Marshfield Clinic

Phase IV Drug Studies, IRB Review

1. SCOPE

1.1. System WIde

2. DEFINITIONS & EXPLANATIONS OF TERMS

2.1. Food & Drug Administration (FDA) Approved Drug – drug that has FDA approval for sale and marketing

2.2. Phase IV Drug Study – test on FDA approved drug for safety and efficacy data for a new population or indication; or to gather long-term surveillance data about the agent's safety and/or efficacy, or to acquire other clinical information about its use.

3. PROCEDURE BODY

Phase IV Drug studies can fit a unique niche in the ongoing evaluation of FDA-approved drugs. Such studies can also invite scrutiny as to whether they are driven by marketing rather than scientific inquiry. In order for the IRB to approve Phase IV Drug studies, all of the requirements at 45 CFR 46.111 1-7,b & 21 CFR 56.111 1-7, b,c must be met. The IRB will give also give careful consideration to the purpose when reviewing a Phase IV Drug study.

3.1. FDA and OHRP Approval Criteria

a. Risks to subjects are minimized;

b. Risks to subjects are reasonable in relation to anticipated benefits;

c. Selection of subjects is equitable;

d. Informed consent will be appropriately documented;

e. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects;

f. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data; and

g. When appropriate, additional safeguards are provided to protect the rights and welfare of vulnerable subjects (including compliance with Part 50, Subpart D).

3.2. Additional Approval Considerations (one of a-g below must be met)

a. The research is required by the FDA.

b. The research is designed to:

- Study the long-term incidence of adverse effects;
- Explore a specific adverse effect; or
- Gather additional, defined information.

c. The research is a long term study of the effect of the drug on morbidity and mortality.

d. The research is a clinical trial to supplement pre-marketing data for a drug approved via FDA Fast Track, Accelerated approval or Priority Review.

e. The research is a clinical trial of the drug in a new population.

f. The research is a clinical trial of the drug for a new indication.

g. A-f do not apply, however, scientific merit of the study been confirmed by the MCRF Research Committee.

4. ADDITIONAL RESOURCES

4.1. References:

- *Levine, Robert J. Ethics and Regulation of Clinical Research. New Haven: Yale University Press, 1988.*
- *45 CFR 46*
- *21 CFR 56*

4.2. Supporting documents available:

- *IRB Initial Review Procedure*

5. DOCUMENT HISTORY

Version No.	Revision Description
1.0	New Document in Document Control transferred from Policy & Handbook Library - #4074.0 (no changes made)
2.0	[This is where revision changes are listed. List format, no bullets or numbers.] Updated to include new linked documents created Added paragraph on archiving (paragraph 3.4)
3.0	

6. DOCUMENT PROPERTIES

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