Memorandum of Understanding
Between
George E. Wahlen Department of Veterans Affairs
Salt Lake City Health Care System
and University of Utah

Effective Date: 12/6/2023

PURPOSE

This Memorandum of Understanding ("MOU") sets forth the agreement between the George E. Wahlen Department of Veterans Affairs Salt Lake City Health Care System ("VASLCHCS") and the University of Utah ("University") concerning the agreed upon arrangements between the same for the use of the University of Utah's Registered Institutional Review Board ("IRB").

- The VASLCHCS maintains Federal Wide Assurance Number FWA00001900 assigned by OHRP.
- The University maintains Federal Wide Assurance Number FWA00003745 assigned by OHRP.

GENERAL AGREEMENT

Both the VASLCHCS and the University have FWAs and so agree to abide by all applicable regulations in the conduct of human subjects research at each facility. The FWA of the University of Utah indicates that the University does not apply the Common Rule (45 CFR 46) to all research overseen by the IRBs. The University acknowledges that all VA research is federally conducted or supported. As such, the Common Rule (38 CFR 16) applies to the oversight of VA research.

INSTITUTION-SPECIFIC AGREEMENTS

The Department of Veterans Affairs Salt Lake City Health Care System agrees to:	
VA1.	Adhere to the federal regulations as codified in 38 CFR 16 & 17; 21 CFR 50 & 56; other pertinent federal regulations and guidance; VA requirements (including VHA Directive 1200.05), and University policies applicable to human subjects research to the extent permissible under federal and VA requirements. All VA policies apply, i.e., VASLCHCS cannot waive policy requirements.

The University of Utah agrees to:	
U1.	Adhere to the federal regulations as codified in 38 CFR 16 & 17; 45 CFR 46 Subparts B-D, 21 CFR 50 & 56; other pertinent federal regulations and guidance; VA requirements (including VHA Directive 1200.05), and university policies applicable to VA human subjects research.

VA2.	Provide the University 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 records and/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 individual(s) designated by the IRB.		**U2.**	Provide the VASLCHCS 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 VASLCHCS's R&D Committee or involved individuals with VA appointments. Provide access to or information from, the IRB records to approved representatives of the VASLCHCS for the purposes of tracking ongoing VASLCHCS research activity.
VA3.	Maintain mutually acceptable policies for monitoring human research and for providing regular communication of results of this monitoring, and other documentation of human subject research, to the R&D Committee. Work with the affiliate to establish a description of the method and frequency of the affiliate's providing information including unredacted IRB minutes, correspondence, and reports of quality improvement activities to the VA R&D Committee. Establish a definition of "timely" provision of such documentation. 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.		**U3.**	Maintain mutually acceptable policies for monitoring human subject research and for regular communication of results of this monitoring and other documentation of human subject research, to the R&D Committee. Work with the VA to establish a description of the method and frequency of the affiliate's providing information including unredacted IRB minutes, correspondence, and reports of quality improvement activities to the VA R&D Committee. Establish a definition of "timely" provision of such documentation.
VA4.	Provide access and training to IRB members regarding VA policies and procedures that govern the VA Human Research Protection Program (HRPP) processes and determinations.		**U4.**	Provide training to VASLCHCS staff and investigators as appropriate for them to comply with University IRB policies and submission procedures as they apply to VA submissions.
VA5.	Adhere to current written IRB Standard Operating Procedures that incorporate procedures for reviewing, approving and exercising oversight of VA human subject research.		**U5.**	Maintain IRB SOPs that include all required procedures for reviewing, approving and exercising oversight of VA human subject research.
VA6.	Promptly inform the IRB of any problems, including complaints, and unanticipated problems involving risks to participants or others; suspension or termination of activities; and serious or continuing noncompliance encountered in VA human subjects research. Report to ORO as required under VHA Directive 1058.01. If the procedures for the review and reporting of events of the IRB differ from, or the timeframes exceed those of, 1058.01, the Director must consult with the VHA Office of Research & Development (ORD) and the appropriate ORO workgroup as to the adequacy of those procedures to protect the interests of VA and those involved in VA research.		**U6.**	Promptly inform the VA of any issues or complaints associated with VA research, i.e., noting the problem, investigator, study and dates. This includes unanticipated problems involving risks to participants or others; suspension or termination of activities; and serious or continuing noncompliance encountered in VA human subjects research related to VA investigators in order for the VA Medical Center Director to fulfill the facility's reporting requirements under VHA Handbook 1058.01. This is accomplished through the ERICA system. Notify the VA if the procedures for the review and reporting of events of the IRB differ from, or the timeframes exceed those of VHA Directive 1058.01.

