# NCH Consent Form Template for Adult Trials

NCH Consent Form Template Version Date: 09/19/2019

## NOTES FOR CONSENT FORM AUTHORS\*:

* This document provides a Template to follow when writing consent forms for the majority of trials. It recognizes the significant differences between various types of trials and provides phase-specific examples of recommended consent form language. This Template is not meant to be fully comprehensive; however, the lay language used and the format of the information should be followed as closely as possible when applying it to a specific study. In all cases, consent form authors should use simple language and be concise.

1. The NCH IRB strongly recommends that consent forms not exceed six to nine pages. Suggestions for making the consent form more concise include:
2. Focus on what makes the study different from the care a patient would typically receive. Instead of trying to cover everything that might happen during the trial, limit the information to the research issues.
3. Eliminate repetition of information.
4. Use lay language and explain concepts simply.
5. Use Times Arial Narrow size 12 font.
6. In the Template, instructions to consent form authors are formatted in a shaded box. Placeholders for protocol-specific details, e.g., drug/intervention names and descriptions, are in italics; however, regular font should be used when inserting the details into the suggested consent form language.
7. A blank line, “\_\_\_\_\_\_\_\_\_\_”, indicates that the local investigator should provide the appropriate information before submitting to the IRB.
8. A simplified study schema should be included in the consent form if the study includes randomization, otherwise it is optional.

* Recommendations for use of educational attachments to the consent form may be found on the last page of this Template. For example, while a lay-language, easy-to-read study calendar is a useful tool for study participants; it should not be part of the main consent form but could be included as an optional attachment. IRB review of attachments is required.

**\*These notes for authors are instructional and should not be included in the consent form distributed to investigators or submitted to IRB’s.**

\*NOTES FOR LOCAL INVESTIGATORS:

1. The goal of the informed consent process is to provide people with sufficient information for making informed choices about participating in research. The consent form provides a summary of the study, of the individual's rights as a study participant, and documents their willingness to participate. The consent form is, however, only one piece of an ongoing exchange of information between the investigator and study participant.

Northwest Community Hospital

INFORMED CONSENT TO PARTICIPATE IN A

# RESEARCH STUDY

#### NCH #\_\_\_\_\_ Study Title for Study Participants: (Insert Lay Title here)

Text Examples for Lay Title:

* **Testing the addition of the antibody, cetuximab, to usual chemotherapy in advanced lung cancer**

OR

* **Testing the combination of two approved chemotherapy drugs after surgery for early stage lung cancer**

OR

* **Testing pioglitazone to prevent oral cancer in people with oral leukoplakia**

#### Official Study Title for Internet Search on <http://www.ClinicalTrials.gov>: (Insert Official Title here)

Principal Investigator: John Doe, M.D.

Co-Investigators: Jane Smith, M.D.

Sponsor: Acme Company

Include information about any conflicts of interest. Specifically:

* 1. State whether any recruitment/retention incentives (such as compensation in the form of money, goods, or services) are offered by the sponsor of this research to the investigators or their agents/employees.
  2. State any significant financial interest in the product or company and add that the principal investigator is compensated for his efforts at no additional cost to the patient

| **Notes to consent form authors about the Study Title:** |
| --- |
| 1. **Section length limit: Both titles together should take up no more than one-quarter page.** 2. Include two titles:    1. The reader-friendly lay title, which is called the “Study Title for Study Participants”.    2. The official title, which can be used by potential study participants for Internet searches and aids in tracking by study administrative personnel. 3. For the lay title:    1. Provide a brief (<20 words) title of the study in lay language.    2. Use general terms.    3. To make title concise, list the usual approach generically; e.g., therapy, surgery; rather than providing specific names, e.g., docetaxel, IMRT, laparoscopy.    4. The study drug should be named. 4. For the official title:   a. Insert study ID number, e.g., Protocol 00-00, and official study title as provided by the study sponsor. |

REQUIRED

Insert this “Key Information” at the beginning of the consent.

Key information includes a brief summary of the following 5 factors which should not be repeated elsewhere in the consent:

1. Consent is being sought for research and that participation is voluntary.
2. The purposes of the research, expected duration of participation and procedures involved in research.
3. Reasonably foreseeable risks or discomforts as a result of participation
4. Reasonably expected benefits to participant or others from research
5. Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant

Suggested language for #1:

This consent form will explain a research study and requirement which you are being invited to take part in. Research studies include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor or a member of the study team for more information.

