

From: Mona Hanna-Attisha [mailto:MHanna1@hurleymc.com]
Sent: Thursday, October 01, 2015 5:52 PM
To: MDHHS-IRB <MDHHS-IRB@michigan.gov>
Cc: Scott, Robert L. (DHHS) <ScottR9@michigan.gov>; Travis, Rashmi (DHHS) <TravisR@michigan.gov>
Subject: Re: MDHHS IRB Approval - 201509-11-EA

Thank you for the rapid approval.

Bob please let me know how I can get the data.

Mona Hanna-Attisha MD MPH FAAP
 Director, Pediatric Residency Program
 Hurley Children's Hospital
 Michigan State University

On Oct 1, 2015, at 5:48 PM, MDHHS-IRB <MDHHS-IRB@michigan.gov> wrote:

Please see the attached determination notice indicating MDHHS IRB approval of your research project for a period of 1 year. A hard copy of this notice will be provided to the Responsible MDHHS Employee. This IRB approval is for the study protocol, IRB application, and the most recent version of study documents in the form submitted to the IRB. Please see the comment section of the determination notice for specific requirements or additional details (if any) related to this approval. Any changes to the protocol or approved study documents must be reviewed and approved by the MDHHS IRB prior to implementation unless those changes are necessary to eliminate apparent immediate hazards to study subjects.

Any severe adverse events or unexpected problems involving risks to research subjects must be reported to the MDHHS IRB as soon as possible (usually within 48 hours of discovery).

Prior to the time this IRB approval expires, a report on the status of this research should be submitted to the MDHHS IRB to facilitate continued MDHHS IRB approval, or study closure.

Don't hesitate to contact the MDHHS IRB with any questions or concerns.

Ian A. Horste, MPH
 Institutional Review Board Administrator/Chair
 Michigan Department of Health and Human Services
 517-241-0806
www.michigan.gov/irb

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<201509-11-EA.pdf>

Peeler, Nancy (DHHS)

From: Wells, Eden (DHHS)
Sent: Friday, October 02, 2015 10:01 AM
To: Travis, Rashmi (DHHS)
Cc: Peeler, Nancy (DHHS); Fink, Brenda (DHHS); Colston, Leslie (DHHS)
Subject: RE: TIME SENSITIVE:: MDHHS IRB Approval - 201509-11-EA

Good to go at 1:30

From: Travis, Rashmi (DHHS)
Sent: Friday, October 02, 2015 6:31 AM
To: Wells, Eden (DHHS)
Cc: Peeler, Nancy (DHHS); Fink, Brenda (DHHS); Colston, Leslie (DHHS)
Subject: Re: TIME SENSITIVE:: MDHHS IRB Approval - 201509-11-EA

Eden

Ok we will wait. Please let us know status after the press conference in ok to share data.

Thanks

Rashmi

Sent from my iPhone

On Oct 1, 2015, at 8:20 PM, Wells, Eden (DHHS) <WellsE3@michigan.gov> wrote:

Governor's Communication Plan states data not to be shared with HURLEY/LHD until I call her/them before 1:30 press conference(about 1 PM) Once Press conference starts at 1:30, that would be fine, I would think!!!!

From: Peeler, Nancy (DHHS)
Sent: Thursday, October 1, 2015 6:20 PM
To: Wells, Eden (DHHS)
Cc: Travis, Rashmi (DHHS); Fink, Brenda (DHHS); Colston, Leslie (DHHS)
Subject: FW: MDHHS IRB Approval - 201509-11-EA

Hi – the IRB approval for Hurley came through late today (5:48pm), and they are asking for the data file (5:52pm).

Dr. Wells, you asked us to coordinate with you on this request, look forward to hearing back from you about next steps.

Nancy

From: Scott, Robert L. (DHHS)
Sent: Thursday, October 01, 2015 6:05 PM
To: Peeler, Nancy (DHHS)
Subject: FW: MDHHS IRB Approval - 201509-11-EA