

Informed Consent Preparation Guide



Main Line Health®

Preparing your informed consent for submission

An incomplete or poorly prepared informed consent form will cause delays in the approval of your clinical research protocol. The following instructions and guidelines have been prepared to assist you in this process.

1. An informed consent is frequently provided by the sponsor but usually requires revisions to conform to our requirements. Please submit a copy of the informed consent provided to you by the sponsor within your iMedRIS submission.
2. Translate all medical terminology and technical terms into layman's terms. The informed consent form should be written at an eighth grade reading level. Various sources are available from the internet to assist you in this process. When including risks or side effects, include a consequence in lay terms for highly technical terms.
3. Spell out abbreviation the first time used (e.g., Food and Drug Administration (FDA)).
4. Refer to the investigator as "investigator" or "study doctor" (not "doctor" or "physician") throughout the document, using the same term throughout. In the examples below, the term investigator is used, but study doctor is acceptable is used consistently throughout.
5. Number pages as follows: for a 4-page consent form (Page 1 of 4, Page 2 of 4, etc.).
6. Font size must be 12 pt.

HEADING

At the top of the first page of the consent form, the following heading should appear in capital letters:

INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title of Study
Principal Investigator

Thereafter, the following sections (in boxes) using the headings shown should appear in the order given:

Include a Summary for Federally sponsored, non-FDA Regulated Research (optional for other types of research)

SUMMARY

1. An informed consent document must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or a subject's legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
2. Informed consent as a whole must present information in sufficient detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or their legally authorized representative's understanding of the reasons why one might or might not want to participate.

BACKGROUND AND PURPOSE

BACKGROUND AND PURPOSE OF STUDY

1. In language understandable to lay subjects, briefly discuss the background of the study. Describe previous human experience, number of patients exposed to date and the outcome. Indicate when human data are not available. Quote relevant animal or in-vitro data if human data are not available. DO NOT COPY AND PASTE STRAIGHT FROM THE PROTOCOL.
2. Describe the purpose of the study, what the study hopes to accomplish, what makes the new drug, procedure or device better potentially than those currently available. State the reason why the particular group of subjects has been chosen to participate. State the number of participating centers, total number of subjects to be included and number of subjects to be studied at Main Line Hospitals.

PROCEDURES

PROCEDURES TO BE FOLLOWED

1. Inform subjects if this is an inpatient or outpatient study. If inpatient, state the expected length of hospital stay, and the number of admissions likely. If outpatient, describe in detail the number of expected visits, expected duration of each, and total time commitment (days/weeks/months, etc.).
2. Describe (in non-technical terms) procedures to be performed throughout study. Inform the subject of the number of times the procedures will be performed and if procedures would be performed regardless of study. Specifically detail special procedures that will be performed and if procedures would be performed regardless of study. Standard definitions for some types of procedures include:
 - CT Scan: X rays with computers
 - MRI Scan: A scan using magnets and computers
 - EKG: Tracing of electrical activity of the heart
 - ECG: A scan of heart motion using high-frequency sound waves
 - MUGA Scan: A scan used to diagnose heart disease that uses a radioactive substance

Reminder: Use Lay Terms for Use in Preparing Informed Consents whenever possible.

3. For drug studies, detail how the drug will be administered (e.g., how many pills/capsules, times per day, with or without meals, etc.). If by injection explain route. Doses (e.g. 10mg/kg) do not normally need to be specified.
4. If applicable, explain terms "double blind", "randomized," and placebo". If the study is placebo controlled, inform the subject of his/her chances to receive either study medication or placebo. Include the IRB standard randomization statement: "Randomization means that you are put into treatment groups by chance. This means that a computer [or another method, if applicable] will by chance assign you to treatment groups in the study. This is done so that each group has a similar mix of subjects of different ages, sex [if the study is not restricted to one sex] and stage of health."
5. Detail all other special instructions regarding concomitant medication, dietary restrictions, etc.
6. Quantitate the amount of blood to be drawn in teaspoons or tablespoons (if applicable).

