Author name: Donovan Martin

Date of review: 11/15/12

Members present: Dawn Ludwig, Chair, Elizabeth Ankeny, Tony Clapp, Evren Guler, Melissa Hensley, Joyce Miller, Brenda Talarico, Hermann Weinlick.

(1) Risks to subjects are minimized. No

Comments:

Section 6A and 8C need revision

(2)Risks to subjects are reasonable in relation to anticipated benefits. No

Comments:

Section 8B and 8E need revision

 (2.a) Data collection method will protect the safety of subjects. No

 Comments:

 Section 6A, 6B and 7A need revision

(3) Selection of subjects is equitable. No

Comments:

Section 9D and 11B need revision

(4) Informed consent will be appropriately documented. No

Comments:

Section 6B and 10C need revision

Consent and Assent forms must be revised

(5) There are adequate provisions to maintain the confidentiality of data. No

Comments:

Section 7A need revision

VOTE: Revise and resubmit, 7 For, 0 Against, 1 Abstain