

MEMORANDUM OF UNDERSTANDING

BETWEEN

WAYNE STATE UNIVERSITY

AND

JOHN D. DINGELL VA MEDICAL CENTER

REGARDING UTILIZATION

OF THE WAYNE STATE UNIVERSITY

INSTITUTIONAL REVIEW BOARDS

A. PURPOSE

1. This Memorandum of Understanding (MOU) sets forth the agreed upon respective authorities, roles, and responsibilities of the Wayne State University (WSU), operating the Institutional Review Boards (IRB) registered IRB#0000325 and IRB#0000327, hereinafter referred collectively to as the WSU IRB or the affiliate, and the John D. Dingell VA Medical Center (JDDVAMC) for the WSU IRB to serve as IRB of Record for JDDVAMC.
2. This MOU does not preclude JDDVAMC continuing to participate in an existing agreement with the Veterans Health Administration Central Office IRB (VHA Central IRB). The WSU IRB does not have oversight of research overseen by the VHA Central IRB.
3. This MOU is entered under the authority of 38 U.S.C. §7303, and satisfies the requirements of the Common Rule (38 CFR 16.114).

B. GENERAL PROVISIONS

1. The conduct of the parties will be guided by the "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" as set forth in The Belmont Report, published by the National Commission for the

Protection of Human Subjects of Biomedical and Behavioral Research in April 1979.

- 2. Parties will adhere to federal regulations codified in 38 CFR 16 & 17, 45 CFR 46 Subparts B-E, 21 CFR 50 & 56; and other pertinent VA and Federal regulations and guidance, including VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research, to the extent applicable. JDDVAMC will adhere to WSU IRB policies applicable to human subjects research to the extent permissible under Federal and VA requirements. JDDVAMC may not waive VA policy requirements.**
- 3. Parties will ensure that research is conducted in compliance with the Health Insurance Portability and Accountability Act (HIPAA). The WSU IRB will serve as the Privacy Board for JDDVAMC. IRB agrees to use VA HIPAA Authorization form provided by JDDVAMC that contains the required elements for VA protocols, as appropriate.**
- 4. In accordance with the Health Insurance Portability and Accountability Act (HIPAA), 45 CFR 164.512(i), and VHA Handbook 1605.01, Privacy and Release of Information, the WSU IRB may grant a HIPAA Waiver of Authorization for use or disclosure of protected health information (PHI) for research reviewed by the WSU IRB, if all criteria for a waiver of authorization are met. The WSU IRB must document these findings as required by 45 CFR 164.512(i).**
- 5. To the extent applicable, parties agree to comply with the provisions of VHA Handbook 1200.05, VHA Handbook 1605.1 §13, and VA Handbook 6500 with respect to reporting to the VAMC Privacy Officer (PO) of any unauthorized use, loss, or disclosure of individually-identifiable patient information of which they become aware. WSU agrees to establish written procedures for such reporting. VA shall have the right to review such WSU written procedures.**
- 6. To the extent applicable, parties agree to comply with the provisions of VA Handbook 6500.2 with respect to reporting to the VAMC Information Security Officer (ISO) of any violations of VA information security requirements of which they become aware. WSU agrees to establish written procedures for such reporting. VA shall have the right to review such WSU written procedures.**
- 7. Parties will develop and maintain mutually acceptable policies for monitoring human subject research and for regular communication of results of this monitoring, and other documentation of human subject's research, to the R&D Committee. Parties will work to establish a description of the method and frequency of the WSU IRB providing information including unredacted IRB minutes, correspondence, and**

reports of quality improvement activities to the VA R&D Committee. In addition, parties will develop SOPs that describe how compliance monitoring, auditing, and reporting to appropriate regulatory authorities will be handled by administrative officials, research compliance officers, and the IRB and its administrators. Parties will provide the results of any internal or external monitoring or audits of human subject research, including inspections by sponsors and regulatory compliance bodies, to the IRB.