RISKS AND SIDE EFFECTS

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1. List all known side effects and risks for the new drug, device or procedure, preferably in bullet points. State if side effects are permanent. Inform subject of his/her chances of developing major side effects (if any). Classify, if possible, side effects by frequency (e.g. likely, less likely, rare, rare but serious).
2. State risks associated with blood drawing (pain, bruising, rarely fainting or infection), having x-rays taken and/or other procedures required of subject.
3. Inform subject that in addition to above, unexpected adverse reactions and/or allergic reactions may occur and describe.
4. Make statement (if applicable) that female patients of child-bearing age, where drug may affect the fetus, must use medically approved contraception throughout the study. Include a relevant statement to cover nursing women as well.
5. Translate all medical terminology and technical terms into layman's terms. The informed consent form should be written at an eighth grade reading level. **WHEN INCLUDING RISKS OR SIDE EFFECTS, INCLUDE A CONSEQUENCE IN LAY TERMS IN PLACE OF HIGHLY TECHNICAL TERMS.**
6. For studies in which there are no known physical risks there is always the possibility of the loss of confidentiality. For these studies, state that: "There are no known risks to subjects in the study except the possible loss of confidentiality. We will do our best to maintain confidentiality."

ALTERNATIVE TREATMENTS

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1. Describe any alternative treatments/procedures available to subjects, including their advantages and disadvantages. Inform the subject that one alternative is not to participate in the study.

BENEFITS

BENEFIT TO RESEARCH SUBJECT

1. Outline any direct medical benefit(s), if any, to be gained by participation in the study. Any benefit(s) from an experimental therapy are at most "possible", not probable or definite.
2. Inform the subject if he/she will be financially compensated and of any other specific benefits (e.g., all evaluations, laboratory tests and medications related to participation that might be provided without cost).
3. Include a statement that participation is voluntary, refusal to participate will not affect your medical care and 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. **I KNOW THAT THIS WORDING IS STANDARD, BUT NEVER LIKED IT. I DON'T KNOW THAT EVERYONE UNDERSTANDS WHAT IT MEANS. IT IS REALLY TRYING TO SAY THAT YOUR MEDICAL CARE WILL NOT BE AFFECTED.**

COMPENSATION

COMPENSATION FOR MEDICAL TREATMENT

1. It must be made clear who will pay for additional medical expenses. Subject must be informed of any financial liability he/she may be expected to assume as a subject. In/out-patient hospital expenses associated with the study must be assumed by third party medical insurance, the investigator/sponsor, or the subject. A statement must be made that insurers may not reimburse expenses when a procedure or treatment is considered to be experimental or when a drug, procedure or device does not have FDA approval.

The provisions for medical care or other care or services for research-related injury language in the consent document should be consistent with written agreement from sponsor.

Hospital administration should be contacted, prior to the initiation of the study regarding the use of an investigational drug, procedure or device in hospitalized patients, to insure that patient reimbursement by third party is not jeopardized.

QUESTIONS/CONTACT PERSONS

Below is the standard MLH IRB approved language for use in MLH IRB approved informed consent forms for the "Contact Person" section.

CONTACT PERSON:

If you experience any research related injuries during the study or if you have questions about the research, you should contact Dr. XXX XXXX at {FILL HIS NUMBER IN HERE} or Dr. {FILL IN CO-PI INFO HERE}.

In addition, if you have any problems, concerns and questions as a research subject, contact the Office of Research Protections at 484-476-2692 to speak to someone independent of the research team or send an email to mlhirb@mlhs.org.

CONFIDENTIALITY

Describe extent to which confidentiality of records identifying the subject by name will be maintained. Inform subject as to who will have access to data (sponsors of the study, authorized representatives of the Food and Drug Administration and the Main Line Hospitals Institutional Review Board, etc.). Also, the consent form should state that if results of study were to be published his/her name would not be revealed in the publication.

