Investigator Agreement

Name of Institution with the Federalwide Assurance (FWA): West Michigan Cancer Center

Applicable FWA #: 00002814

Individual Investigator/Co-Investigator's Name: ________________________________

Specify Research Covered by this Agreement: ___________________________________

(1) The above-named Individual Investigator has reviewed: 1) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (or other internationally recognized equivalent; see section B.1. of the Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions); 2) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46 (or other procedural standards; see section B.3. of the Terms of the FWA for International (Non-U.S.) Institutions); 3) the FWA and applicable Terms of the FWA for the institution referenced above; and 4) the relevant institutional policies and procedures for the protection of human subjects.

(2) The Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.

(3) The Investigator will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement.

(4) The Investigator will abide by all determinations of the Institutional Review Board (IRB) designated under the above FWA and will accept the final authority and decisions of the IRB, including but not limited to directives to modify, suspend or terminate participation in designated research activities.

(5) The Investigator acknowledges that the IRB approval is a temporary authority that may be withdrawn at any time if warranted by the conduct of the research.

(6) The investigator acknowledges that the IRB may request to review research records, interview subjects, observe the manner in which the research is conducted or observe the informed consent process.

(7) The Investigator will complete any educational training required by the Institution and/or the IRB prior to initiating research covered under this Agreement.

(8) The Investigator will report promptly to the IRB any proposed changes in the research conducted under this Agreement. The investigator will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

(9) The Investigator will report promptly (within 48 hours) to the IRB any unanticipated problems/Serious Adverse Events/Serious Medical Events involving risks to subjects or others in research covered under this Agreement (45 CFR 46.103(b)(5)).

(10) The Investigator will notify the IRB prior to enrolling vulnerable populations such as Wards of State or Prisoners into the study.

(11) The investigator acknowledges that neither subject recruitment nor any part of the research may commence until the final IRB approval is received. Final IRB approval will be provided to the investigator in the form of a letter.
(12) The Investigator, when responsible for enrolling subjects, will obtain, document, and maintain records of informed consent for each such subject or each subject’s legally authorized representative as required under HHS regulations at 45 CFR part 46 (or any other international or national procedural standards selected on the FWA for the institution referenced above) and stipulated by the IRB. The investigator will provide the study participants a copy of the signed informed consent document approved by the WMCC IRB.

(13) The Investigator will disclose any conflict of interest to study subjects during the consent process and in the consent document. The Investigator will disclose any conflict of interest to the IRB on the Conflict of Interest Disclosure form.

(14) The Investigator acknowledges and agrees to cooperate in the IRB’s responsibility for initial and continuing review, record keeping, reporting, and certification for the research referenced above. The Investigator will provide all information requested by the IRB in a timely fashion.

(15) The Investigator will provide a written report for IRB approval about the research project before the approval expiration date. If approval for continuation has not been issued by the IRB prior to the expiration date, the investigator is obligated to suspend all subject recruitment activity in the project until the IRB has issued approval for continuation.

(16) The Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the IRB.

(17) Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable federal regulations and state law.

(18) The investigator will submit to the IRB a final report, abstract, or manuscript within thirty days of completion of the data analysis.

(19) This Agreement does not preclude the Investigator from taking part in research not covered by this Agreement.

(20) The Investigator acknowledges that he/she is primarily responsible for safeguarding the rights and welfare of each research subject, and that the subject’s rights and welfare must take precedence over the goals and requirements of the research.

(21) The investigator acknowledges that the IRB will report serious and continuing actions of non-compliance to the appropriate regulatory agencies.

Investigator/Co-Investigator Signature: _____________________________ Date __________

Name: __________________________________________________________ Degree(s) __

( Last) (First) (Middle Initial)

Address: ______________________________________________________ Phone: _

_________________________ (City) __________________________ (State/Province) (Zip/Country)

FOR OFFICE USE ONLY:

FWA Institutional Official (or Designee): ___________________________ Date: __________________________

(Print Name) (Title)