Community Healthcare System
Central Institutional Review Board
901 MacArthur Blvd., Munster, IN 46321
Phone: 219-836-6862

Formatting an Informed Consent Document
CHS CIRB Guidelines
Addendum II

1. The language of the consent must address the required elements of consent.
2. All consents should be placed onto the Hospital Formatted Consent Template which can be downloaded for use on the CHS Intranet.
3. Font size: 12 point or larger
4. Font type: Times New Roman or Arial – Do not mix font types
5. Include a footer on EACH PAGE with:
    a. Version date: This should be the version date for the consent which may be different from the protocol version date
    b. Short title: This is optional and only needs to be included at the sponsor's direction
    c. Page number: Example: Page 1 of 1
    d. Revision date: the date the consent was last revised by the clinical research coordinator
    e. It is not necessary to include a line for the subject to initial each page during the consent process unless required by the sponsor.
6. Be sure to use simple terms that are readily understood by the subject. A "Glossary of Lay Terms" may be referenced on the website www.drcomhs.org.
7. You may run a Readability Statics program on the document: Tips to make the document more reader friendly:
    a. When possible, change words from 3 or more syllables to 2 syllables
    b. Break up compound sentences (those that contain and, but so, because) into 2 short sentences
    c. Change all passive voice sentences to active voice (change "a sample will be drawn" to "we will take a sample".
    d. Numbered or bulleted instructions or lists are easier to read than when the same information is presented in sentence/paragraph form. An example would be the risks of drug or procedure.
    e. Use lower case rather than all capital letters.
    f. Allow more white space by using wider margins.
    g. "Justify" text rather than "aligning" to the right (like a newspaper format)
8. Run Spelling and Grammar checks
9. A HIPAA Addendum should accompany all Investigational Consents unless the HIPAA/Confidentiality verbiage is contained in the sample language from the sponsor. The verbiage from the sponsor must contain all of the information required by HIPAA.

10. It is highly recommended that there be separate consents for optional tissue, blood, etc. collection, i.e., when the subject can still participate in the main study without giving consent for the optional collections.
11. LEGEND:
    - The language of the consent must address the required elements or questions in ***bold red italics.***
    - Examples/suggestions of sample language are in **bold print.**
    - Any further prompts, suggestions or instructions are in *[italics*].
    - Any language that is required or highly recommended is in [green].

First page(s) of the consent must list:

STUDY TITLE

[The Title listed on the consent should match the title listed on the protocol]

[*List all investigators participating in the study with their contact information*]

Local Study Doctor:	Principal Investigator
	Address
	Phone Number
Local Co-Study Doctors:	Investigator (s)
	Address
	Phone Number
Study Sponsor:	Name
	Address and phone (if appropriate)

Following is suggested language to address the required elements of informed consent.

INTRODUCTION

What is the purpose of the study? Who is conducting the study?

This is a clinical trial (a type of research study). The main goal of a research study is to learn things to help patients in the future. The main goal of regular medical care is to help each patient. No one can promise that a research study will help you. Taking part in a research study is your decision. No one can make you take part. Please take your time to make your decision. Discuss it with your family and those whose opinion you value.

You are being asked to take part in this study because you have _____

WHY IS THIS STUDY BEING DONE?

Provide a description of the question that the study seeks to answer.

The purpose of this study is to _____ .

Phase I studies:

Test the safety of _____(drug/intervention**) and see what effects (good or bad) it has on you and your _____(**disease state or condition**).**

OR

Find the highest dose of a _____(drug**) that can be given without causing severe side effects.**

Phase II studies:

Find out what effects (good and bad**) _____ (**drug/intervention**) has on you and your _____ (**disease state or condition**).**

Phase III studies:

Compare the effects (good and bad) of the _____(drug/intervention**)**

with _____(commonly used drug/intervention**) on you and your _____**

(disease state or condition).

Currently, there is no effective treatment for this type of _____ (disease state or condition).

OR

We do not know which of these two commonly-used treatments is better.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Include the number of participants at the site where the research will be conducted and other study sites for multi-site studies.

