TITLE: Re-Consenting Subjects Guidance		POLICY/PROCEDURE NUMBER: 12.2	
AUTHOR:	Jana L. Lacera, RN, MSA, CDM	APPLICABLE TO:	CHS CIRB
SUPERSEDES:	None	ISSUED BY:	CHS CIRB
DATE ORIGINATED:	4/2019	DATE EFFECTIVE:	11/2020
Page 1 of 3			

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

POLICY STATEMENT/PURPOSE:

The CHS CIRB requires disclosure to subjects of significant new findings that develop during the course of a research study, which may affect the subject's willingness to continue participation in the research study. Significant new findings often result in changes to the consent form or protocol after subjects have signed a consent document. The purpose of this policy is to provide guidance to the clinical research staff regarding the types of information the CHS CIRB considers to constitute significant new findings, what changes to the protocol or consent form should and should not be conveyed to subjects and the means through which the CHS CIRB expects significant new findings or changes to be conveyed to subjects.

The policy is not meant to be all inclusive but merely to provide a general guide. Each case will be examined by the CHS CIRB prior to making a determination if the subject should or should not be re-consented. Guidance from the sponsor will be considered. The determination will be conveyed to the principal investigator in writing.

CHS CIRB Review of significant new findings or changes

1. The principal investigator should report all significant new findings and the plan/method that will be used to disseminate the information to the subjects prior to its dissemination. However, if the information presents an apparent immediate risk or hazard to the subject, the principal will report the new information and why the information was given to the subjects prior to CHS CIRB review.
2. When reporting the plan/method to disseminate the information, the principal investigator should include the script that was used for an oral presentation and/or the written materials that were provided to the subject.

What constitutes significant new findings that require reporting to subjects?

Significant new findings generally include, but are not limited to:

1. Changes in potential or actual risks or benefits to subjects. Examples include:
    a. Changes in standard of care, such that participation in research can increase risk to subjects (i.e., subjects would be deprived of the standard of care by continuing to take part in the research study)
    b. Identification of new risks to subjects currently receiving the study treatment
    c. Identification of potential late-term effects for subjects who completed study treatment
    d. Discovery that a life threatening or severely debilitating side effect occurs more frequently than previously expected
2. Addition or deletion of study procedures or change in the number of required visits. Examples include:
    a. Addition of monitoring procedures
    b. Addition of new instruments or questionnaires to the study
    c. Collection of new or different information from subjects

3. Substantive alterations to the treatment subjects expect to or currently receive. Examples include:
    a. The frequency of dosing is increased or decreased
    b. The dose of the study drug is increased or decreased
    c. The route of study drug administration is altered

How to report significant new findings or changes to subjects

The presentation of significant new findings to subjects can be accomplished through various means, including the following:

1. A telephone call to subjects to report the significant new findings. The telephone call should be documented in the research file regarding when and who provided the new information to subjects. This method is encouraged when verification that subjects have received the information is needed (e.g. , due to potential increased risks) and subjects are no longer being seen in person or a significant gap in time would occur between when the new findings were discovered and the next scheduled contact with the subject. Signing the revised consent can then occur on the next scheduled visit.
2. A letter to subjects is another method that can be used to report significant new findings. This mode of communication may be suitable for information that needs to be communicated to subjects when they are no longer seen by the research in person and which are not life threatening or time sensitive.
3. Significant new findings or changes in the protocol can be conveyed via a consent form addendum rather than revising the consent document. If a revised consent form will be used instead of an addendum the revisions should be highlighted to draw the subject's attention to the new information.

When re-consenting subjects should not be pursued

The CHS CIRB is aware that study sponsors often request or require researchers to present consent documents to subjects to sign (re-consent) when they have been revised, regardless of the significance of the new information or change. In some cases asking subjects to sign a revised consent form is inappropriate and may result in needless burden on the subject by presenting irrelevant information and potentially diluting the impact of significant new findings at another time.

Examples of situations that the CHS CIRB may not approve re-consenting subjects include:

1. Minor, administrative changes or corrections (i.e., version number or date, addition of an investigator, minor clarifications made by the sponsor).
2. A minor increase in the number of subjects to be enrolled in the study
3. New risk information about the study drug is discovered which are not late effects and all subjects have completed study treatment
4. Addition of new study procedures or additions of study visits that do not pertain to subjects already enrolled in the study (e.g., changes made to screening procedures that only affect new subjects)

REFERENCES:

45 CFR §46.115, 45 CFR §46.116
21CFR §50.25, 21 CFR §56.115

ACCEPTED BY:

Elizabeth Yee
VP Clinical Ancillary Services

Andrej Zajac, MD
Chair CHS CIRB

Jana L. Lacera, RN, MSA, CDM
Human Protections Administrator, CHS CIRB
Director, IRB/Bio-Ethics

DATE(S) REVISED:

REVIEWED BY: CHS CIRB 5/7/2019, 11/2020

Date	Initials
11/2020	JL