You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. Researchers find continuing to collect follow up data on people who have stopped taking part in a study early valuable. If you decide stop before the study ends, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

Suggested language for #2:

The purpose of this study is to look at\_\_\_\_\_. If you agree to participate, your participation will last for\_\_\_\_. While most of the tests and procedures you will have while on this study are a part of your standard of care treatment, there are tests/procedures/drugs you will be expected to undergo/take which are specific to this study. These include:

Suggested language for #3: (add specific risks of any research-related drugs or procedures; do not add risks of standard of care procedures):

There are risks to you through participating in this study. One risk is the risk of a breach of your confidential information. Every precaution will be taken to protect your information.

Because this study only involves the collection of a sample/information that is being collected as a part of your standard of care, we don’t anticipate any physical risks to you.

Add if applicable: This study may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.

Suggested language for #4:

This study may or may not help you because researchers do not know how the study drugs will compare to the usual approach. This study may help researchers learn things that may help people in the future.

Or

This study is not expected to help you directly, however your participation may help researchers learn things that help people in the future.

Suggested language for #5:

#### What is the usual approach to my (insert type of condition, early detection, prevention, diagnosis, other)?

| **Notes to consent form authors:** |
| --- |
| 1. **Section length limit: This section should be between five and nine sentences and take up no more than one-quarter page.** 2. State the usual intervention received if not participating in a study. 3. Avoid naming specific drugs as these could change with the availability of new treatments. |

**Other text to include:**

#### What are the study groups (or describe the study, include how many people will take part)?

| Notes to consent form authors: |
| --- |
| 1. **Section length limit: This section should be between seven and ten sentences and take up no more than three-quarters page.** 2. Provide a brief, phase-specific description of the study groups. 3. Insert the names and types of drugs/agents/interventions as needed. 4. For randomized studies, if the assignment is not 1:1, include a brief description of the assignment. 5. Clearly identify the investigational arm(s). 6. If modifying the Template language is necessary, use simple, concise, lay language. 7. For randomized studies: A computer will randomly put you in a study group. Once you are put in a group, you cannot switch to another group. Neither you nor your doctor can choose which group you will be in. |

#### Can I stop taking part in this study?

Use the following text for all studies:

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

Your study doctor may terminate your participation in this study if you do not follow the instructions required for your participation in this study. If your participation is terminated, your doctor will discuss why, and discuss next steps with you.

#### What are my rights in this study?

Use the following text for all studies:

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Questions regarding concerns about the conduct of the study or the rights of research subjects or a research related injury should be directed to the Northwest Community Hospital IRB Chairman, Bruce Bank, M.D. at 847-618-5036

#### What are the costs of taking part in this study?

Use the following text when applicable:

The (study agent) will be supplied at no charge while you take part in this study. The cost of getting the (study agent) ready and giving it to you (As appropriate, add: “…is also provided at no charge.” Or “…is not paid by the study sponsor so you or your insurance company may have to pay for this.”) It is possible that the (study agent) may not continue to be supplied free while you are on the study. Although not likely, if this occurs, your study doctor will talk to you about your options.

You and/or your health plan/insurance company will need to pay for all of the other costs of (As appropriate, add: “caring for” Or “preventing” Or “treating”) you r medical condition while in this study, including the cost of managing any side effects. Before you decide to be in the study, you should check with your health plan or insurance company to find out exactly what they will pay for.

There may be other costs that may be incurred as a result of taking part of this study (e.g., transportation, child care). Personal costs resulting in your participation in this study will not be covered by the physician or study sponsor.

**Will I be paid to be in this study?**

*Sample Statements:*

1) You will/will not receive payment for taking part in this study. (add if applicable) Northwest Community Hospital may receive a minimal fee from the study sponsor to defray administrative costs of the study.

***Privacy***

*A separate consent form will be provided that describes what information will be collected from you and shared with others.*

#### What happens if I am injured or hurt because I took part in this study?

Use the following text for all studies:

"If you are injured or become sick and need medical care, seek treatment right away. As soon as you are able, call your study doctor and let them know what happened. In the event that you have an injury or illness that is related to your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. You will be responsible for any associated co-payments or deductibles as required by your coverage.  
>  
> If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, NCH will explain how to apply for financial assistance, and will help you in applying for that assistance, however you may not be eligible. By signing this form or participating in this study you do not waive any of your legal rights."

