TITLE: Informed Consent		POLICY/PROCEDURE NUMBER: IRB 12	
Author:	Jana L. Lacera, RN, MSA, CDM	Applicable To:	CHS CIRB
Supersedes:		Issued By:	CHS CIRB
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	CFNI		Community Hospital		St. Catherine Hospital		St. Mary Medical Center
X	Munster, Indiana	X	Munster, Indiana	X	East Chicago, Indiana	X	Hobart, Indiana

POLICY/PROCEDURE STATEMENT/PURPOSE:

"Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or 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."

"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 legally authorized representative's understanding of the reasons why one might or might not want to participate." CFR 45 §46.116 (i)(ii)

The informed consent process provides a meaningful exchange of information between the clinical investigator and the study subject. It is an ongoing exchange between the subject and the research team throughout the research study. Before legally effective informed consent may be obtained, the investigator, or a person designated by the investigator, should provide the subject or the subject's legal authorized representative (LAR) ample time and opportunity to inquire about details of the trial and to decide whether or not to participate in the trial. All questions about the trial should be answered to the satisfaction of the subject or the subject's legal representative.

The CHS CIRB has the final authority on the content of the consent document that is presented to the prospective study subjects. The CHS CIRB may require that information, in addition to that specifically required by applicable regulation or the sponsor, be given to subjects when, in the CHS CIRB's judgment, the information would meaningfully add to the protection of the rights and welfare of the subjects.

The CHS CIRB may choose to observe the consent processes employed by an investigator during a Quality Monitoring Audit.

The elements of an informed consent as required by federal regulation and citations are outlined in the *Elements of Informed Consent* (Addendum 1). It is preferred by the CHS CIRB that the informed consent be re-formatted according to the *Formatting an Informed Consent Document* (Addendum 2), *Additional Model Language (*Addendum 3) and the sample *HIPAA Authorization* (Addendum 4).

DEFINITIONS:

Assent: An individual's (not authorized to give legal consent) affirmative agreement to participate in research obtained in conjunction with permission of the individual's parents or legally authorized representative. Mere failure to object should not be construed as assent.

Children (minor): According the federal regulations, children are "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conduct." Per Indiana State Law, "minors" are defined as "persons less than 18 years of age;" therefore, are considered "children" for purposes of the regulations.

EXCEPTION: According to Indiana State Law, a minor may consent for himself/herself if any of the following are true:

a. By law the minor is considered emancipated;
b. The minor is at least fourteen (14) years of age, not dependent on a parent for support, is living apart from parents or from an individual *in loco parentis;* AND has management of his/her own affairs;
c. The minor is or has been married;
d. The minor is in the military service of the United States; OR
e. The minor is authorized to consent to the health care by any other statute.

CHS CIRB: Community Healthcare System Central Institutional Review Board

Cognitively Impaired: Having a psychiatric disorder (e.g. psychosis, neurosis, personality or behavior disorder), or organic impairment (e.g. dementia), or a developmental disorder (e.g. mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including individuals under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and individuals with severely disabling physical handicaps may also be compromised in their ability to make decisions in their best interest.

Confidentiality: The assurance that certain information that may include a subject's identity, health, behavior, or lifestyle information or a Sponsor's proprietary information would not be disclosed without permission from the subject or sponsor.

Delegated authority to consent on behalf of incapable party: Per Indiana Code 16-36-1-6, an individual authorized to consent to health care for another who for a time will not be reasonably available to exercise the authority may delegate the authority to consent during that time to another individual. The delegation; (1) must be in writing; (2) must be signed by the delegate; (3) must be witnessed by an adult; and (4) may specify conditions on the authority delegated. Unless the writing expressly provides otherwise, the delegate may not delegate the authority to another individual.

Good Clinical Practice (GCP): A standard by which clinical trials are designed, performed, monitored, audited, recorded, analyzed, and reported so that there is public assurance that the data are credible, and that the rights, integrity, and confidentiality of subjects are protected.

Human Subject: A living individual about whom an investigator (whether professional or student) (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generated identifiable private information or identifiable biospecimens.

