

TITLE: Barriers to Informed Consent		POLICY/PROCEDURE NUMBER: IRB 12.1	
AUTHOR:	Jana L. Lacera, RN, MSA, CDM	APPLICABLE TO:	CHS CIRB
SUPERSEDES:	None	ISSUED BY:	CHS CIRB
DATE ORIGINATED:	6/11/2007	DATE EFFECTIVE:	11/2020
Page 1 of 5			

- CFNI Munster, Indiana
- Community Hospital Munster, Indiana
- St. Catherine Hospital East Chicago, Indiana
- St. Mary Medical Center Hobart, Indiana

POLICY STATEMENT/PURPOSE:

The Belmont Report identifies “justice” and “respect for persons” as two fundamental ethical principles that must underlie the conduct of all human subjects’ research. The principle of justice requires that the burdens and benefits of research are equitably distributed. The principle of respect for persons requires that “adequate standards for informed consent are satisfied” so that subjects are provided with sufficient meaningful information to decide whether they want to enroll in a research study.

45 CFR §46.116 states “...the information that is given to the subject or the [legal] representative shall be in language understandable to the subject or representative...” For the purposes of this policy, “understandable language” will be construed as any method of communication that will insure effective communication when providing a potential subject with information during the consent process.

DEFINITIONS:

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. If the subject and/or the legal representative refuse the services of a witness, the PI should document the refusal with the name and relationship of the witness to the subject on the consent and in the medical record. Whenever possible, the witness should be provided copies of the relevant consent documents well before (24 to 48 hours) the consent conversation with the subject.

Interpreter: A person who has been **certified** to relay medical information. The interpreter may also serve as the witness. The person may be offering interpreter services for the deaf, limited English proficiency (LEP) subject, or those subjects with low literacy. The interpreter may not be a family member or close personal friend of the subject or a member of the research team. If the subject and/or the legal representative refuse the services of an interpreter, the PI should document the refusal with the name and relationship of the interpreter to the subject on the consent and in the medical record. The certified interpreter must be present during the entire informed consent process. After completing the translation for the consent process, the interpreter will document their services by signing the informed consent with the notation “Interpreter” beneath the signature line and the research team will document their participation in the medical record. Whenever possible, interpreters should be provided copies of the relevant consent documents well prior to (24 to 48 hours) the consent conversation with the subject.

TITLE:	Barriers to Informed Consent	POLICY/PROCEDURE NUMBER:	12.1
DEPARTMENT(S):	CHS CIRB	Page 2 of 5	

Principal Investigator (PI): The person responsible for the conduct of the clinical trial at a trial site.

Short Form Consent: a one page form that identifies the PI, the title of the study, and summarizes the elements of informed consent, but does not describe any specific research study. States that the required elements of consent were presented orally to the subject by the PI (or designate). Must be signed by the subject, the PI, the individual presenting the information if different from the PI, and an impartial witness who observed the presentation of information.

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

Written Summary: 45 CFR §46.116 requires that the “IRB shall approve a written summary of what is to be said to the subject or the representative” when using a short form consent. For the purposes of this policy the written summary will be the same as the CHS CIRB approved informed consent.

SCOPE:

Subjects with Limited English Proficiency (LEP)

Consent Option #1: Long Form Written Consent

When the subject population of any research study is expected to include a significant number of subjects who are not fluent in English but are fluent in any single language other than English, the CHS CIRB requires a full translation of the English version of the study’s approved consent document.

