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NCIPC Determination of Applicability of Human Subjects Regulations, Request to Classify Project as Not Involving Human Subjects or Research

Project/FOA Title Evaluation of the SAMHSA PDMP Electronic Health Record (EHR) Integration and Interoperability Expansion Program

Science Officer(s) Christopher Jones Division: DVIP Telephone: 770-488-3944
Ethics verification number: 15069

Project Officer(s) _____ Division: _____ Telephone: _____
Ethics verification number: _____

Proposed Project Dates: Start: ___/___/___ Ending: ___/___/___

Award Title:

Award Institution:

Funding Mechanism # N/A – Interagency agreement and IPA

- FOA#:
- Cooperative Agreement #: 1H79TI024479-01
- Grant #:
- Contract#:

Funding Sponsor: CDC

Number of Participants in Study:

Intramural or Extramural: Intramural

Categories of data collection that do not constitute human subjects research **OR** do involve human subjects but CDC not engaged are listed below. Please check appropriate category:

X **I. Activity is not research.** Primary intent is public health practice: disease/injury control, surveillance, improvement of programs or services. Objectives focused on a specific population.

- ___ **A.** Epidemic/endemic **disease/injury control** activity; collected data directly relate to *immediate* disease control needs.
- ___ **B.** Routine **disease/injury surveillance** activity; data used for disease control program or policy purposes for a specific health condition/disease in a specific population and setting. (Includes disease reporting)
- X **C. Program evaluation** activity; data are used primarily for assessing, monitoring or improving a program in a specific population/setting.

Justification: Please attach project goals/aims, objectives, design, setting and participants, methods, and data sources.

-OR-

___ **II. Activity is research but does NOT involve identifiable human subjects.** Primary intent is to develop or contribute to generalizable knowledge.

___A. Activity is research involving collection/analysis of data about health facilities or other organizations or units, which are *not individual persons*.... or...

___B. Activity is research involving data and/or specimens from *deceased persons*.

Justification: Please attach project goals/aims, objectives, design, setting and participants, methods, and data sources.

-OR-

___**III. Activity is research involving human subjects but CDC – including employees, visiting scientists, fellows, and on-site contractors (but not off-site contractors or other collaborators) - will NOT obtain data by intervening or interacting with participants and will NOT have access to identifiable (including coded) private data or biological specimens.**

Justification: Please provide a summary of CDC's role and explain that CDC will not be "engaged" in either obtaining data by intervening or interacting with participants or have access to identifiable data. Staff can have access to data that have been stripped of the codes that link information to individuals and still be considered to not be "engaged" in human subjects research. Also, please attach a summary of project goals/aims, objectives, design, setting and participants, methods, other data sources and plans for local IRB review.

Once local IRB approval has been obtained please forward a copy (electronic preferred) to **Jahlani Akil** - the Human Subjects Contact - for records keeping purposes.

Attach project description in enough detail to clarify "non-human subjects", "non-research" or "not-engaged" nature of the product.

Comments/Rationale:
Although CDC Human Subjects (IRB) review is not required in this instance, investigators/project officers are expected to adhere to ethical principles and standards by respecting and protecting to the maximum extent possible the privacy, confidentiality and autonomy of participants. All applicable State and Federal privacy laws must be followed.

Additional Comments:

Required Signatures:

Tamara H — 8/14/13

Division Official (e.g., Director or ADS) — **Date**

Jahlani Akil — 8/21/2013

National Center Human Subjects Contact — **Date**