8. Parties will maintain a current Federalwide Assurance (FWA). Any changes to the FWA, any lapse in approval, restriction, suspension, termination, or failure to maintain an approved FWA by any of the parties to this MOU will be reported to the other immediately in writing.
9. Parties will prohibit collaborative involvement in JDDVAMC human subject research of any institution that does not have a Federalwide Assurance (FWA) or other Assurance acceptable to the ORO Executive Director.
10. Parties will cooperate in developing and maintaining current written IRB Standard Operating Procedures (SOP) that incorporate procedures for reviewing, approving, and exercising oversight of JDDVAMC human subject research.
11. Parties will promptly inform each other of any complaints from subjects or others; unanticipated problems involving risks to subjects or others; apparent serious adverse events; suspension or termination of activities; and apparent serious or continuing noncompliance encountered in JDDVAMC human subjects research. The JDDVAMC will report to ORO as required under VHA Handbook 1058.01 and the WSU IRB will provide JDDVAMC with information needed to fulfill the facility's reporting requirements.
12. JDDVAMC will nominate 2 or more VA member-representatives (and alternates when possible) to each IRB that reviews JDDVAMC research. The WSU IRB will appoint the VA representation as full voting members of the IRB (i.e., review all protocols, not just VA protocols). JDDVAMC representatives must be at least 1/8 VA-salaried (not IPA or WOC). At least one JDDVAMC member must have scientific expertise. At least one VA voting member must be present during full board review of JDDVAMC research. WSU IRB will provide updated roster(s) to the JDDVAMC facility within 15 days of IRB membership change. JDDVAMC will submit current IRB rosters to ORO within 30 days of a membership change in accordance with applicable VHA Handbooks 1058.01 and 1058.03.
13. The JDDVAMC Medical Facility Director (Institutional Official) is the individual legally authorized as Signatory Official to commit the JDDVAMC

to an Assurance. The IO serves as the official representative of the institution to external agencies and oversight bodies, and provides all written communication with external departments, agencies, and oversight bodies. The IRB agrees to establish effective communication methods to enable the JDDVAMC Institutional Official to comply with requirements for reporting noncompliance to external oversight bodies such as OHRP, FDA, NIH, and other applicable Agencies.

14. Information security will be in place to protect the rights of study participants and the data. Each protocol for JDDVAMC research will be evaluated by the JDDVAMC Information Security Officer and Privacy Officer to determine whether information security is properly accounted for and make recommendations (e.g., encryption, data use agreement) as necessary. The Privacy Officer will determine that all issues identified in a given protocol have been addressed before the research is initiated. (VHA Handbook 1200.05.)
15. Parties will develop and maintain effective communication and cooperation mechanisms sufficient to ensure adequate protections for human research subjects and will actively cooperate in resolving any problems encountered in either the VA facility's Human Research Protection Program ("HRPP") or, to the extent that VA research is impacted, in WSU's HRPP.
16. Parties will maintain JDDVAMC human subjects research records for the required time frame following project termination in accordance with VA Policy. Where WSU maintains IRB and other research records for a shorter period of time than required by VA RCS 10-1, parties will cooperate to provide an acceptable mechanism to transfer records relating to VA research to the JDDVAMC facility or provide the VA and the VHA Office of Research Oversight ready access to these records for copying.
17. Parties will advise each other of requirements for reporting by investigators or IRB members of Conflicts of Interest in conducting or reviewing research and will adhere to those requirements. Parties will communicate any issues that occur.
18. Research staff will assist the IRB in a review, typically every two years, of IRB files for all active JDDVAMC protocols to ensure completeness, accuracy, and compliance with VA regulations; and assist with pre-review of VA adverse events, as necessary.

C. RESPONSIBILITIES OF THE WSU IRB

The WSU IRB Institutional Official assures JDDVAMC that WSU IRB will carry out the following functions and responsibilities in accordance with all applicable requirements:

1. Provide the JDDVAMC facility and ORO with access for review and copying any IRB or other records, documents, or reports relevant to compliance reviews of research conducted or supported by VA, approved by the JDDVAMC facility's R&D Committee, or involving individuals with VA appointments. This access will be provided to any individual(s) designated by the JDDVAMC Research Office.
2. Provide JDDVAMC R&D Committee copies of unredacted IRB Meeting minutes. Provide the JDDVAMC with draft minutes of IRB meetings within fifteen (15) WSU business days of the meeting date. JDDVAMC agrees to treat as strictly confidential any information related to non-VA research contained in any information provided herein. When minutes are approved by the voting members at a subsequent IRB meeting, the minutes shall be signed by the IRB Chair, or a qualified voting member of the IRB designated by the Chair, and shall be forwarded to the JDDVAMC as soon as possible.
3. Provide access to or information from, the IRB database to approved representatives of the VA for the purposes of tracking ongoing VA research activity.
4. Provide training to JDDVAMC staff and investigators as appropriate for them to comply with affiliate IRB policies and submission procedures as they apply to JDDVAMC submissions.
5. Report the results to the JDDVAMC Institutional Official of any internal or external monitoring or audits of the affiliate's research, including inspections by sponsors and regulatory/compliance bodies, that impact VA research or the status of the JDDVAMC HRPP.
6. Ensure that all IRB Chairs and members have received the appropriate training as IRB members, including training to ensure that they are knowledgeable about applicable VA requirements.
7. Require that all VA requirements for informed consent, including specific indemnification and notification language, will be used for all JDDVAMC human subject research.