1. For initial review of a study, the Principal Investigator (PI) will submit only the English version of the CHS formatted consent and HIPAA Addendum for review.
2. Following CHS CIRB approval of the study, the PI must have the consent and HIPAA Addendum translated into the languages of the anticipated LEP subjects. The PI may use the translator services provided by the sponsor; the services approved by the Community Healthcare System, Language Line; or a service known to the PI or Sponsor.
3. Prior to being used, all translated versions of the CHS CIRB approved forms and written evidence of the translator’s qualifications must be submitted to the CHS CIRB for approval.
4. During the course of the study when using the approved translated forms, the PI must provide a certified interpreter who is fluent in both English and the language that is understandable to the subject and/or legal representative. The interpreter should be available throughout the course of the study when presenting study related treatment to the subject.
5. All forms shall be signed by the PI, the person presenting the information, the subject and/or legal representative and the interpreter and/or witness. The interpreter should note “Interpreter” under the signature line.
6. The subject and/or legal representative will receive copies of all forms.
7. The PI (or authorized individual) must document this process in the subject’s study record.

Consent Option #2: Short Form Consent

During the course of the study, when an unanticipated non-English speaking subject is encountered, the PI may either translate the CHS CIRB approved consent form into the language of the subject using the procedure described in Consent Option #1 or use the short form process.

1. The PI must obtain copies of the CHS CIRB approved consent, HIPAA Addendum and Short Form Consent in English and the Short Form Consent in the language of the subject. The CHS CIRB approved consent in English will serve as the Written Summary. Note: If there is no translation of a Short Form Consent in the desired language readily available, the English version may be used along with the services of an interpreter.
2. The PI must provide an interpreter and/or witness who is fluent in both English and the language that is understandable to the subject or legal representative. The interpreter should be available throughout the course of the study when presenting study related treatment to the subject.

TITLE:	Barriers to Informed Consent	POLICY/PROCEDURE NUMBER:	12.1
DEPARTMENT(S):	CHS CIRB	Page 3 of 5	

3. All forms shall be signed by the PI, the person presenting the information, the subject and/or legal representative and the interpreter and/or witness. The interpreter should note "Interpreter" under the signature line.
4. The subject and/or legal representative will receive copies of all forms.
5. The PI (or authorized individual) must document this process in the subject's study record.
6. If the Short Form Consent has been used with a significant number of subjects in any one language and enrollment is ongoing, the PI is expected to submit a protocol modification to the CHS CIRB with a translation of the approved English version of the CHS formatted consent, HIPAA Addendum and written evidence of the translators qualifications for approval using the Abbreviated Protocol Submission Form.
7. During the continuing review process, the CHS CIRB will require the PI to report each use of the short form process.

Low Literacy or Blind Subjects

During the course of the study, the PI may encounter an individual subject who is capable of providing legally effective informed consent but is incapable of reading the informed consent and must rely solely on an oral presentation of the study.

1. The PI must obtain copies of the CHS CIRB approved consent, HIPAA Addendum and a Short Form Consent.
2. The PI must provide a witness to the oral presentation during the consent process.
3. The PI may provide a witness to any oral presentation of written material during the course of the study if deemed appropriate.
4. All forms shall be signed by the PI, the person presenting the information, the subject and/or legal representative and the interpreter and/or witness.
5. The subject and/or legal representative will receive copies of all forms.
6. The PI (or authorized individual) must document this process in the subject's medical record.

Deaf Subjects

During the course of the study, the PI may encounter an individual subject who has limited or a complete inability to hear the information presented during the consent process and the course of the study.

1. The PI must obtain copies of the CHS CIRB approved consent and HIPAA Addendum. The CHS CIRB approved consent in English will serve as the Written Summary.
2. In the case of a deaf subject who communicates by signing, the PI shall provide an impartial sign language interpreter during the consent process. The interpreter should be available throughout the course of the study when presenting study related treatment to the subject.
3. All forms shall be signed by the PI, the person presenting the information, the subject and/or legal representative, if appropriate, and the interpreter and/or witness.
4. The subject and/or legal representative will receive copies of all forms.
5. The PI (or authorized individual) must document this process in the subject's medical record.

Note: The cost of the Language Interpreter Services or the Sign Language Interpreter Services will be the responsibility of the PI.