Impartial Witness: A person, who is independent of the research, who cannot be unfairly influenced by people involved with the research, who does not have a coercive relationship with the subject, who attends the informed consent process if the subject or the subject's legally authorized representative cannot read or comprehend, and who reads any informed consent form and any other written information supplied to the subject. In cases where a subject is unable to read or sign the informed consent, an impartial witness attests that the subject has been completely informed of the nature of the study and has consented to participate.

Informed Consent: An ongoing process by which a subject or legal representative voluntarily confirms his or her willingness to participate in a particular research project, after having been informed of all aspects of the research that are relevant to the subject's decision to participate. Informed consent is often, but not always, documented by means of a written, signed, and dated informed consent form with documentation, which is retained in the subject's record.

In Loco Parentis: Someone who acts in place of a parent.

Legally Authorized Representative (LAR): Defined in the federal regulations as an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. In Indiana, a health care representative (as defined by state law) is the equivalent of the federal defined legally authorized representative.

Minimal Risk: The probability and magnitude of harm and discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (as defined in 45 CFR 46.102(i).

OHRP: Office of Human Research Protections

Permission: The agreement of parent(s) or guardian(s) to the participation of their child or ward in research.

Persons authorized to consent for incapable parties: Per Indiana Code 16-36-1-5, if an individual incapable of consenting has not appointed a health care representative or the healthcare representative is not reasonably available or declines to act, consent to health care may be given by:

a. A judicially appointed guardian of the person or a representative appointed; or
b. By a spouse, a parent, an adult child, or an adult sibling, if:
    1. There is no guardian or other representative;
    2. The guardian or other representative is not reasonably available or declines to act; or
    3. The existence of the guardian or other representative is unknown to the health care provider; or
c. The individual's religious superior, if the individual is a member of a religious order.

Prisoner: According to 45 CFR 46.303(c), a prisoner is defined as any individual involuntarily confined or detained in a penal institution. This term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of states or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. It is important to note that this category of special protections also includes situations where a research subject may become a prisoner after the research has commenced.

Risk: The possibility of harm to participants in a research study.

Signed: includes any symbol executed or adopted by a party with present intention to authenticate writing.

Vulnerable subjects: Persons not capable (e.g. mentally, emotionally, or physically impaired) of appropriately judging the risks/benefits of their participation in a research study. Also, individuals with incurable disease, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, refugees, minors, persons with developmental disabilities or mental retardation or mental illness, pregnant women, and those incapable of giving consent or whose capacity for giving informed consent is limited. Other vulnerable persons may include individuals whose willingness to volunteer in a research project may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response in case of refusal to participate. Examples include students, subordinate personnel, members of the armed forces, and persons in detention (prisoners).

<u>Investigator Responsibilities for the Informed Consent Document</u>

1. Ensure that the consent document conforms to the requirements established by the CHS CIRB and contains the elements required by the federal regulations prior to submission for approval. The investigator may delegate the development and processing of the consent document to appropriate members of the research staff.
2. Before involving a human subject in research, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.
3. An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
4. The information that is given to the subject or legally authorized representative shall be in language understandable to the subject or legally authorized representative. This may include obtaining the

services of a certified interpreter, a sign language interpreter, or sound amplification devices. The investigator may reference CHS CIRB Policy 15.1 Barriers to Informed Consent. The investigator may reference the *Glossary of Lay Terms* on the web site: www.drcomhs.org.

5. The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
6. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or 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.
7. 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 fact, but rather facilitated the prospective subject's or legally authorized representative's understanding of the reasons why on might or might not want to participate.
8. No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor , the institution, or its agents from liability for negligence.
9. The consent documents must contain a HIPAA Statement that contains all of the required elements or the investigator may use the HIPAA Addendum Template.
10. Submit a "Financial Interest Disclosure Addendum" if the investigator has answered "Yes" to any portion of Part C, "Education/Conflict of Interest Requirements" on the Submission Form.
11. Maintain a copy of the most current CHS CIRB approved consent. The consent must bear the CHS CIRB approval stamp.

