



NOT HUMAN RESEARCH DETERMINATION

November 27, 2018

[Heather Kane](#)

919-541-6738, x26738

hkane@rti.org

Dear [Heather Kane](#):

On 11/27/2018, the IRB reviewed the following protocol:

Type of Review:	Initial Study
Title:	SMARTool Pilot Replication Project
Investigator:	Heather Kane
IRB ID:	STUDY00020271
Funding Source:	DHHS OASH
Customer/Client Name:	The MITRE Corporation
Project/Proposal Number:	0214683.003.000.001
IND, IDE, or HDE:	None

The IRB determined that the proposed activity is not research involving human subjects as defined by DHHS regulations.

Although RTI IRB oversight of this activity is not required, this determination applies only to the activities described in the IRB submission and may not apply should any changes be made. If the nature or scope of the activity changes and there are questions about whether the revised activities constitute human subjects research, you should contact the IRB to discuss whether a new submission and determination is necessary.

Sincerely,
The RTI Office of Research Protection