Short Form Consent Prior to Emergent Procedure

In rare instances, it may be inappropriate to approach a potential subject with the CHS CIRB approved informed consent in an urgent or emergent care setting due to the nature of the protocol or the condition of the potential subject. Because individuals receiving urgent or emergent care frequently may be vulnerable to coercion or undue influence, even if temporarily, additional protections may be required to ensure the subject's consent to participate in research is truly voluntary and sought under circumstances that minimize the possibility of coercion or undue influence. The Short Form Consent may be used in very limited circumstances by the PI to obtain informed consent from a potential subject. The CHS CIRB will evaluate each request to use the Short Form Consent on a study by study basis.

TITLE:	Barriers to Informed Consent	POLICY/PROCEDURE NUMBER:	12.1
DEPARTMENT(S):	CHS CIRB	Page 4 of 5	

Scenarios when a Short Form Consent may be appropriate:

- The Short Form Consent has been incorporated into the design of the study by the Sponsor.
- A patient is going to the cath lab or surgery for an emergent interventional procedure. The physician/investigator is aware that an *investigational drug/device that is currently under study* may provide a benefit to the patient; however, he will not be sure that the patient will meet the inclusion criteria until examining the results of the procedure.
- A patient is going to the cath lab or surgery for an emergent interventional procedure. The physician/investigator is aware that an *approved drug/device is currently under study for an unapproved indication* may be beneficial to the patient; however, he will not be sure that the patient will meet the inclusion criteria until examining the results of the procedure.

Scenarios when a Short Form Consent process should not be utilized.

- The PI has not received prior approval to use the Short Form Consent from the CHS CIRB.
- The potential subject has received conscious sedation (amnestic).
- The potential subject has a life threatening condition necessitating the use of a test article, no standard acceptable treatment is available, and there is not sufficient time to obtain full CHS CIRB approval. This is the emergency use of a test article. Refer to Policy IRB 12 "Emergency Use of a Test Article"

Procedure for application and use of the Short Form consent for emergent procedures

1. The PI must apply for the use of the Short Form during the initial submission process. A copy of the Short Form Consent must accompany the submission documents. Only a CHS CIRB approved Short Form Consent may be used during the conduct of the study.
2. The PI must provide the CHS CIRB a thorough explanation as to why approval to use the Short Form Consent process is necessary to conduct the study.
3. If approved, the PI must provide an impartial witness who has prior knowledge of the study when using the Short Form Consent who attests to; 1) the subject understands the protocol and the consequences of agreeing to become part of the study, i.e., the 12 elements of informed consent and 2) the subject understands that they may or may not qualify for the study.

NOTE: The impartial witness may not be clinical research staff employed by the PI.

4. All forms shall be signed by the PI, the person presenting the information, the subject and/or legal representative and the impartial witness.
5. The subject and/or legal representative will receive copies of all forms.

NOTE: It is not required that the subject be re-consented using the CHS CIRB approved informed consent following the procedure. As with any other informed consent, the subject should be provided with information regarding the study on an ongoing basis.

6. The PI (or authorized individual) will document this process in the subject's study record.
7. During the continuing review process, the PI will inform the CHS CIRB of each subject where the Short Form Consent process was used including those subjects that were unable to be included in the study.
8. The CHS CIRB will conduct random interviews with subjects to assess the effectiveness of the Short Form consent process.

TITLE:	Barriers to Informed Consent	POLICY/PROCEDURE NUMBER:	12.1
DEPARTMENT(S):	CHS CIRB	Page 5 of 5	

CROSS REFERENCE(S):

Short Form Consent

- English
- Spanish

CHS CIRB Policy: Informed Consent IRB 15

CHS CIRB Policy: Emergency Use of a Test Article IRB 12

CHS CIRB Policy: Quality Assurance Activities: Audits and Monitors

REFERENCES:

45 CFR §46.116

ACCEPTED BY:

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REVIEWED BY: CHS CIRB 10/10/2007, 6/2010, 6/2012, 5/2015, 3/2018, 11/2020

Date	Initials
6/2010	JL
4/2012	JL
5/2015	JL
12/2017	JL
11/2020	JL