

USA

exceptions for minimal risk studies) by the IRB to ensure the safety and welfare of participants, pursuant to the regulation provided in 45 CFR 46. The IRB conducts review and approval for all human subjects research activities conducted under its jurisdiction. This jurisdiction includes research conducted or directed:

- By USA faculty, staff, students, affiliates or outside researchers and occurs on the property of the University of South Alabama regardless of funding sources
- By an outside researcher involving USA faculty, staff, students, or affiliates.

The VP for Research and Economic Development is the Institutional Official for the institution for IRB purposes through the Federalwide Assurance Agreement.

The IRB shall have authority to determine if an activity constitutes human subjects research or exempt status research as defined in federal regulations. The IRB shall employ a review process which conforms to the Federal Policy for Protection of Human Subjects, and the current assurance, between University of South Alabama and

one institution, with somewhat peripheral involvement by investigators at the other. In effect, this constitutes a deferral of the right of review by the institution with lesser involvement, which retains responsibility for ensuring compliance with all IRB requirements. An "IRB Authorization Agreement" is the form of agreement executed between the institutions to document this delegation of IRB oversight. The University of South Alabama may be either the institution deferring to another institution or the institution to which the IRB review is delegated. All requests for such delegations should be referred to the Director, Office of Research Compliance and Assurance. The Director, in consultation with the IRB and the Institutional Official as appropriate, will determine whether the institution will agree to the deferral. If the decision is to agree to the IRB delegation, the Director will be responsible for executing the agreement.

2.2.1 Human Research Activities Performed at Other Institutions

All research activities performed by, or under the direction of, USA personnel or which use University resources or facilities, must comply with applicable USA policies and procedures, regardless of funding and whether performed in USA facilities or at offsite locations.

2.2.2 Requirements for Approval of Research at Non-USA Facilities

Any human subjects rele(w)1tc1 (N)0. (h(i)4 (n)10 (w)10 (po)2 (l)4 he)13 ((o)2 (r)T0 Tc

Biomedical Research (IRB Registration 0000286). Research involving educational, social and behavioral sciences is reviewed by IRB #2 - Non-biomedical (IRB Registration 00011574).

History:

Effective Date:

Revisions: November, 2018

Responsible Office:

Office of Research Compliance and Assurance