WHAT IS INVOLVED IN THE STUDY?

What are the procedures and treatments that will be followed in the study? Which treatments experimental, which are FDA approved? Which treatments would be considered standard of care, which are study related?

[For randomized studies]

You will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. Which group you are put in is done by a computer. Neither you nor the researcher will choose what group you will be in. You will have an _____(equal, one in three, etc.) **chance of being placed in any group.**

If you take part in this study, you will have the following tests and procedures:

[*List procedures and their frequency*] *[For randomized studies, list the study groups and under each describe categories of procedures. Include whether a patient will receive treatment at home, in the hospital, or in an outpatient setting. If objectives include a comparison of interventions, list all procedures, even those considered standard.*]

[*Provide simplified schema and/or calendar of tests and procedures that the subject will need to comply with.*]

- *Procedures that are part of routine care and may be done even if you do not join the study.*
- *Standard procedures being done because you are in this study.*
- *Procedures that are being tested in this study.*
- *Include the approximate amount of blood that is drawn in teaspoons.*
- *Include the approximate amount of time it will take to complete any questionnaires.*

HOW LONG WILL I BE IN THE STUDY?

How long will I be in the study? Will I be provided with additional information about this study in the event that new findings develop during the course of the study which may relate to my willingness to continue?

We think you will be in the study for _____. (Months, weeks, until a certain event)

[*When appropriate, state that the study will involve long-term follow-up.*]

The study doctor may withdraw you from the study without your consent for one or more of the following reasons:

- **Failure to make or reschedule one or more of your scheduled visits.**
- **You do not follow the instructions for the study.**
- **New information has become available about the study.**
- **You have serious side effects.**
- **Your study doctor decides that it is no longer in your best inters to continue.**
- **Your condition gets worse.**
- **You are pregnant, plan to become pregnant or plan to father a child.**
- **The study is canceled by the sponsor.**

You may stop being in the study at any time. However, if you decide to stop being in the study, we encourage you to talk to your study doctor [*provide contact information of investigator and sponsor if appropriate*] **and your regular doctor first.**

[*Describe any serious consequences of sudden withdrawal from the study and outline the procedure the subject may use to withdraw]*

WHAT ARE THE RISKS OF THE STUDY?

What are the reasonably foreseeable risks or discomfort to myself and are there any risks which are not currently foreseeable?

See Addendum III for Additional Model Language

While on the study, you are at risk for these side effects. You should discuss these with your study doctor _____ (name of study doctor) **and/or your regular doctor. There also may be other side effects that we cannot predict. Other drugs will be given to make side effects less serious and uncomfortable. Many side effects go away shortly after the _____** (name of drug/intervention) **is stopped, but in some cases side effects can be serious or long-lasting or permanent.**

[*List (**lists are easier to read than paragraphs**) by regimen the physical and nonphysical risks of participating in the study in categories of "very likely" and "less likely but serious." Nonphysical risks may include such things as the inability to work. Highlight or otherwise identify side effects that may be irreversible or long-term or life threatening.*]

Risks and side effects related to the _____ (drug, device or procedures) **we are studying include:**

[*List risks related to the investigational aspects of the trial.*]

A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant0 that are currently unforeseeable.

See Addendum III for Additional Model Language

Reproductive risks: Because the drugs in this study can affect an unborn baby, you should not become pregnant or father a baby while on this study. You should not nurse your baby while on this study. Ask about counseling and more information about preventing pregnancy.

For more information about risks and side effects, ask the researcher or contact _____.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

What are the reasonably expected benefits to me or others?

Participating in research is not the same as getting regular medical care. The purpose of regular medical care is to improve your health. The purpose of a research study is to gather information. If you agree to take part in this study, there may or may not be direct medical benefit to you. We hope the information learned from this study will benefit other patients with _____ (disease state or condition) **in the future.**

The possible benefits of taking part in the study are the same as receiving _____ (stand drug, device, and intervention) **without being in the study.**

[Include a statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.]