VA7.	May nominate VA member-representatives to each of the University IRB panels that review VA research. VA member-representatives will be full voting members of the IRB (i.e., review all protocols, not just VA protocols). Nomination of an R&D Committee member to the IRB as a VA representative is strongly encouraged. Has readily available access to, accurate up-to-date rosters for all IRB panels.		**U7.** May appoint VA representation to each IRB that is an IRB of record for VA research protocols. VA member-representatives will be full voting members of the IRB (i.e., review all protocols, not just VA protocols). Appointment of an R&D Committee member to the IRB as a VA representative is strongly encouraged. The VA Research Compliance Officer is a consultant to the IRB. Provide readily available access to local rosters promptly after any IRB membership change. Comply with HHS-OHRP and Food and Drug Administration (FDA) requirements for mandatory reporting of information related to FDA-regulated research on the HHS-OHRP IRB Registration.
VA8.	Promptly notify the University of any modifications to, or changes in the status of, the VASLCHCS's Federalwide Assurance FWA or changes to the status of the Assurance documents.		**U8.** Promptly notify the VASLCHCS of any modifications to, or changes in the status of, the University's Federalwide Assurance (FWA).
VA9.	Not enter into collaborative involvement in VA human subject research with any Institution that does not have a FWA or other Assurance acceptable to the ORO Executive Director. VA will only use its IRBs of record or IRBs of entities that have FWAs as permitted by VA policy.		**U9.** Maintain a current FWA. The University will not involve the VASLCHCS in any human subject research with collaborators that do not have an FWA or other Assurance acceptable to the ORO Executive Director.
VA10.	Follow SOPs that were developed to describe how compliance monitoring, audits, and reporting to appropriate regulatory authorities will be handled by administrative officials, and compliance officers. Provide the results of any internal or external monitoring or audits of human subject research activity to the IRB. This includes inspections by sponsors and regulatory/compliance bodies.		**U10.** Follow SOPs that were developed to describe how compliance monitoring, audits, and reporting to appropriate regulatory authorities will be handled by administrative officials, compliance officers, and the IRB and its administrators. Report the results of any internal or external monitoring or audits of research activity at the University that impact VA research or the status of the VA HRPP to the VA Institutional Official. This includes inspections by sponsors and regulatory/compliance bodies.
VA11.	Maintain effective communication and cooperation mechanisms sufficient to ensure adequate protections for human subjects. Actively cooperate with the University in resolving any problems encountered in either HRPP.		**U11.** Maintain effective communication and cooperation mechanisms sufficient to ensure adequate protections for human research subjects. Actively cooperate with the VASLCHCS in resolving any problems encountered in either the VASLCHCS HRPP or, to the extent that VA research is impacted, in the University's HRPP.

VA12. Should the IRB not fulfill its obligations, the VA will advise termination of this agreement (MOU) and institute its own internal IRB or affiliate with another University or VA operated IRB as permitted by VA policy. The termination of this agreement with the University will be in an orderly manner so as not to harm subjects or put subjects at risk. If the VASLCHCS determines transfer of oversight of research to another IRB is necessary, the transfer will be conducted in accordance with VHA Handbook 1058.03. Review and renew the MOU every three years, or more frequently as needed, and make any revisions necessary to reflect current arrangements.		**U12.** Termination of this agreement (MOU) with the VA will be conducted in an orderly manner so as not to harm subjects or put subjects at risk. The IRB will follow the policy and procedure for protection of research participants as described in the written SOP. The University agrees to continue oversight of VA research until such time the VASLCHCS had transferred IRB oversight to the new IRB in accordance with VHA Handbook 1058.03.
VA13. Ensure that all key VA personnel engaged in research meet both VA and IRB training requirements and maintain a tracking system.		**U13.** Ensure that all IRB members and Chairs have received appropriate training as IRB members. Facilitate training that will ensure IRB members are knowledgeable about applicable VA policy.
VA14. Provide all VA requirements for informed consent to the University.		**U14.** Require that all VA requirements for informed consent, including specific indemnification and notification clauses will be used for all VA human subject research activities.
VA15. Provide the University a copy of the annual VASLCHCS R&D Committee review and evaluation of the IRB structure, function, and performance.		**U15.** Allow necessary access for annual evaluation of the IRB by the VASLCHCS. The University will review the annual evaluation of the IRB structure.
VA16. Require that the VA Research Compliance Officer (RCO) has access to the IRB's records to the extent necessary for the RCO to fulfill research auditing requirements.		**U16.** Make available to the RCO access to the IRB's records to the extent necessary for the RCO to fulfill research auditing requirements.
VA17. Ensure that no human research will be conducted without IRB approval or determination that the activity is exempt from review. Assure that R&D Committee approval is obtained in accordance with VA policy.		**U17.** Understand that no VA human research can be conducted without both IRB approval (or determination that the activity is exempt from IRB review) and VA R&D Committee approval in accordance with VA policy.
VA18. Ensure the University understands the required time frame for record retention in accordance with VA policy. In the event the University does not maintain the research records for the required time frame, provide an acceptable mechanism to transfer records relating to VA research to the VA facility.		**U18.** Maintain VA human subject research records at the University in accordance with VA Policy. Provide the VAMC and the VHA Office of Research Oversight (ORO) ready access to these records for review and /or copying. Consult with the VA, and transfer such records to the VA if requested, before destruction of any VA records maintained by the IRB.
VA19. Ensure that research is conducted in compliance with the Health Insurance Portability and Accountability Act (HIPAA). The University fulfills the role of IRB and Privacy Board for VA studies. The VA ensures that the authorization document is consistent with the consent document and provides VA HIPAA Authorization form 10-0493 with required VA elements if using standalone HIPAA authorization. If combined form is used, all required elements must be present.		**U19.** Ensure that research is conducted in compliance with the Health Insurance Portability and Accountability Act (HIPAA). The University fulfills the role of IRB and Privacy Board for VA studies. The IRB-Privacy Board reviews and approves waivers of authorization and agrees to use VA HIPAA Authorization form 10-0493 that contains the required elements for VA protocols, as appropriate.

