



June 4, 2021

Everly Macario, Sc.D, MS, Ed.M
IQ Solutions, Inc.
11300 Rockville Pike, Suite 901
Rockville, MD 20852

RE: FDA CTP 2021 Educational Outreach Focus Groups with Health Educators

Dear Everly Macario:

Using the exemption review process, the E&I administrative review team has accepted your study in accordance with 45 CFR 46.101(b)(2ii). Please keep this approval document with your study records.

- E&I determined that the study qualifies for an exemption from the need for IRB review.
- This determination does not include, and should not be taken to imply, any approval of the study or its consent process or form.
- Researchers are advised that they should adopt the principles in The Belmont Report or an appropriate ethical code in the conduct of their studies.
- Researchers are advised to maintain excellent communication with institutional and site authorities.
- All researchers must comply with relevant state and federal regulations.

E&I Assigned Study ID:	21095 - 01
Date of Certification:	June 3, 2021
Date of Check-In:	June 2, 2022

Minimum Responsibilities of the Research Team:

1. Report any protocol violations, and or serious and related unanticipated problems involving risks to your subjects or others in a timely manner.
2. Submit any desired modifications for review and consideration prior to carrying out such changes.
3. Submit an update of your study activities before the check-in date noted above.

Thank you for choosing E&I and please feel free to contact us anytime, we are here to help.

Sincerely,

Teresa Majors

Teresa Majors
Organizational Official

cc: Lauren Rufino, lrufino@iqsolutions.com
Rinal Patel, rpatel@iqsolutions.com
Sarah Byrnes, sbyrnes@iqsolutions.com

