TANEY COUNTY HEALTH DEPARTMENT

IRB MEMORANDUM OF UNDERSTANDING

Memorandum of Understanding between and among human research protection programs at Taney County Health Department and

_____ for IRB review of human subject research.

AGREEMENT

This Memorandum of Understanding (MOU) sets forth an agreement by and between the Human Research Protection Program (HRPP) Institutional Review Board (IRB), at the Taney county Health Department (TCHD) and the _____. This MOU concerns reliance by the HRPP IRB at the _____, (Relying Agency) on the review and approval, or determination of exemption, of human subject research, by the TCHD HRPP (Reviewing Agency).

TYPES OF RESEARCH COVERED BY THIS AGREEMENT

This MOU applies to human subject research as defined by federal and state statutes and regulations that is determined to be exempt or is eligible for IRB review.

COMPLIANCE WITH AGENCY GUIDANCE

This MOU meets the requirements for designation of another institution's IRB as the reviewing IRB, as set forth in Office for Human Research Protections' (OHRP) guidance.

DEFINITIONS

a. **Human Subject Research** - The definition of human subject research is that set forth in *45 CFR § 46.102* and *21 CFR § 50.3, §103, §312.3* and *§812.3*.

b. **Institutional Official** – The Institutional Official is the Signatory Official for TCHD to assure compliance with regulations governing protection of human subjects. The OHRP requires the Institutional Official to be a high-level official who has the authority to represent the institution.

RELIANCE ON ANOTHER IRB; TRAINING

The Institutional Officials signing below agree that the HRPP at (agency named above)_____may accept and rely on the TCHD HRPP determination of exemption or the review and approval of research involving human subjects meeting the definition in paragraph 4 above, with the exception that studies in which individuals involved in the design, conduct or reporting of research at either the relying or reviewing agency who have not undergone training on subject protection shall not be eligible to rely on this MOU.

COMPLICANE WITH FEDERAL AND STATE LAW

A determination of exemption or review and approval of human subject research under this agreement shall be conducted in accordance with all relevant federal and state statutes and regulations governing the protection of human subjects, and with all relevant agency policies pertaining to the protection of human subjects participating in research for which the Reviewing Agency is responsible.

INFORMED CONSENT

Research that is subject to this agreement and which is not eligible for a determination of exemption, shall employ a consent process, including a consent form, consent waiver, or alteration of consent that meets all federal and state requirements and is approved by the TCHD HRPP IRB.

DETERMINING REVEIWING IRB

a. The reviewing IRB shall be at the Taney County Health Department.

b. Exceptions to this provision shall be determined by the TCHD HRPP Director, specifically if it is determined that the research requires Federal Wide Assurance (FWA).

DUTIES AND RESPONSIBILITIES OF PRINCIPAL INVESTIGATORS

a. The Principal Investigator (PI) at the **Relying Agency** shall:

i. Complete and sign a Request for Review of Research Protocol, IRB Form 1, and Protocol template and forward to the Agency Supervisor of the Relying Agency before the study is submitted to the Reviewing Agency HRPP for initial review, amendment, and/or continuing review; and

ii. Follow the standards and guidelines of the HRPP of the Reviewing IRB for the reporting of any post approval events, including adverse events, other safety information, and/or protocol violations or incidents.

b. The IRB at the **Reviewing Agency** shall:

i. Review the submitted documents and determine if the proposal is exempt, requires an expedited review, or requires a full-review.

ii. Actively communicate with all study investigators at all relying agencies to make sure that the necessary and required coordination of any research activities including notification of post-approval events takes place.

DUTIES AND RESPONSIBILITES OF THE REVIEWING IRB

a. Review and Oversight – The reviewing IRB shall conduct initial and continuing reviews, and shall review amendments to approved protocols and reports of unanticipated problems and serious and/or continuing noncompliance. The reviewing IRB shall have the authority to suspend or terminate the research. The HRPP of the reviewing IRB shall notify relying HRPPs of any determinations of unanticipated problems, serious or continuing noncompliance, and suspensions and terminations.

b. Approval Letter – The HRPP of the reviewing IRB shall send a copy of its Approval Letter to the relying HRPP(s) IRB(s).

c. Right to Decline to be IRB of Record – An agency's HRPP may decline, on a case-by case basis, to be the reviewing IRB for research conducted at another location. If this occurs, the HRPP of the IRB being asked to review will notify all relevant parties.

d. Record Keeping – The HRPP of the reviewing IRB will keep records of studies subject to this MOU. The records will include at a minimum the date the application is submitted, review determinations, dates of approval, location of research activity, and oversight actions.

DUTIES AND RESPONSIBILITIES OF THE RELYING HRPP

a. Acknowledgement Letter - The HRPP of the relying IRB will issue an Acknowledgement Letter to the PI of the relying agency informing him or her of its decision to rely on another campus' review and will send a copy of the Acknowledgement Letter to the HRPP of the reviewing IRB.

b. Compliance and Oversight - The HRPP of the relying IRB shall monitor compliance with the terms and conditions of the reviewing IRB's approval of research being conducted at the relying agency. The HRPP of the relying IRB shall advise the HRPP of the reviewing IRB of any incidents of noncompliance or unanticipated problems of which it becomes aware including, but not limited to, violations of human research protection regulations.

c. Right to Decline to Rely – An agency HRPP may decline, on a case-by-case basis, to rely on IRB review conducted by TCHD. If this occurs, the HRPP of the relying IRB shall notify the PI seeking to rely, the HRPP at the reviewing agency of its decision not to rely.

d. Record Keeping - The HRPP of the relying IRB will keep records of studies subject to this MOU. The records will include at a minimum the date the Notice of Intent to Rely was submitted, administrative review determinations, dates of approval by the Reviewing IRB, and location of research activity, as well as oversight actions.

DUTIES AND RESPONSIBILITIES OF BOTH THE REVIEWING AND THE RELYING HRPP

a. The HRPPs of both the reviewing and relying agencies will ensure that local institutional reviews and approvals are in place before the research commences at each site. This includes, but is not limited to, institutional biosafety review, radiation safety review, review and management of conflict of interest, and others as required.

b. Reporting Unanticipated Problems and/or any Serious and/or Continuing Noncompliance – The HRPPs of the reviewing and relying IRBs shall immediately report to the reciprocal HRPP any unanticipated problems involving risks to subjects or others or any incidents of serious and/or continuing noncompliance. This reporting duty is in addition to and does not replace the investigator's duty to report unanticipated problems or serious and/or continuing noncompliance as required by government regulation and institutional policies and procedures.

c. Cooperation - The HRPPs of the reviewing and relying IRBs shall cooperate fully with the reciprocal HRPP concerning this agreement. Relevant documentation to support review, compliance and oversight by the respective HRPPs will be made available to the reciprocal HRPP upon request. Each HRPP will make available records applicable to regulatory and accrediting agency activity if and when the reciprocal HRPP requires such records.

d. MOU on File - This MOU must be kept on file at the HRPPs that are party to this agreement and must be provided to OHRP upon request.

EXECUTION

The undersigned Institutional Officials of the HRPPs at Taney County Health Department and at the _____ have read and agreed to all of the terms above. This MOU shall remain in effect unless or until revoked or superseded by a revised Memorandum of Understanding.

SIGNATURES

Authorized Official of TCHD	Robert Niezgoda, Signatory Official
Authorized Official of _____	Printed Name and Title

Revised 9/15