WHAT OTHER OPTIONS ARE THERE?

Are there any appropriate alternatives, procedures or course of treatment that might be advantageous to me?

Instead of being in this study, you have these options: _____

[*List alternatives including commonly used therapy.*]

- **No further therapy at this time with supportive care to help you feel more comfortable**
- **Receive the same treatment (drug or device) without being in the study**
- **Receive another type of treatment (drug or device) which the study doctor can tell you about**

You may get _____ (study treatments/drugs at this Center and other Centers) **even if you do not take part in the study.**

Please talk to your regular doctor about these and other options.

WHAT ABOUT CONFIDENTIALITY?

Will my identity and participation in this study be kept confidential?

A HIPAA Addendum should accompany all Investigational Consents unless the HIPAA/Confidentiality verbiage is contained in the sample language from the sponsor.

Confidentiality when the research involves the collection of identifiable private information or identifiable biospecimens:

a. *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 search studies without addition informed consent from the subject or the legally authorized representative, if this might be a possibility; or*
b. *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.*

[Statement above is a new element of informed consent and is not optional under CFR 45 §46]

See Addendum III for Additional Model Language

WHAT ARE THE COSTS?

Will I be compensated for my participation in this study?

Will there be any additional costs to myself if I choose to participate in the study?

If I require emergency medical care while I am a participant in this study, will care be provided to me, and if so, at what cost?

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.

[Statement above regarding subject's biospecimens is a new additional (optional) element of consent and should be used "when applicable".]

You will receive no payment for your participation in this study. Taking part in this study may lead to added costs to you or your insurance company. Please ask about any expected added costs or insurance related questions.

If, during the study, the _____ (Investigational Drug) **becomes commercially available, you may have to pay for the amount of drug needed to complete the study.**

[The language in this paragraph is highly recommended]

FINACIAL DISCLOSURE

The investigator and the sponsor have the obligation to disclose any financial interest or financial contracts between the investigator, the sponsor and the institution to the subject at the time of consent.

See Addendum III for Additional Model Language

[The use of this language is required on all consents. A "Financial Disclosure Addendum" is required by the CHS CIRB if the investigator has answered "Yes" to any portion of Part G, "Conflict of Interest" on the Submission Form.]

You should know that [Investigator] has a significant financial interest (e.g. a separate financial relationship with the sponsor) that could potentially compromise or influence the Investigator's professional judgment or actions in the performance of the study or could otherwise adversely affect the rights and welfare of the human subjects enrolled in the study. The Investigator has disclosed that personal financial interest to the CHS CIRB. While the CHS CIRB has determined that [Investigator's] financial interest is unlikely to have any such negative impact on subjects, such negative impact is always possible, and therefore are being disclosed to you. Please discuss with the study doctor any questions you may have about this.

See Addendum III for Additional Model Language

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Who do I contact if I have any questions regarding my rights as a participant?

For questions about your rights as a research participant, contact the Community Healthcare System Central Institutional Review Board (which is a group of people who review the research to protect your rights) or the Human Protections Administrator (the patient advocate) at 219-703-1514.

[The language in this paragraph is required.]

If I refuse to participate in this study, may I discontinue my participation at any time? Can my participation be terminated without my consent? What will be the consequences if I decide to withdraw from the study?

[Consent forms should not include any exculpatory language through which the subject or the legally authorized representative is made to waive or to appear to waive any of the subject's legal rights, or

releases or appears to release the investigator, the sponsor, the organization or its agents from liability for negligence.]

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. No matter what decision you make, leaving the study will not affect your medical care.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

[The language contained in the 2 paragraphs above is required.]

[*Or when a Data Safety and Monitoring Board exists:*]

A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study. We will tell you about the new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

[If collecting genetic information for the study, insert the following:]

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.**

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

See Addendum III for Additional Model Language

WHAT IF I AM INJURED AS A RESULT OF THE STUDY?

For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

In the event of an emergency, dial 911 immediately. If you need emergency care, be sure to tell the care providers that you are in a research study. Contact the study doctor as soon as possible.

