

REQUEST for Project Determination & Approval - NCHHSTP ADS/ADLS OFFICE

This form should be used to submit proposals to the NCHHSTP ADS/ADLS Office for determination that have not begun and do not require routing to the CDC Human Research Protection Office. Projects eligible for this classification are (1) non-research activities; (2) research that does not involve identifiable human subjects, and (3) human subject research in which CDC is not "engaged". See page 3 for helpful definitions and weblinks.) Do **NOT** use this form for "exempt" human subject research, those protocols must be routed to HRPO.

Project Title MyLife MyStyle Evaluation Project

Project Locations/Country(ies): Los Angeles County, CA

Project Officer(s) Amy Fasula, Jocelyn Patterson Division: DHAP Telephone: 4)639-2902, 4)639-6437,

Proposed Project Dates: Start: 5 / 1 / 2010 End: 4 / 30 / 2015

Please check appropriate category and subcategory:

- I. Activity is not human subjects research.** Primary intent is public health practice or a disease control activity.
- A.** Epidemic or endemic disease control activity; collected data directly relate to disease control (e.g. Epi-AIDs; provide Epi-AID number & documentation of request for assistance, if division policy). Epi-AID # _____
- B.** Routine disease surveillance activity; data used for disease control program or policy purposes.
- C.** Program evaluation activity; data are used primarily for that purpose.
- D.** Post-marketing surveillance of effectiveness or adverse effects of a new regimen, drug, vaccine, or device.
- E.** Laboratory proficiency testing.
- II. Activity is not human subjects research.** Primary intent is public health program activities.
- A.** Public health program activity (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).
- B.** Activity is purely administrative (e.g., purchase orders or contracts for services or equipment).
- III. Activity is research but does NOT involve identifiable human subjects.**
- A.** Activity is research involving collection or analysis of data about health facilities or other organizations or units which are not individual persons.
- B.** Activity is research involving data or specimens from deceased persons.
- C.** Activity is research using unlinked or anonymous data or specimens: **ALL** (1-4) of the following are required:
1. No contact with human subjects is involved for the proposed activity...**and**...
2. Data or specimens are/were collected for another purpose...**and**...
3. No extra data/specimens are/were collected for **this** purpose...**and**...
4. Identifying information was: (one of these must be checked)
- a. not obtained
- b. removed prior to this submission, or prior to CDC receipt, so that data cannot be linked or re-linked with identifiable human subjects
- c. protected through an agreement. (*CDC investigators and the holder of the key linking the data to identifiable human subjects enter into an agreement prohibiting the release of the key to the investigators under any circumstances. A copy of the agreement must be attached).
- IV. Activity is research involving human subjects but CDC involvement does not constitute "engagement in human subject research".** Select only one option below: 'A' indicates the project is funded, 'B' or 'C' indicate there is no current funding.
- A.** This project is conducted under a grant or cooperative agreement award mechanism. **ALL** of the following 3 elements are required:
1. CDC employees or agents do not intervene or interact with living individuals for research purposes.
2. CDC employees or agents do not obtain individually identifiable private information.
3. Supported institution must have a Federalwide Assurance (FWA) and project must be reviewed by a registered IRB linked to the supported institution's FWA.
- Supported Institution/Entity Name Los Angeles County Department of Public Health
- Supported Institution/Entity FWA # #00000071 FWA Expiration Date 3/17/2013
- Expiration Date of IRB approval 1/28/2012 *Attach copy of the IRB approval letter.
- 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 current CDC funding).
- 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 current CDC funding).

Definitions and Links

Division Notes/Comments:

Project Title: My life my style Evaluation Project
* Please complete.

NCHHSTP ADS/ADLS Review Date received in NCHHSTP ADS /ADLS Office: March 7, 2011

Concur, project does not require human subject research review beyond NCHHSTP
or

Project constitutes human subject research that must be routed to CDC HRPO

Comments/Rationale: Per partner IRB approval for
22 Jan 2011-21 Jan 2012 data analysis
and related activities

- Additional Comments:**
1. This form cannot be used to document human subject research that is exempt from human subjects regulations; such research must be submitted to the CDC Human Research Protection Office.
 2. Although CDC IRB review is not required for projects 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 privacy laws must be followed.
 3. Although this project may not constitute "research" involving human subjects, informed consent may be appropriate. Information disclosed in the consent process should address all applicable required elements of informed consent.

Signed: Salaam Seman, MPH, DrPH
Name
Associate (or Acting or Deputy Associate) Director for Science, NCHHSTP
OR
Associate Director for Laboratory Science, NCHHSTP
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

March 18, 2011
Date