University of Maryland, Baltimore
Institutional Review Board (IRB)
Phone: (410) 706-5037
Fax: (410) 706-4189
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APPROVAL OF RESEARCH NOTIFICATION

Date: September 6, 2018

To: Howard Dubowitz
RE: HP-00078770
Type of Submission: Initial Review
Type of IRB Review: Expedited

Approval for this project is valid from 8/21/2018 to 8/20/2019

This is to certify that the University of Maryland, Baltimore (UMB) Institutional Review Board (IRB) approved the above referenced protocol entitled, "*The Safe Environment for Every Kid (SEEK) Model: Dissemination and Implementation*".

The IRB has determined that this protocol qualifies for expedited review pursuant to Federal regulations 45 CFR 46.110, 21 CFR 56.110, & 38 CRF 16.110 category(ies):
(6) - Collection of data from voice, video, digital, or image recordings made for research purposes.

(5) - Research involving materials (data, documents, records, or specimens) that have been collected for any purpose, or will be collected solely for non-research purposes.

(7) - Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

The IRB made the following determinations regarding this submission:
- Subpart D Determination for research involving children: 45 CFR 46.404/21CFR 50.51.
- Subpart B Determination for pregnant women/fetuses: 45 CFR 46. 204.
- A waiver of documentation of consent has been approved per 45 CFR 46.117(c)(2) / 21 CFR 56.109(c)(1).
- A waiver of consent has been approved per 45 CFR 46.116(d).

This study is approved to enroll 0 local participants.

This study is approved to enroll 739 worldwide participants.

Below is a list of the documents attached to your application that have been approved:
Eligibility Checklist for HP-00078770 v7-26-2018-1532617044673
Inclusionary Criteria
SEEK NIH Proposal 2018
References Related to SEEK
SEEK Qualtitative Assessment

SEEK PCP Survey
SIC
Implementation Leadership Scale
SEEK PQ
EBPAS - CAL40 Evidence Based Practice Attitudes.docx
SEEK Parent's View of Child's Healthcare
Implementation Climate Scale
SEEK PCP Questionnaire
SEEK Office Staff Survey

In conducting this research you are required to follow the requirements listed in the INVESTIGATOR MANUAL. Investigators are reminded that the IRB must be notified of any changes in the study. In addition, the PI is responsible for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103(4)(iii)). The PI must also inform the IRB of any new and significant information that may impact a research participants' safety or willingness to continue in the study and any unanticipated problems involving risks to participants or others.

DHHS regulations at 45 CFR 46.109 (e) require that **continuing review** of research be conducted by the IRB at intervals appropriate to the degree of risk and **not less than once per year.** The regulations make **no provision for any grace period extending the conduct of the research beyond 8/20/2019.** You will receive continuing review email reminder notices prior to this date; however, it is your responsibility to submit your continuing review report in a timely manner to allow adequate time for substantive and meaningful IRB review and assure that this study is not conducted beyond **8/20/2019**. Investigators should submit continuing review reports in the electronic system at least six weeks prior to this date.

Research activity in which the VA Maryland Healthcare System (VAMHCS) is a recruitment site or in which VA resources (i.e., space, equipment, personnel, funding, data) are otherwise involved, must also be approved by the VAMHCS Research and Development Committee prior to initiation at the VAMHCS. Contact the VA Research Office at 410-605-7000 ext. 6568 for assistance.

The UMB IRB is organized and operated according to guidelines of the International Council on Harmonization, the United States Office for Human Research Protections and the United States Code of Federal Regulations and operates under Federal Wide Assurance No. FWA00007145.

If you have any questions about this review or questions, concerns, and/or suggestions regarding the Human Research Protection Program (HRPP), please do not hesitate to contact the Human Research Protections Office (HRPO) at (410) 706-5037 or HRPO@umaryland.edu.