VA20.	Adhere to requirements of the University IRB regarding reporting by investigators or IRB members of Conflicts of Interest in conducting or reviewing research. Advise the University of any issues that occur. Advise the University of VA requirements for reporting by investigators or IRB members of financial conflicts of interest. Advise the University of any issues that occur.		**U20.** Advise the VASLCHCS of requirements for reporting by investigators or IRB members of Conflicts of Interest in conducting or reviewing research. Advise VASLCHCS of any issues that occur. Adhere to VA's requirements for investigator or IRB member reporting of financial conflict of interest. Advise VASLCHCS of any issues that occur.
VA21.	Agree to cooperate with IRB accreditation process at the University.		**U21.** Maintain accreditation in good standing.
VA22.	Adhere to requirements of the University regarding data sharing, data transfer, and information security between the two institutions.		**U22.** Adhere to requirements of the VASLCHCS regarding data sharing, data transfer, and information security between the two institutions.
VA23.	Follow procedure for ISSO and Privacy officer review of VA research as nonvoting members of R&D committee.		**U23.** Cooperate with VA in supporting procedures for ISSO and Privacy Officer review of VA research as nonvoting members of the R&D Committee.
VA24.	VA will comply with the provisions of VA Directive 6500 with respect to reporting to the VAMC Privacy Officer of any unauthorized use, loss, or disclosure of individually-identifiable patient information of which it becomes aware.		**U24.** The University IRB agrees to comply with the provisions of VA Directive 6500 with respect to reporting to the VAMC Privacy Officer of any unauthorized use, loss, or disclosure of individually-identifiable patient information of which it becomes aware. University further agrees to follow written procedures for such reporting.
VA25.	VA will comply with the provisions of VA Handbook 6500.2 with respect to reporting to the VAMC Information System Security Officer of any violations of VA information security requirements of which it becomes aware.		**U25.** The University IRB agrees to comply with the provisions of VA Handbook 6500.2 with respect to reporting to the VAMC Information System Security Officer of any violations of VA information security requirements of which it becomes aware. University further agrees to establish written procedures for such reporting.
VA26.	The VA Facility Director (Institutional Official) is the individual legally authorized as Signatory Official to commit an institution 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.		**U26.** The University IRB agrees to establish effective communication methods to enable the VA Institutional Official to comply with requirements for reporting noncompliance to external oversight bodies such as OHRP, FDA, NIH, and other applicable Agencies.
VA27.	Where the VHA Central Office IRB and National Cancer Institute Central IRB, or other external IRBs VA Salt Lake City may rely on, have jurisdiction of some VA Research at the facility, the University IRB does not have oversight of such research. Where the NCI CIRB has oversight of VA research but does not perform all necessary oversight functions such as HIPAA review, the University IRB has limited responsibility to assist the VA R&D Committee with oversight of the research as described in local SOPs.		**U27.** The University IRB acknowledges that it does not have oversight of research overseen by the VHA Central Office IRB, the National Cancer Institute Central IRB, or any other external IRB VA Salt Lake City may rely on. Where the NCI CIRB does not provide certain review required by regulation, the University IRB agrees to assist the VA R&D Committee by providing HIPAA or other review to the R&DC as described in local SOPs.

ANGELA WILLIAMS

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Angela D. Williams, Pharm.D., M.S.
Director
George E. Wahlen Department of Veterans Affairs
Salt Lake City Health Care System

Date

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Erin Rothwell
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12/6/2023

Erin Rothwell, Ph.D., M.S.
Vice President for Research
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Date