Memorandum of Understanding
Between
John D. Dingell VA Medical Center and
Wayne State University
Concerning
Utilization of the Wayne State University Institutional Review Board

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Effective Date: 5/26/ **, 2006**

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1. Purpose

This Memorandum of Understanding (MOU) sets forth the express agreement between John D. Dingell VA Medical Center (VA Medical Center) and Wayne State University concerning the VA Medical Center utilization of University's Institutional Review Boards (IRBs) [Registered IRB# IRB0000325, IRB00000326, IRB00000327, IRB00000328, and IRB00004717]. Both parties assure that all of their pertinent activities related to human subject research will comply with all requirements as set forth in the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled the Belmont Report. In addition, the requirements set forth in Title 45, part 46 of the Code of Federal Regulations (45 CFR 46) will be met for all research as well as the Department of Veterans Affairs regulations at Title 38 Code of Federal Regulations Part 16 (38 CFR 16), and all other pertinent Veterans Health Administration (VHA) policies and procedures, including policies and procedures of the Office of Research & Development (ORD) and Office of Research Oversight (ORO) issued in Manuals, Handbooks and other relevant authorized Directives. This agreement is applicable to all research involving human subjects, and all other activities which even in part involve such research, if either:

a. the research is sponsored by the VA, or
b. the research is conducted by or under the direction of any employee or agent of the VA in connection with his or her institutional responsibilities, or
c. the research is conducted by or under the direction of any employee or agent of the VA using any property or facility of this institution, or
d. the research involves the use of the VA's protected health information to identify or contact human research subjects or prospective subjects.

An investigator is considered an employee of the VA Medical Center when the investigator has an appointment at the Medical Center that is compensated, or without compensation (WOC), or is employed through an intergovernmental personnel agreement (IPA). Investigators may have faculty or clinical appointments at Wayne State University.

2. **Both parties agree to:**

a. Maintain a Human Research Protections Program (HRPP) and to actively cooperate with each other in resolving any problems encountered in either HRPP.
b. Maintain the currency of the Federal Wide Assurance (FWA) of their institution and promptly notify each other of any modifications to the FWA or changes to the status of the Assurance documents. Both parties agree that they will not enter into collaborative human research with an institution that does not hold a Federal Wide assurance.
c. Assure that research is conducted in compliance with the Health Insurance Portability and Accountability Act (HIPAA).
d. Fully and actively support the regulatory responsibilities and accreditation process at each others institution by providing any necessary information or assistance and to notify each other if there are any changes in the accreditation status of their institution.

e. Ensure that each institution has ready access to any records, reports, communications, etc. as necessary for review by appropriate officials.
f. Promptly inform the other institution of any issues or complaints associated with VA research. This includes serious/unanticipated adverse events observed in VA research, and research noncompliance in accordance with IRB SOPs and VA Research Service policies. Any loss of patient information will be immediately reported to the VA Privacy Officer through the ACOS/Research.
g. Report the results of any external monitoring or audits of research activity at their institution that impact upon VA research or the status of their HRPP. This includes visits by sponsors and regulatory/compliance bodies.

3. **John D. Dingell VAMC <u>agrees to:</u>**

a. Allow the University IRB to review all VA protocols (including exempt), conduct continuing reviews, adverse event reporting, amendments and to conduct quality assurance reviews of all VA research activities.
b. Assure that the R&D Committee considers the IRB review, and provides initial approval prior to the conduct of covered VA human subjects research. Provide information to the IRB about significant issues that come to light in the VA approval process that might affect the conduct of a protocol. Assure that no human research will be conducted without IRB approval or determination that the activity is exempt from review.
c. Provide access to research subjects clinical records and/or case files to IRB as required for monitoring research activity. This includes any IRB member or designee.
d. Provide access and training to IRB regarding VA policies and procedures that govern the VA Human Research Protection Program (HRPP) processes and determinations.
e. Appoint two individuals to represent the VA Medical Center on each IRB that reviews VA research. VA representatives will be VA salaried for at least 5/8 FTEE. At least one member will have scientific expertise. VA IRB representatives will have full voting membership of the IRB. At least one representative must be a member of the R&D Committee. At least one VA representative will be present during full board review of VA research.
f. Provide all necessary VA procedures and policies for inclusion in the University IRB SOP, so that the SOP can effectively be shared as one document.
g. Assure that all key VA personnel engaged in research meet both VA and IRB training requirements and that there is a tracking system.
h. Provide and facilitate the use of VA Forms 10-1086 by the University IRB.
i. Adhere to requirements of University IRB regarding reporting of Conflict of Interest for IRB members.
j. Pay Wayne State University Human Investigation Committee any funds received for IRB review.

4. **Wayne State University <u>agrees to:</u>**

a. Review all VA protocols (including exempt), conduct continuing reviews, adverse event reporting, amendments and conduct quality assurance reviews of all VA research activities. IRB review and approval of VA research shall be conducted in accordance with 38 CFR 16, 45 CFR 46 Subparts A through D, 21 CFR 50 and 56 (where applicable), and all relevant academic Wayne State University policies and VA rules and policies as set forth in writing in VA Handbooks.
b. Require that the VA Form 10-1086, which includes specific indemnification and notification clauses, will be used as the informed consent form for all VA human subject research. The IRB will stamp approval on each page of the approved VA consent.
c. Serve as the Privacy Board for VA research protocols.
d. Provide training to VA Medical Center staff and investigators as appropriate for compliance with University IRB policies and submission procedures as they apply to VA submissions.
e. Maintain an IRB SOP that incorporates, by inclusion, VA policies and procedures applicable to reviewing VA human subjects research.
f. Appoint two VA representatives as full voting members to each University IRB that is the IRB of record for VA research protocols. VA representatives will be VA salaried for at least 5/8 FTEE.

At least one member will have scientific expertise. A VA voting member must be present during full board review of VA research.

g. Ensure that all IRB members and Chairs have received the appropriate training as IRB members. Facilitate training that will ensure IRB members are knowledgeable about applicable VA policy.
h. Appoint a representative of Affiliation Partnership Council to the VA R&D Committee.
i. Maintain all documents reviewed by its IRB in connection with VA research protocols, including any communication with investigators, and make such documents available to the VA R&D office upon request for 5 years following project termination or transfer them to the VA before destruction.
j. Advise the VA of requirements for reporting Conflict of Interest for IRB members.
k. Annually provide the VA with statistical information in order to conduct the annual review of the University IRB. A copy of such review will be provided to the IRB.
l. Provide the VA with minutes of each IRB meeting within 3 weeks of the meeting.

5. Revision or Termination

This agreement may be modified or altered by mutual agreement of the parties. Any modification or alteration must be in writing and signed by both parties. This MOU will expire 36 months from the date of execution unless renewed by mutual agreement of the parties. This agreement may be terminated at any time by either party upon thirty (30) days written notification. The termination must be done in a manner which would not harm the subjects, put the subjects at risk or harm the financial interests of either institution. This agreement will be reviewed for revision by each institution when the FWA for that institution is submitted for renewal. Revisions may be proposed at that time, if necessary, but may be proposed at any time.

Director VA Medical Center — Date: 5/26/06

Title Wayne State University — Date: 5/24/06

Approved by:

Network Director (VISN11) — Date: 6/6/06

FORM APPROVED
OFFICE OF THE GENERAL COUNSEL

Courtesy Copy to: Office of Research Oversight (10R)