

Date: January 14, 2013

To: Melissa Romaine

From: Juesta Caddell, Ph. D. *JMC*
IRB Director

Subject: Human Subjects Research Determination

Re: Survey of State and Territorial Title V Maternal and Child Health
(MCH) Programs

Thank you for providing the RTI IRB information about RTI's role in providing program evaluation for the above-mentioned project.

Per your email communication and follow up teleconference discussion, you have stated that the surveys will be sent to the state's MCH director and are collecting information to obtain data on expenditures the MCH program makes for select clinical, medical, and dental services to children served through the state's MCH program. The data from the survey will be used to evaluate the program and are not intended to contribute to generalizable knowledge. In addition, although the state's MCH contact provides data, the data collected are not about this individual, rather the data are about the state's expenditures.

Therefore, I have determined that this project does not involve research with human subjects as defined by the US Code of Federal Regulations (45 CFR 46.102)—specifically these activities would not be considered "research" as defined by that code nor are human subjects involved. Therefore, approval/exemption of your activities by the RTI IRB is not necessary.

Should the parameters of these activities change such that the data could be used for scientific purposes to contribute to generalizable knowledge or to involve human subjects, then RTI IRB review and approval or exemption may be required. Please inform the IRB office of any changes in the planned work.

Please note that RTI requirements related to privacy, data security, and document management still apply even though this activity is not considered human subjects research.

Please feel free to contact me with any questions.

Thank you.