3556 Caroline St., Room 110 St. Louis, MO 63104 Phone: 314-977-7744

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Re: Confirmation of Not Human Subjects Research

Dear Investigator,

This confirms receipt of your materials (IRB #24428). In making determinations of what constitutes human subjects research and requires IRB review, the Saint Louis University IRB uses definitions provided in the federal regulations.

Per <u>45 CFR 46.102</u>, *research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. *Human subject* means a living individual about whom an investigator conducting research obtains 1) data through intervention or interaction with the individual or 2) identifiable private information.

To constitute human subjects research and require IRB review, proposed activities must meet the definition of involving research *and* human subjects. It has been determined that your proposed activities do not. This study involves retrospective data analysis only, and the data to be received from the MO DHSS for this work will be obtained in a de-identified state, (i.e., data will not be identifiable). Thus, according to the federal regulations, your project does not constitute human subjects research.

Please refer to the decision charts (chart 1 in particular) from the Office for Human Research Protections (OHRP) for more information:

http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c1

Based on the information you provided, we have determined that your project does not require IRB oversight. Please call the IRB office at 314-977-7744 or email <u>irb@slu.edu</u> if you have any questions.

Sincerely,

Karen Robertson, MBA, CIP Operations Manager Institutional Review Board