CONFIDENTIALITY

You understand that your information is protected under the Health Information Portability and Accountability Act (HIPAA) and that you will be asked to sign a separate authorization form related to the permitted uses and disclosures of your information.

There is a risk of loss of confidentiality from your participation in this study. We will do our best to prevent the disclosure of your identity.

Alternatively, you may wish to combine the HIPAA Authorization and the Informed Consent in a single document, as appropriate. Refer to the HIPAA Authorization template and ensure all required elements are included:

- Description of PHI to be disclosed as part of the study
- Who may use or disclose the information
- Who may receive the information
- Purpose of each use or disclosure
- Expiration date of authorization
- Right to revoke authorization in writing and how to do it
- A statement that re-disclosures of PHI may no longer be protected
- Signature of the subject and date

STUDY SPECIFIC INFORMATION

Include the following information when appropriate for the research.

1. Studies Involving the Collection of Genetic Information

Genetic information is defined as: An individual's genetic tests (including genetic tests done as part of a research study); Genetic tests of an individual's family members (defined as dependents and up to and including 4th degree relatives); Genetic tests of any fetus of an individual or family member who is a pregnant woman, and genetic tests of any embryo legally held by an individual or family member utilizing assisted reproductive technology; The manifestation of a disease or disorder in an individual's family members (family history); or Any request for, or receipt of, genetic services or participation in research that includes genetic services (genetic testing, counseling, or education) by an individual or an individual's family members.

Suggested Informed Consent wording:

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

Health insurance companies and group health plans may not request your genetic information that we get from this research.

Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

2. Federally sponsored, Non-FDA Regulated Research (optional for other types of research) involving identifiable private information or identifiable biospecimens:

MAIN LINE HEALTH OFFICE OF RESEARCH PROTECTIONS

- a. 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) One of the following additional elements of informed consent may be required:

(i) 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;

(ii) 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).

3. Additional Elements of Informed Consent

1. Research involving more than minimal risk:
Include 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.
2. A statement that the particular treatment or procedure may involve risks to the subject (or the embryo or fetus, the subject is or may become pregnant), which are currently unforeseeable.
3. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
4. Any additional costs to the subject that may result from participation in the research.
5. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
6. A statement that significant new findings developed during the course of the research, which may related to the subject's willingness to continue participation, will be provided to the subject.
7. The approximate number of subjects involved in the study.
8. For sponsored studies, explain the financial relationship between the sponsor and the principal investigator.
9. Federally sponsored, non-FDA Regulated Research (optional for other types of research) when applicable include a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.

4. Conflict of Interest Disclosure - Principal Investigator/Research Staff

An actual or potential conflict of interest* ("COI") exists when an individual's judgment about a matter could be biased or influenced by some other matter. COIs can arise whenever primary purposes (for example, the protection of human subjects or the integrity of the research) are actually or potentially in conflict with secondary purposes (for example,

personal benefit or financial gain). When an actual or potential COI exists, the information should be disclosed in the Consent Form.

The template language below is intended to serve as a guide. The language may be modified to best inform the research subjects of any conflicts of interest.

a. Use for any type of equity interest (stocks, stock options, patent rights intellectual property rights, etc.)

This research study is supported by (FILL IN SOURCE HERE). The study doctor could benefit financially from the results of this research. The study doctor could gain or lose money depending on the results of this study. If you would like more information, please ask the study doctor.

b. Use for any type of salary, payments for services or gifts (e.g., consulting fees or honoraria, etc.)

This research study is supported by (FILL IN SOURCE HERE). The study doctor receives extra money from XX that is not part of this research. If you would like more information, please ask the study doctor.

**Refer to MLH IRB Policy III: Conflicts of Interest: Researchers and Research Staff*

5. FDA-Regulated Studies

a. The following statements must be included in the consent forms for FDA-regulated studies

1. Include a statement that the FDA may inspect the records
2. For all interventional drug, biological product, and device clinical investigations (Excluding Phase 1 studies) the following statement must be included: "A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Web site at any time."

b. Other considerations for FDA-regulated studies

The subject or the subject's legally authorized representative must sign and date the consent document.