    EXCEPTION: For all Non-Local studies, the consent will not be stamped with the CHS CIRB approval stamp.

Investigator Responsibilities in Obtaining Informed Consent

1. If permitted by the sponsor and the CHS CIRB, the investigator may delegate the duty of obtaining informed consent to appropriate members of the research team. The investigator is responsible for assuring that training has been provided for all research staff involved in the consent process. The person conducting the consent process must sign the informed consent document as the "person obtaining consent," as well as obtain the signature of the subject and/or LAR.

   NOTE**:** It is not necessary for the investigator to sign the consent if he has not participated in the consent discussion.

2. Unless informed consent is waived or altered, ensure that all study subjects or the LAR sign and receive a copy of the CHS CIRB approved informed consent document.

   NOTE: The only exceptions to the informed consent process requirement are:
   a. Individual studies which have been certified as "Exempt" from CHS CIRB review.
   b. Individual studies where the CHS CIRB has waived the requirement to obtain all or elements of informed consent or the documentation of consent.

3. Identify who is legally authorized to give consent for the subject.

   NOTE: If the subject is physically or mentally unable to provide consent, then the LAR may be approached to give consent for the subject. Careful attention should be given to any potential impairment or barrier that may affect the subject's ability to give legally effective informed consent.

4. Note in the subject's study record and/or the medical record that the consent process occurred.
5. File the original signed consent document with the subject's study record. A copy of the consent document will be provided to the subject or the legally authorized representative and a copy will also be placed in the subject's medical record, if appropriate.
6. Continue the informed consent process throughout the subject's participation in the study.

Investigator Responsibilities for Revisions to the Informed Consent Document

1. Ensure that the consent and any other written information to be provided to subjects is revised whenever important new information becomes available that may be relevant to the subject's willingness to participate. Any such revisions must receive CHS CIRB approval prior to use. Immediate hazards should be communicated to the subject upon receipt of the new information or as directed by the sponsor. The new information must be reported to the CHS CIRB as soon as received from the sponsor.
2. If the new information poses an increased risk to the subject, the investigation must suspend further enrollment of subjects until approval for modification to the consent is received from the CHS CIRB.
3. Utilize the correct revised version of the CHS CIRB stamped, approved consent when enrolling any new subjects in the study. In situations where the consent has been revised and approved by the CHS CIRB, the newly approved revised informed consent will be stamped with the new approval date.
4. FDA does not require re-consenting of subjects that have completed their active participation in the study or of subjects who are still actively participating when the change will not affect their participation, for example when the change will be implemented only for subsequently enrolled subjects.

   Those subjects who are presently enrolled and actively participating in the study should be informed of any change if it might relate to the subject's willingness to continue their participation in the study; including but not limited to:
   a. Findings by the DSMB
   b. A statistical trend in SAEs that can be correlated directly to participation in the research, i.e., use of the experimental drug or treatment
   c. Modifications to the protocol that modify risk and/or benefit
   d. Duration of participation
   e. Collection of PHI or biospecimens that were not originally part of the protocol or informed consent document

   Changes that do not require re-consent unless specifically requested by the sponsor, the local IRB or at the discretion of the investigator include but are not limited to:
   a. Administrative/clerical changes to the protocol/ICF
   b. Modifications to the protocol/IF that do not modify risk and/or benefit
   c. The sponsor has provided a letter of explanation to the subject
   d. Addition of an investigator.

5. In the event that re-consent is not required by the sponsor, NCI CIRB, or the CHS CIRB, the investigator may decide that the subject requires re-consenting. Similarly, in situations where the subject has been off study medications for an extended period of time and it is not in the best interest of the subject, the investigator may decide that re-consent is not warranted. The investigator should clearly document the reasons to consent or not re-consent.
6. Provide a copy of the revised signed consent to the subject or LAR. The previously signed consent should be retained in the study record.

