anxiety
Transdermal	Through the skin
Vascular	Relating to blood vessels
Washout period	The amount of time it takes a drug to completely leave the body

Appendix B: Sample HUD Consent Form

Humanitarian Use Device (HUD)
Consent Form

Allina Health's policy requires the use of a consent form for an HUD even though it is not an FDA requirement.

- You may cut and paste the entire content below to create a consent form or incorporate specific language into an existing consent form. Please make sure that you maintain a consistent font size and style (e.g., 12 point Times New Roman) throughout the document when inserting text into the template.
- This document includes instructions on how to write a consent form. The instructions are in RED. Delete or replace all instructions prior to submitting this form for IRB review.
- Please note: Because the use of an HUD is not research and does not entail data collection, there is no Confidentiality section in this consent form. If the physician is collecting data, please add information about confidentiality measures to this form.

Protocol Title: Insert the full title of the device.

Investigator: Insert the investigator's name and his/her hospital/clinic/organization.

Manufacturer: Insert the name of the sponsor and, if applicable, state whether the sponsor is also the manufacturer of the device.

Description of the Device and FDA Designation
Research has not been done to test whether the <name of the device> will help treat your condition. The Food and Drug Administration (FDA) is allowing the manufacturer <name of the manufacturer> to market (sell) the device and doctors to use it under a Humanitarian Device Exemption. The FDA decided that the likely risks of the device are reasonable compared with the possible benefits and compared to other treatments for conditions like yours. The FDA has approved the use of this device to treat fewer than 4000 people a year. But the effectiveness of the device for your condition has not been tested. Neither Dr. <name of the doctor> nor the manufacturer is doing research to test the effectiveness of the device.

Subject Selection
You are receiving this device because < explain why the patient needs this device.>

Study Procedures and Duration
If you agree to receive this device, we will ask you to do the following: <Insert information about what will happen and what tests and procedures the patient will undergo, etc.>

Risks and Discomforts
The device has the following risks:

-

<List the known risks and/or discomforts the subject may experience.>

Benefits of Receiving the Device
Possible benefits you may experience include the following:

-

<List the possible benefits.>

Alternatives
Alternative treatments for patients with <insert condition or symptom> include the following:

-

<Insert list or description of alternative procedures.>

OR

If there is no alternative treatment, include this statement: There is no alternative treatment for <insert condition or symptom>.

Costs
You and/or your insurance provider will be responsible for the costs of the device and all related care. Please check with your insurance company to see if it will cover the costs of the device. If your insurance refuses to pay, you will be responsible for the cost of the device and your treatment.

Voluntary Participation
Your decision whether or not to receive this device will not affect your current or future care with <insert physician's name> or at <insert hospital/ clinic/ organization>.

Contacts and Questions
The physician(s) approved to use this device is/are <list physician(s) name(s)>. You may ask any questions you have now. If you have questions later, you can contact <him or her> at <insert telephone number>.

If you have any questions about your rights or complaints about your care related to this device, please direct them to the Allina Health Institutional Review Board Administrative Office at 612-262-4920.

You will be given a copy of this form.

Statement of Consent:

I have had the opportunity to ask questions and have had my questions answered. I have been given enough time to consider whether I want to receive this device. I agree to receive it.

Required signature lines on all consent forms:

_____
Printed Name of Patient

_____ _____
Signature of Patient Date

_____ _____
Printed of Person Obtaining Consent Role (physician, nurse, etc.)

_____ _____
Signature of Person Obtaining Consent Date

Appendix C: Sample Short Form

Consent to Participate in Research

You are being asked to be in a research study.

Before you agree, the researcher will tell you the following things about the study:

- The purposes, procedures, and duration of the research
- Any procedures that are experimental
- Possible risks, discomforts, and benefits of the research
- Other potentially beneficial alternative procedures or treatments
- How he or she will maintain confidentiality

The researcher will also tell you about the items listed below if they apply to this study:

- Any available payment or medical treatment if you are hurt
- The possibility of unforeseeable risks
- Circumstances when the researcher may stop your participation
- Any extra costs you may have
- What happens if you decide to stop participating
- When you will learn about new findings that may affect your willingness to continue in the study
- How many people will be in the study

If you agree to be in the study, you will receive a signed copy of this document.

You may contact ____name____ at ___phone number__ any time you have questions about the research or what to do if you are injured because of the study.

You may contact ____name____ at __phone number__ if you have questions about your rights as a research subject.

Your participation in this research is voluntary, and you will not lose benefits if you refuse to be in the study or if you decide to stop. Your decision whether or not to participate will not affect your current or future care with ____name____.

Signing this document means that the research study has been described to you orally and that you voluntarily agree to participate.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Witness Date

_____

Printed Name of Person Obtaining Consent

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent