Attachment A4. RTI IRB Determination Memo

RTI INTERNATIONAL | Memorandum

Date: January 20, 2017

To: Stephanie Teixeira-Poit

From: Juesta Caddell
IRB Director

Subject: Human Subjects Research Determination

Re: Paul Coverdell National Acute Stroke Program (2015-2020) Evaluation, 0214571.006

Thank you for providing the RTI IRB information about RTI's role in the process and outcome evaluation of the Paul Coverdell National Acute Stroke Program (PCNASP).

Per your communication and attached communication from CDC, RTI staff are limited to participating in program evaluation activities. All the data collected are intended to constitute a process and outcome evaluation of the PCNASP. The project 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 these activities 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.