



NOT HUMAN RESEARCH DETERMINATION

November 27, 2018

[Heather Kane](#)

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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