When a subject withdraws, the data collected on the subject to the point of withdrawal remains as part of the study and may not be removed (i.e. the consent may not give permission to have data removed).

A researcher may ask subject who is withdrawing whether the subject wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study. If so, the discussion must distinguish between study related intervention and continued follow-up of associated clinical outcome information (such as medical course or laboratory results obtained through non-invasive chart review), and address the maintenance of privacy and confidentiality of the subject's information. **NOTE: the researcher must obtain consent for this limited participation in the study, assuming it was not described in the original consent.**

If a subject who withdraws from the informational portion of the study and does not consent to continued follow-up of associated clinical outcome information, the researcher may not access subject's medical record or other confidential reports for purposes related to the study. The researcher may consult public records and use data collected prior to withdrawal.

6. Consistency of Informed Consent with Sponsor Written Agreement (Contract or Funding Agreement)

The provisions for medical care or other care or services for research-related injury language in the consent document should be consistent with written agreement from sponsor.

SIGNATURES

The Main Line Hospitals IRB has a Decisionally Impaired to Consent and Surrogate Consent policy (Policy XXIV). If the research protocol is approved to offer experimental treatments to subjects incapable of making autonomous choices where the risks to the subject are reasonable in relationship to any anticipated benefits to subjects, and to the importance of the knowledge that may reasonably be expected to result from the research, the procedures described in this policy apply. Also, the informed consent form must contain a section for the signature of the subject's legally authorized representative. The signature section below is the MLH IRB approved signature section for use in informed consent forms for studies approved to enroll this population of subjects.

SIGNATURE PAGE FOR STUDY NOT APPROVED FOR SURROGATE CONSENT

SIGNATURE OF RESEARCH SUBJECT

I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I will be given a copy of this (INSERT NUMBER OF PAGES HERE)-page consent form.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES.

Subject Signature

Printed Name of Subject

Date

CERTIFICATION OF INVESTIGATOR OR PERSON OBTAINING CONSENT

I have discussed this research study with the subject using a language that is understandable and appropriate. I believe that I have fully informed this subject of the nature of this study and its possible benefits and risks and I believe the subject understood this explanation.

*Signature of Investigator
or person obtaining consent*

*Printed Name of Investigator
or person obtaining Consent*

Date

SIGNATURE PAGE FOR STUDY **APPROVED** FOR SURROGATE CONSENT

SIGNATURE OF RESEARCH SUBJECT OR RESEARCH SUBJECT'S LEGALLY AUTHORIZED REPRESENTATIVE

I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I will be given a copy of this (INSERT NUMBER OF PAGES HERE)-page consent form.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES.

Subject Signature

Printed Name of Subject

Date

CERTIFICATION OF INVESTIGATOR OR PERSON OBTAINING CONSENT

I have discussed this research study with the subject using a language that is understandable and appropriate. I believe that I have fully informed this subject of the nature of this study and its possible benefits and risks and I believe the subject understood this explanation.

*Signature of Investigator
or person obtaining consent*

*Printed Name of Investigator
or person obtaining Consent*

Date

SIGNATURE OF LEGALLY AUTHORIZED REPRESENTATIVE (When legally authorized representative provides consent)

*Signature of Legally
Authorized Representative*

*Printed Name of Legally
Authorized Representative*

Relationship to Subject

Date

Witness Signature

Printed Name of Witness

Date

*Signature of Investigator
or person obtaining consent*

*Printed Name of Investigator
or person obtaining Consent*

Date

VERBAL TELEPHONE CONSENT (If legally authorized representative is not available to sign the above consent)

Printed Name of Legally Authorized Representative

Relationship to Subject

Date

*Signature of Investigator
or person obtaining consent*

*Printed Name of Investigator
or person obtaining Consent*

Date

Witness Signature to Verbal Consent

*Printed Name of
Witness to Verbal Consent*

Date