Legal Services Department
Institutional Review Board
Phone: (716) 821-4477
Fax: (716) 821-4465

Informed Consent Checklist[1]

A summary of the study must be written at the beginning of the form. This must include what is happening in the study, why the study is being done, potential problems that may arise and potential outcomes. (examples below)

Informed consent must include the following:

- Written in layman's language understandable to the people being asked to participate.
- A statement that the study involves research.
- An explanation of the purposes of the research.
- The expected duration of the subject's participation.
- A description of the procedures to be followed.
- Identification of any procedures which are experimental.
- A description of any reasonably foreseeable risks or discomforts. If there are none, this should be stated.
- A description of any benefits to the subject or to others that may reasonably be expected from the research. If there are none, this should be stated.
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
- An explanation of whom to contact for answers to pertinent questions about the research and the research subjects' rights, and whom to contact in the event of research-related injury to the subject.
- 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.

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

- Additional elements, as appropriate:
  - A statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable.
  - Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
  - Any additional costs to the subject that may result from participation in the research.
  - The consequences of the subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
  - A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.
  - The approximate number of study participants.

[1] The IRB may waive some or all elements of informed consent if (a) the research involves no more than minimal risk to the subjects; (b) the waiver or alteration 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; and (d) whenever appropriate, the subjects will be provided with additional pertinent information after participation

Consent Form to Participate in a Research Study

[Delete red text, and replace with your answers. Be sure to use simple English.]

Title of Study: The title of your research

Protocol Number: The protocol number can be found on IRBnet

Investigators:

Person 1
(716) 555-1234
Address
Buffalo NY, 14203

Person 2 (if necessary)
(716) 555-1234
Address
Buffalo NY, 14203

Emergency Contact: Name
(716) 555-1234 email address
Address, Buffalo NY, 14203

Summary: who, why, what, where, when and potential side effects and outcomes. (Examples are available on IRBNet.org or Compliance 360)

Why was I asked to participate in the study?

You are being asked to take part in a research study because […]

Your participation is voluntary which means you can choose whether or not to participate. If you decide not to participate, you will not lose any benefits that you are otherwise entitled. Before you make a decision to participate in this study, you should understand the possible risks and benefits of being in the study, and understand your responsibilities as a participant. Ask as many questions as you would like about this study before giving your consent.

What is the purpose of the study?

The purpose of the study is to learn more about […]

The study is being conducted by […]

How long will I be in the study?

Example: The study will take place over a period of 6 months.

How many other people will be in the study?

You will be one of […] people in the study locally. […] research participants are expected to be enrolled nationally.

Where will the study take place?

The study will take place at…

What will I be asked to do?

Explain the process of the study, and the actions that will be asked of study participants. Be detailed and thorough about tests and procedures. If the participant has multiple visits, add a chart or table for clarity.

What are the risks?

Be detailed and thorough about the risks that a study participant may experience. Provide a statistic for the likelihood of each risk. If it is a very rare risk, you may disclose that the occurrence rate for that risk is less than 1%.

How will I benefit from the study?

Example: There may be no immediate benefit to you. However, your participation could help us understand the effects of […], which may benefit others.

What other choices do I have?

[…]

What happens if I do not choose to participate?

[…]

You may choose to join the study or you may choose not to join the study. Your participation is voluntary. There is no penalty if you choose not to join the research study. You will not lose any benefits or advantages that are currently coming to you, or would come to you in the future. No one will be upset with your decision. If you are currently receiving services and you choose not to volunteer in the research study, your services will continue. There are no negative consequences if you choose not to participate.

WHEN IS THE STUDY OVER?

[…]

Example: The study is expected to end after all participants have completed all visits and all the information has been collected.

The study may be stopped without your consent for the following reasons:

- The study team feels it is in the best interest for your safety not to continue.
- You have not followed the study instructions.
- The study team, the sponsor, federal regulators, the hospital, or the CHS Institutional Review Board can stop the study anytime.

Can I leave the study before it ends?

[…]

You have the right to leave the study at any time during your participation. There is no penalty or loss of benefits to which you are otherwise entitled if you decide to leave the study. Withdrawal will not interfere with your current or future care. If you no longer wish to be in the research study, please contact Name, at (716) 555-1234 or email address, and ask to be removed from the study.

