REGULATIONS FOR IRB REVIEW OF HUMAN RESEARCH

In accordance with 45 CFR 46.111 and 21 CFR 56.111, all of the following requirements must be satisfied in order to approve human subject research.

1 or i. Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design, and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2 or ii. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the Importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3 or iii. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as Children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

4 or iv. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by regulations.

5 or v. Informed consent will be appropriately documented, in accordance with, and to the extent required by the regulations.

6 or vi. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

7 or vii. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(viii) For purposes of conducting the limited IRB review required by § 46.104(d)(7)), the IRB need not make the determinations at paragraphs (a)(1) through (7) of this section, and shall make the following determinations: (i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of § 46.116(a)(1)-(4), (a)(6), and (d); (ii) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with § 46.117; and (iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Since MCW does not currently allow for Broad consent – ignore the above criteria and move on to viii below.

8 or viii. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.