8. Annually provide the VA R&D Committee with necessary access and information needed to conduct the annual review of the WSU IRB structure, function, and performance required under VHA Handbook 1200.01. This information should include, but is not limited to, the number of protocols (both total and VA specific) reviewed, approved, expedited, exempt, and continued. Additionally, the number of Adverse Events, Unexpected Problems, and Significant Adverse Events reported. A copy of the final review will be provided to the IRB.
9. Understand that no VA human research can be conducted without both IRB approval (unless determination that the activity is exempt from IRB review) and JDDVAMC R&D Committee approval as required under VHA Handbook 1200.01.
10. Either become accredited by an accrediting body, or participate in the HRPP accreditation process with the JDDVAMC including allowing access to the necessary records, documents, reports, and personnel for the JDDVAMC to become accredited.
11. Review JDDVAMC protocols, conduct continuing reviews, and review adverse event reporting, amendments and determination of exempt and non-human subject research.

D. RESPONSIBILITIES OF JDDVAMC

The JDDVAMC's Institutional Official assures that JDDVAMC will assume the following responsibilities in accordance with all applicable VA and other Federal requirements. JDDVAMC will:

1. Provide the IRB access to all relevant investigator records (including data files, regulatory files/binders, case report forms, sponsor queries, internal and external monitoring reports, and audit reports); research subjects' clinical and research records or case files; and facility research records (including sponsor agreements), as required for oversight and monitoring of research activity. This access will be provided to any individual(s) designated by the IRB.
2. Provide access and training to IRB members regarding VA policies and procedures that govern the VA Human Research Protection Program (HRPP) processes and determinations.
3. Pay WSU an annual IRB fee for services of WSU's HRPP including IRB review and oversight and conflict of interest review and management according to the fee schedules attached as Exhibits A and B hereto, as may be modified from time to time by WSU-IRB in accordance with its

published fee schedule. JDDVAMC shall pay WSU's invoices within sixty (60) days.

4. Establish procedures for the JDDVAMC Information Security Officer (ISO) and the VA Privacy Officer (PO) review of VA research as non-voting members of the R&D Committee. Assure JDDVAMC investigators provide the WSU IRB with copies of the ISO and PO reviews.
5. Provide the results of any internal or external monitoring or audits of human subject research, including inspections by sponsors and regulatory/compliance bodies, to the IRB.
6. Ensure that all key JDDVAMC personnel engaged in human research meet both WSU's and the VA facility's training requirements and that there is a tracking system to document such training.
7. Make available to the affiliate all VA requirements for informed consent.
8. Make available to the WSU IRB the annual JDDVAMC review and evaluation of the IRB structure, function, and performance required under VHA Handbook 1200.01.
9. Ensure that no human research is conducted without IRB approval or determination that the activity is exempt from IRB review. Assure that R&D Committee approval is obtained as required under VHA Handbook 1200.01. The R&DC and the VAMC Institutional Official may not approve research which has been disapproved by the IRB.
10. Become accredited and/or maintain accreditation of the JDDVAMC HRRP in good standing by the accrediting body designated by the Veterans Health Administration.

E. TERMINATION PROVISIONS

1. This MOU will go into effect when signed.
2. This MOU may be amended or modified only by written instrument executed by an authorized signatory for each party.
3. This MOU must be reviewed and revised as conditions change and renewed every 3 years per VHA Handbook 1058.03. The MOU must be amended when there is a change in any of the signatory officials, with a copy of the amendment sent to ORO.
4. This MOU may be terminated at any time for any reason by either party upon written notification of intent to terminate to the other party in

accordance with this paragraph. The termination must be done in a manner which would not harm subjects or put subjects at risk. Parties shall send notices by registered or certified mail by U.S. Postal Service with return receipt, or by an express/overnight commercial delivery service, with delivery prepaid to the authorized representative of each party listed in the signatory page below. Notices shall be properly addressed to the other party at the addresses provided below or to any other address designated in writing by the other party.

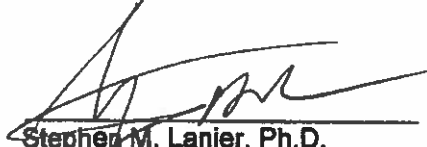
5. Upon notice of intent to terminate, WSU and WSU IRB agree that IRB oversight of JDDVAMC research will not be terminated until all the JDDVAMC research is transferred to the oversight of another IRB or safely closed. This MOU may be amended to describe the timetable and process for termination.

Signature Page:



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Date: 2/4/16



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