

APPROVAL OF PROTOCOL

July 3, 2017

Esther Chernak, MD, MPH, FACP
Dornsife School of Public Health
Drexel University

Dear Dr. Chernak:

On July 3, 2017 IRB reviewed the following protocol:

Type of Review:	Initial
Title:	Effective Communication in Public Health Emergencies - Developing Patient-Centered Tools for Children and Youth with Special Health Care Needs and Individuals with Autism Spectrum Disorders
Investigator:	Esther Chernak, MD, MPH, FACP
IRB ID:	1705005423
Funding:	Center for Disease Control & Prevention
Grant Title:	Effective Communication in Public Health Emergencies - Developing Patient-Centered Tools for People with Special Health Care Needs
Grant ID:	001779/00011442
IND, IDE or HDE:	None
Documents Reviewed:	HRP 211 Application Form, HRP 201 Contact Forms, Conflict of Interest Forms, HRP-503 Template Protocol, HRP-502 Parent Permission Consent Form, Assent, Data Collection Tools, Recruitment Materials, and Parents/Caregivers Study Fact Sheet,

According to 45 CFR 46, 110, this study is Approved Expedited Categories 6 and 7. This study will enroll 900 subjects recruited from via Pennsylvania Chapter of the American Academy of Pediatrics, the PA AAP Medical Home Initiative program for Children and Youth with Special Health Care Needs (CYSHCN) in Pennsylvania, and with the Center for CYSHCN at St. Christopher’s Hospital for Children to complete surveys, and to participate in interviews & focus groups.

Risks to Children: 45 CFR 46.404 – Minimal Risk

According to 45 CFR 46.408 (a) and 45 CFR 46.116 (d) this study has been approved with a Waiver or Alteration of the Parental Permission Process

Assent will be obtained from all children.

The IRB approved the protocol from July 3, 2017 to July 2, 2018 inclusive.


Before May 18, 2018 which is 45 days prior to study closure, you are to submit a completed “FORM: Continuing Review Progress Report (HRP-212)” and required attachments to request continuing approval or closure.

If continuing review approval is not granted before the expiration date of July 2, 2018 approval of this protocol expires on that date.

In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103).

Sincerely,

**Teresa C
Hinton**

 Digitally signed by Teresa C Hinton
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Teresa C Hinton

On Behalf of the IRB #3 Committee

Member, Institutional Review Board #3