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Institutional Review Board Assurance No. FWA00005304

March 24, 2023

Re: IRB Membership

To Whom It May Concern:

Saint Louis University (SLU) maintains an Assurance Document with the US Public Health Service. The SLU Federal Wide Assurance number, FWA00005304, is listed on the Office for Human Research Protections web site which is <u>http://www.hhs.gov/ohrp/</u>. SLU has three registered Institutional Review Boards (IRBs): IRB00000158, IRB00003984, and IRB00005627.

The compositions of the SLU IRBs are in accordance with the regulations of both the Food and Drug Administration and the Public Health Service. The SLU IRBs are comprised of both full and alternate Board members. The IRBs are duly constituted, fulfilling all requirements for experience, expertise and diversity to appropriately review protocols submitted to the IRBs for consideration, including protocols in which vulnerable populations are asked to participate.

Regarding expertise in matters of medical and scientific review, the Board includes several medical doctors, PhDs with specialties in the biomedical, behavioral, and social sciences, and registered nurses. Legal counsel is provided by attorneys with training specific to institutional commitments and healthcare law. Pharmaceutical expertise is provided by a PharmD. When appropriate, a prisoner representative advises the Board for studies involving prisoners. Further, community members – individuals not affiliated with Saint Louis University – are present within the Board.

The IRB, which includes both men and women, consists of a racially and culturally diverse group of individuals who utilize their backgrounds, in addition to their professional training, to address the significant issues that encompass safeguarding the rights and welfare of human subjects involved in research. When necessary, consultants with additional expertise are asked to contribute to protocol review.

In order to avoid individual contacts to members of the IRB, it is the operating procedure of this office to not release the membership list.

Further inquiries regarding IRB membership can be directed to irb@slu.edu or (314) 977-7744.

Sincerely,

Lee Seabrooke

Lee Seabrooke, PhD Institutional Official Associate Vice President for Research Saint Louis University