How will confidentiality be maintained and how will my privacy be protected?

[…]

Example: The research team will make every effort to keep your private information strictly confidential, as required by law. The Institutional Review Board (IRB) at Catholic Health System is responsible for protecting the rights and welfare of research volunteers like you. The IRB has access to study information. Federal regulators such as the FDA may require access to study information. Your name and any identifiable information will be removed from those documents. Any documents where you can be identified by name will be kept in a locked drawer in the study team's office. These documents will be kept confidential. All the documents will be destroyed when the study is over. Study related information will be kept on a password protected computer or on a disk that is stored inside a locked compartment.

What happens if I am injured from being in the study?

[…]

The study team will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties for the costs of the care you get for the injury, but you may also be responsible for some of them. Catholic Health System has no program to compensate for injuries related to research. You do not give up your legal rights by consenting to this form. If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed on this consent form.

Will I have to pay for anything?

[…]

Will I be paid for being in this study?

[…]

Who can I call about questions or complaints?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with Name, at (716) 555-1234 or email address. If a member of the research team cannot be reached, or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board at Catholic Health System with any question, concerns, or complaints by calling (716) 821-4477.

Name	Signature	Date
Study Representative/Witness	Signature	Date

Summaries for Consent Forms

Please feel free to use these examples in creating your own consent summaries for your studies. The updated Final Rule states a clear and concise summary must contain the following elements:

1) The fact that consent is being sought for research and that participation is voluntary
2) The purpose of the research, expected duration or the prospective subjects participation, and procedures to be followed in research
3) The reasonably foreseeable risks or discomforts to the prospective subject
4) The benefits to the prospective subject or others that may reasonably expected from the research
5) Appropriate alternative procedures or courses of treatment, if any that might be advantageous to the prospective subject.

Example 1: Non-Drug Treatment/ Therapy

The purpose of this research study is to determine the effectiveness of **AwesomeNewTherapy** in the treatment of patients with **BadDisease**. Participation in this research study is voluntary; and you or your guardian must consent to participation in this research.

Study participants will undergo a screening process to determine eligibility, which should take **X** hours and will include the following tests: **BloodTestQ, PhysicalTestP, and a Survey**. Once the screening is complete, participants will begin **AwesomeNewTherapy: W times a week for Y weeks for a total of Z visits**. Some participants may be selected receive **StandardTherapy** for the same time. Each visit will take **R** hours to complete. Participants may be asked questions or given surveys before and after these appointments. Follow-up phone calls will be made **G** months after completion of treatment. This study will last approximately **J** months.

The risks for participation include the possibility of injury during either **AwesomeNewTherapy or StandardTherapy** and loss of confidentiality.

By participating in this research, we are hoping patients who receive **AwesomeNewTherapy** will have better healing time than **StandardTherapy** patients; although this is not guaranteed. If you choose not to participate, **StandardTherapy** will be offered to you by your physician, if appropriate.

If you are interested in learning more about this study, please continue reading this consent form. You may choose not to participate at any point in this process.

Example 2: Drug Treatment/ Therapy

The purpose of this research study is to determine the effectiveness and best dose of **SuperDrug** in the treatment of patients with **DeadlyDisease**. Participation in this research study is voluntary; and you or your guardian must consent to participation in this research.

Study participants will undergo a screening process to determine eligibility, which should take **X** hours and will include the following tests: **BloodTestQ, PhysicalTestP, and a Survey**. Some of these tests are part of standard are and some are for study purposes. Once the screening is complete, participants will begin their dose of **SuperDrug: W times a week for Y weeks for a total of Z visits**. Some participants may be selected receive **RegularDrug** for the same time. The drug will be given **by mouth/IV/intramuscular** at **S** location by **T**. You will be evaluated at each visit to assess for disease progression and side effects.

There are risks to this study drug that are described in this document. Some risks include: SideEffect1, SideEffect2, SideEffect3…etc…

By participating in this research, we are hoping patients who receive **SuperDrug** will have better healing time/ disease regression than **RegularDrug** patients; although this is not guaranteed. If you choose not to participate, **RegularDrug** will be offered to you by your physician, if appropriate.

If you are interested in learning more about this study, please continue reading this consent form. You may choose not to participate at any point in this process.