Request for Project Determination & Approval – Office of the Associate Director for Science (OADS)

This form should be used to submit proposals to the Office of the Associate Director for Science (OADS) for research/nonresearch determination(s) and requirements for IRB review/approval.

☒ New Request ☐ Amendment

Project Title: 618 Evaluation: Engaging Health Plans in Implementing Evidence-Based Strategies		Project Location Country(ies): USA
CDC Principal Investigator (SEV#): Naomi Chen-Bowers, SEV# 13792		
CDC Project Officer(SEV#): Melanie Ross, SEV# (in progress)	Division: OD/OADP	Telephone: 770 488-6036
Proposed Start Date (mm/dd/yyyy): 07/01/2017	Proposed End Date (mm/dd/yyyy): 06/30/2020	

Collaborating Institutions (List other collaborating institutions in the protocol or in a separate document)

CoAg, Grant, or contract #:	CDC-RFA-OT13-130203	IRB Exp. Date (if applicable): N/A
Title of CoAg, Grant, or Contract	Building Capacity of the Public Health System to Improve Population Health	
Supported Institution/Entity Name	Changelabs Solutions	
Supported Institution/Entity FWA #	N/A	FWA Exp. Date (mm/dd/yyyy): N/A

Please check appropriate category and subcategory:

☐ **I. Activity is NOT human subjects research. Primary intent is public health practice or a disease control activity (Check one)**

- ☐ A. Epidemic or endemic disease control activity; if applicable, Epi-AID #
- ☐ B. Routine surveillance activity (e.g., disease, adverse events, injuries)
- ☐ C. Program evaluation activity
- ☐ D. Public health program activity*
- ☐ E. Laboratory proficiency testing

*e.g., service delivery, health education programs, social marketing campaigns, program monitoring, electronic database construction and/or support, development of patient registries, needs assessments, and demonstration projects intended to assess organizational needs, management, and human resource requirements for implementation

☒ **II. Activity is research but does NOT involve human subjects (Check one)**

- ☒ A. Activity is research involving collection or analysis of data about health facilities or other organizations or units (NOT persons).
- ☐ B. Activity is research involving data or specimens from deceased persons.
- ☐ C. Activity is research involving unlinked or anonymous data or specimens collected for another purpose.
- ☐ D. Activity is research involving data or specimens from animal subjects.§

§Note: Approval by CDC Institutional Animal Care and Use Committee (IACUC) may be required.

☐ **III. Activity is research involving human subjects but CDC involvement does not constitute "engagement in human subject research."** CDC employees or agents will not intervene or interact with living individuals or have access to identifiable information for research purposes. Appropriate IRB or ethics committee approval is required prior to approval.

(Check one)

- ☐ A. This project is funded under a grant/cooperative agreement/contract/award mechanism
- ☐ B. CDC staff provide technical support that does not involve possession or analysis of identifiable data or interaction with participants from whom data are being collected (No CDC Support[β]).
- ☐ C. CDC staff are involved only in manuscript writing for a project that has closed. For the project, CDC staff did not interact with participants and were not involved with data collection (No CDC Support).
- ☐ D. Activity is research involving linked data, but CDC non-disclosure form 0.1375B is signed.[γ]

β See definition of support on page 3

γ Access to linked data is permitted under any of the above sub-categories if CDC investigators and the holder of the key linking the data to identifiable human subjects enter into an agreement using CDC form 0.1375B, prohibiting the release of the key to CDC investigators under any circumstances. The purposes of the planned research do not contradict the terms of consent under which the information or specimens were collected, whether that consent was documented or not documented.

☐ **IV. Activity is research involving human subjects that requires submission to CDC Human Research Protection Office (Check one)**[α]

- ☐ A. Full Board Review (Use forms 0.1250, 0.1370-research partners)
- ☐ B. Expedited Review (Use same forms as A above)
- ☐ C. Exemption Request** (Use forms 0.1250X, 0.1370-research partners)
- ☐ D. Reliance[δ]
  - ☐ 1. Request to allow CDC to rely on a non-CDC IRB (Use same forms as A above, plus 0.1371)
  - ☐ 2. Request to allow outside institution to rely on CDC IRB (Use same forms as A above, plus 0.1372)

α There are other types of requests not listed under category IV, e.g., continuation of existing protocol, amendment, incident reports.

δ Exemption and reliance request is approved by CDC Human Research Protection Office (HRPO).

Amendment: If this request is an amendment to an existing project determination. Please include a brief description of the substantive change or modification below and attach both clean and marked copies of the amended protocol or project outline.

Submission: Attach a protocol or project description (See standard format below) in enough detail to justify the proposed category.

Approval Chain
Investigator → Director/Deputy Director or ADP/ADS → HRPO Human Subjects Mailbox (humans@cdc.gov).

OADS Review

☒ Project does not require additional human subject research review at this time.

☐ Project constitutes human subjects research that must be routed to CDC HRPO.

Comments Rationale for Determination:

Approvals/Signatures:	Date:	Remarks:
Investigator	8/24/17	
Director/Deputy Director or ADP/ADS	8/24/17	
OADS/HRPO Human Research Protection Office	8/29/17	

Note: Although CDC IRB review is not required for certain projects (categories I, II & III) approved under this determination, CDC investigators and project officers are expected to adhere to the highest ethical standards of conduct and to respect and protect to the extent possible the privacy, confidentiality, and autonomy of participants. All applicable country, state, and federal laws must be followed. Informed consent must be appropriate and should address all applicable elements of informed consent. CDC investigators should incorporate diverse perspectives that respect the values, beliefs, and cultures of the people in the country, state, and community in which they work.

Definitions