

Date: October 14, 2014
To: Deborah Porterfield and Sara Jacobs
From: Juesta Caddell *JMC*
IRB Director
Subject: Human Subjects Research Determination
Re: Evaluation of the National Diabetes Prevention Program
RTI Project 0211965.046.000.001

Thank you for providing the RTI IRB information about RTI's role in an evaluation of CDC-funded National Diabetes Prevention Program (NDPP) grantees.

Per your communication, RTI staff is limited to participating in program evaluation activities. Any information and data obtained from these activities are not intended to contribute to generalizable knowledge and the evaluation is not designed to contribute to generalizable knowledge.

I have determined that RTI is not involved in 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. Therefore, approval/exemption of your activities by the RTI IRB is not necessary.

Should the parameters of the planned project change such that the data could be used for scientific purposes to contribute to generalizable knowledge, 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.