**REQUIRED:**

Include one of the following statements regarding the collection of private information or identifiable bio-specimens for future research:

* + 1. Identifiers might be removed and if so, the de-identified information or bio-specimens may be used for future research without additional informed consent

OR

* + 1. The subject's information or bio-specimens will not be used or distributed for future research studies even if identifiers are removed.

AND:

A statement that the subject's bio-specimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.

AND:

A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.

AND:

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).

#### Where can I get more information?

Use the following text for all studies:

You may contact \_\_\_\_\_at \_\_\_\_\_\_ for more information about participation in this study.

Required for all applicable clinical research studies involving interventions with devices or drugs: 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 Web site will include a summary of the results. You can search this Web site at any time.

*[Note to Informed Consent Authors: the above paragraph complies with the FDA regulation found at 21 CFR 50.25(c) and must be included verbatim in all informed consent documents. The text in this paragraph cannot be revised.]*

#### Who can answer my questions about this study?

Use the following text for all studies:

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (insert name of study doctor[s]) at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (insert telephone number).

#### Pregnancy and contraception (add if applicable)

*Sample Statement:*

Example 1: If you are a man, since it is unknown whether this therapy may affect a child you may father, it is recommended that you use an effective method of birth control while you are participating in this study, and for six months following your termination from this study. Due to possible unforeseen risks, contraceptive barriers preventing or reducing the exposure to body fluids are recommended.

Example 2: You should not become pregnant or father a baby while on this study because the drugs in this study can affect an unborn baby. Women should not breastfeed a baby while on this study. It is important you understand that you need to use birth control while on this study. Check with your study doctor about what kind of birth control methods to use and how long to use them. Some methods might not be approved for use in this study. *[Include a statement about possible sterility when appropriate. For example, “Some of the drugs used in the study may make you unable to have children in the future.” If appropriate include a statement that pregnancy testing may be required.]*

#### My Signature Agreeing to Take Part in the Main Study

| Notes to consent form authors: |
| --- |
| 1. **Section length limit: This section should be four to five sentences and take up no more than one-quarter page.** |

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed copy of this form. I agree to take part in the main study and any additional studies where I circled ‘yes’. (Note to protocol authors – remove italicized text if not applicable. Remove italics, if the text does apply.)

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| Patient (Print Name): |  |  |
|  |  |  |
| Patient Signature: |  | (Date) |
| (or Legal Guardian) |  |  |
|  |  |  |
| Witness (Print Name): |  |  |
|  |  |  |
| Witness Signature |  | (Date) |
|  |  |  |
| Person Conducting  Informed Consent Discussion (Print name) |  |  |
|  |  |  |
| Person Conducting Informed Consent Discussion(Signature) |  | (Date) |
|  |  |  |
|  |  |  |
| Principal Investigator (Print Name): |  |  |
|  |  |  |
| Principal Investigator Signature: |  | (Date) |

**Note to Consent Form Authors and Investigators:**

## Recommendations about Attachments to the Consent Form (CF)

1. Attachments should contain information for the study participant that is considered optional, and is not required for their understanding of the proposed research. Attachments may provide clarification, additional education, or provide information about other facets of overall cancer care.
2. All required information should be contained within the CF itself. If the information is considered mandatory for the participants’ understanding of the proposed research, then it should be in the CF.
   1. If a therapy or procedure is truly part of the research design – whether it is drug therapy, surgery, minimally invasive therapy, imaging, etc., then information describing this therapy/procedure should be part of the CF.
   2. There is a difference between interventions that are part of standard care vs. a new indication of an already marketed intervention when research is being done. Marketed or available interventions (including scans) that are being used for a new indication should be treated as an experimental intervention and their side effects should be in the CF.
3. A study calendar is useful to include as an optional attachment.
4. Patient advocates have recommended attaching a calendar that is easy for study participants to understand, conveying what has to be done, when, and for how long. It should help the study participant plan his/her life during the study. It should not be formidable-looking or too complicated in format, especially as dates and timing often change during the course of treatment due to unforeseen events.
5. Friendly reminder – attached consent materials to the CF must be reviewed and approved by the IRB.