

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.

N/A

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

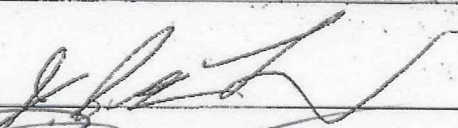
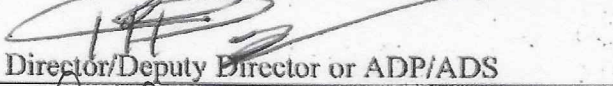
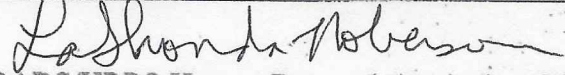
Approval Chain

Investigator → Director/Deputy Director or ADP/ADS → HRPO Human Subjects Mailbox (huma@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  | 4/28/19 | |
| Director/Deputy Director or ADP/ADS  | 5/16/19 | |
|  OADS/HRPO Human Research Protection Office | 5/14/19 | |
| | | |

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 may 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