Investigator Responsibilities under Special Circumstances

1. Obtaining Informed Consent via Telephone
   a. There may be situations when obtaining informed consent from subjects over the telephone is appropriate. In these situations, the consenter must document that the informed consent process took place by making an appropriate notation regarding the process in the proper files.
   b. Informed consent may only be obtained via telephone when written documentation of informed consent has been waived by the CHS CIRB. Alternatively, if subjects will be signing the consent document after having discussed the research study with a member of the research team over the telephone, a waiver of written documentation of the informed consent is not required. In this case, the person discussing the research study with the potential subject should sign and date the consent document prior to mailing it to the potential subject. Appropriate notation should be made in the subject's records indicating that the process took place. Once the subject receives,

signs, and returns the informed consent document to the study site, the document should again be signed and dated by the appropriate member of the research team who receives the document.

NOTE: Before implementing either of these processes, the investigator must first obtain the appropriate CHS CIRB approval to do so.

2. Obtaining Informed Consent via Fax
    a. There may also be situations when obtaining informed consent from subjects via fax is appropriate. This is acceptable in situations where the informed consent process has already been appropriately conducted in person. For example, it is acceptable for the informed consent process to take place in person, to allow the potential subject time to take the consent document home in order to consider participation, and then have the subject sign and fax the informed consent document back to the research site. In this case, the consenter should sign the consent document and make appropriate notes to the subject's records upon completion of the informed consent discussion. The subject may then fax a signed copy of the consent document to the research site (preferably to the consenter and/or the investigator). Upon receipt, the investigator or appropriate designee should again sign and date the document as acknowledgement of receipt and make appropriate notations to the subject's record. The subject should still return the signed original consent document at the next visit or to the research site at his/her earliest opportunity. The appropriate recipient of the signed original consent document should sign and date it, file it with the faxed copy, and make appropriate notes to the subject's record. The notes to file coinciding with the dates and signatures on the consent documents provide the source documentation that confirm and explain how the process occurred.

3. Informed Consent with Special (Vulnerable) Populations

Research involving vulnerable populations requires an extra measure of vigilance from the CHS CIRB. Vulnerable populations include; children, pregnant women, nursing home residents, employees, educationally and economically disadvantaged, the terminally ill, prisoners, decisionally impaired, the homeless, and students. The task for the CHS CIRB is to protect the rights and welfare of these potential study subjects by weighing the risks and benefits of the study, the method used to recruit the subjects and the type of study proposed by the investigator. The following groups have specific requirements prior to and during the consenting process in the federal regulations.

a. **Prisoners**. Because prisoners represent a vulnerable population, involvement of such a population calls for additional requirements to be met prior to consenting and enrolling them. The CHS CIRB must determine that these requirements have been met and grant approval for the involvement of prisoners in a research staff before the investigator or other members of the research team may consent them.

Only certain types of research may be conducted utilizing prisoners as subjects:

1. Study of the possible causes, effects, and processes of incarceration,
    - And of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.
2. Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.
3. Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) the study may proceed only after OHRP has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register.
4. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the CHS CIRB to control groups which may not benefit from the research, the study may

proceed only after OHRP has consulted with experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register.

NOTE: When prisoner research is reviewed by the CHS CIRB, membership in attendance at that meeting will include a prisoner representative with appropriate background and experience to serve in that capacity.

b. **Cognitively Impaired.** Research involving subjects who are mentally ill or subjects with impaired decision-making capacity warrants special attention. Research involving these populations frequently presents greater than minimal risk and may include a research design that calls for washout, placebo, or symptom provocation. In addition, these populations are considered to be vulnerable to coercion.

1. In instances where the subject is cognitively impaired, the CHS CIRB must consider whether adequate provisions are made for soliciting the assent of the subject when in the judgment of the CHS CIRB, the subject is capable of providing assent. In addition, the CHS CIRB will consider the procedure proposed for evaluating the mental status of prospective subjects, whether the subjects' mental status may change during the course of the study, and how investigators will identify persons authorized to give legally valid consent on behalf of individuals judged incapable of consenting on their own behalf. The CHS CIRB must be aware that for some subjects, their decision making capacity or those with decreasing capacity to give consent, a re-consenting process with surrogate consent may be necessary. Although incapable of providing legally effective informed consent, some persons may resist participating in a research protocol approved by their LAR. Under no circumstances may subjects be forced or coerced to participate.