Subjects who believe that they have sustained an injury as a result of participating in this study should report the injury to _____(investigator's name) at _____ (phone number).

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

Clearly indicate who the subject can call if they have any questions or problems? Include necessary phone numbers.

WHERE CAN I GET MORE INFORMATION?

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

[Statement above is a new additional (optional) element of consent and should be used "when applicable".]

You will get a copy of this form. You may also request a copy of the protocol (full study plan). _____ (investigator's name) **is available to answer any questions you have.** [*Include all contact information for the investigator(s) and clinical research staff*]

[*Include any contact information about other trials, national web sites, information services, etc., that may be required by the sponsor or may benefit the patient.*]

[As of January 4, 2011, all consents for registered trials must include the FDA required statement:]

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.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- **Follow the instructions of the study doctor and staff.**
- **Keep your study appointments. If it is necessary to miss an appointment, please contact the study staff to reschedule as soon as you know you will miss the appointment.**
- **Tell the study doctor and staff about any side effects, doctor visits, changes in medications, or hospitalizations that you may have had since your last study visit.**
- **Tell the study doctor and staff if you believe you might be pregnant.**
- **Ask questions as you think of them.**
- **Tell the study doctor and staff if you change your mind about staying in the study.**
- **Tell others that you are in a research study.**
- **While participating in this research study, you should not take part in any other research study without approval from the study doctor of each study.**

[The section regarding Participant Responsibilities is optional but recommended]

Signature Page

[There must be documentation in the subjects' source document as to the reason the Legally Authorized Representative (LAR) is signing the consent for the subject, i.e., Healthcare Power of Attorney, Appointment of a Healthcare Representative, Guardianship, Physician Orders for Scope of Treatment listing a Legally Appointed Representative. You may also reference CHS Policy; Healthcare Consent for more information.]

See Addendum III for Additional Model Language

Patient Statement

My signature on this consent form means the following:

- The study has been fully explained to me and all of my questions have been answered.
- I understand that I may ask questions at any time during the study by contacting _____ at _____.
- I understand what will be required of me to participate in this study.
- I understand that I may withdraw my consent at any time during the study but should notify my doctor first.
- I agree to take part in this study.
- I will receive a copy of this form.

_____ _____

Signature of Subject or Subjects' Legally Authorized Representative — Date

_____

Printed Name of Subject or Subjects' Legally Authorized Representative

_____

LAR's Authority to Act for the Subject

I attest that the participant named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

_____ _____

Signature of Person Explaining Consent — Date

_____

Printed Name of Person Explaining Consent

[If the witness is a certified medical interpreter, this information should be documented under their signature and a copy of their credentials placed in the subject's source record. If the discussion was conducted over the phone, i.e., Language Line, the research staff should document the name of the person and list the name of the service that was used beneath the signature line.]

Witness Statement

I was present during the explanation of this study. The patient was given the opportunity to ask questions. The patient voluntarily gives his/her consent to participate in this study.

_____ _____

Witness Signature Date

_____

Witness Printed Name

[This section is optional. There are no federal requirements that the investigator must sign the consent. However, the investigator may document that he/she has participated in the consent process in either the signature line for the "person conducting the consent" by adding the statement below to the Investigational Consent.]

Statement of Investigator Obtaining Informed Consent

I have fully explained the details of this study to my patient. In my judgment, there was sufficient access to information, including risks and benefits, to make an informed consent.

_____ _____

Investigator Signature Date

_____

Investigator Printed Name

Further References:

Food and Drug Administration 21 CFR §50

Health and Human Services 45 CFR §46 Updated to reflect the revised Common Rule as of January 19, 2017

International Conference on Harmonization; Good Clinical Practices E6 §4.8.1

Community Hospital Policy: “Healthcare Consent”

CHS CIRB Policy: IRB 15: Informed Consent

Adapted from the “Informed Consent Template”, National Cancer Institute

Informed Consent Guidelines, Revised 12/04, 3/05, 6/05, 7/05, 8/06, 2/08, 4/2012, 2/2018