2. Therefore, research involving persons considered cognitively impaired may only be approved when the following conditions apply:
   a. Only incompetent persons or persons with impaired decision making capacity are suitable as research subject.
   b. The proposed research entails no significant risks, tangible or intangible, or if the research presents some probability of harm, there must be at least a greater probability of direct benefit to the subject.
   c. Procedures have been devised to ensure that a subject's LAR is well informed regarding their roles and obligations to protect incompetent subjects or persons with impaired decision making capacity.

c. **Children:** Children are considered a vulnerable population because their physical and intellectual capacities are limited and as such, special considerations are necessary. The CHS CIRB, when reviewing research involving children as subjects must consider the benefits, risks, and discomforts inherent in the proposed research and assess their justification in light of the expected benefits to the child-subject or to society as a whole.

Only certain types of research may be conducted utilizing children as subjects:
1. Research not involving greater than minimal risk.
2. Research involving greater than minimal risk, but presenting the prospect of direct benefit to the subject.
3. Research involving greater than minimal risk with no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
4. Research that is not otherwise approvable, but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. (With this category, the CHS CIRB must consult the Secretary of DHHS and a panel of experts for concurrence).

In research with children, written parental permission is required. Permission from parents is usually indicated in a form similar to a subject consent form, constructed to request "your child" to participate. If the CHS CIRB determines that the research involves greater than minimal risk, signatures from both parents are necessary. However, in some cases, the CHS CIRB may

determine that it is acceptable for only one parent to provide permission when one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. In other cases, such as child abuse or treatment of venereal disease, parental permission may not be appropriate. The CHS CIRB can grant a "waiver of parental consent" if it is determined that the research will provide great benefit to the population being studied and that obtaining parental consent may put the subject at considerable risk.

Once parental permission has been obtained, the agreement of the child is required by the CHS CIRB and this can be documented in an assent. An assent of the child requires that the child be given an explanation of the proposed research procedures in a language that is appropriate to the child's age, experience, maturity, and condition. This explanation should also include a discussion of any discomforts and inconveniences the child may experience if he or she agrees to participate. Parental permission may overrule a child's decision not to participate in therapeutic settings. If there is a disagreement between the parent and the minor child, the case will be referred to the hospital's Bio-Ethics Committee for mediation".

Department Responsibilities

1. Perform an initial review of the consent by the department prior to submission to the convened CHS CIRB.
2. The department will forward the consent to an independent reviewer with the appropriate expertise if the study involves a vulnerable population prior to submission to the convened CHS CIRB.
3. The Checklist for Initial review of Proposals will serve to document the review and provide any additional comments or notes to the convened CHS CIRB.

REFERENCE
Office of Human Research Protections 45 CFR §46
Food and Drug Administration 21 CFR §56
Food and Drug Administration 21CFR §50
International Conference on Harmonization Guidelines 4.8
Indiana Health Care Consent Law IC 16-36-1

CROSS REFERENCE:
CHS CIRB Forms: Informed Consent Guidelines
Financial Interest Disclosure Addendum
HIPAA Authorization
Consent to Participate in Research (Short Form) English and Spanish
CHS CIRB Policy: IRB 15.1 "Barriers to Informed Consent"
CHS CIRB Policy: IRB 16; "Waiver of Consent"
Community Healthcare System Policy and Procedure: "Healthcare Consent"

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Reviewed and Accepted by the CHS CIRB on 8/9/05, 1/10/07, 10/10/2007, 6/10/2008, 6/2010, 6/2012, 8 2014, 2/2015, 3/2018

REVIEWED BY:

Date	Initials
9/2007	JL
6/2010	JL
4/2012	JL
7/2014	JL
5/2015	JL
12/2017	JL