Request for Project Determination & Approval – LSPPPO ADS Office

This form should be used to submit proposals to the LSPPPO ADS Office for determination that have not begun and do not require routing to the CDC Human Research Protection Office at this time. Projects eligible for this classification are (1) non-research activities; (2) research that does not involve identifiable human subjects; (3) human subject research in which CDC is not "engaged".

Project Title: Cytology Workload Assessment and Measure

Project Location/Country(ies): USA

Project Officer(s): MariBeth Gagnon Division: DLSS Telephone: 404 498-2745

Proposed Project Dates: Start: August 31, 2013 End: August 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' indicates there is no current funding**

- ☐ **A.** This project is funded under a grant/cooperative agreement/contract award mechanism.
  ALL of the following 3 elements are required:
  - ☐ 1. CDC employees or agents will not intervene or interact with living individuals for research purposes.
  - ☐ 2. CDC employees or agents will 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:
    Supported Institution/Entity FWA # FWA Expiration Date (mm/dd/yyyy):
    Expiration Date of IRB approval: *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).

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.

Although this project may not constitute "research" involving human subjects, informed consent may be appropriate. Information conveyed in an informed consent process should address all applicable required elements of informed consent.

Definitions and Links

OHRP defines *research* as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research, whether or not these activities are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102

OHRP defines a ***human subject*** as a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) Data through intervention or interaction with the individual, or
(2) Identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture), and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102

OHRP considers that an institution becomes ***"engaged"*** in human subjects research when its employees or agents intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes. An institution is automatically considered to be "engaged" in human subjects research whenever it receives a direct HHS award to support such research. In such cases, the awardee institution bears ultimate responsibility for protecting human subjects under the award. http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html. ***Agents*** include all individuals performing institutionally designated activities or exercising institutionally delegated authority or responsibility, e.g., contractors.

CDC defines ***surveillance*** as "the ongoing, systematic collection, analysis, and interpretation of health data essential to the planning, implementation, and evaluation of public health practice, closely integrated with the timely dissemination of these data to those who need to know. The final link of the surveillance chain is the application of these data to prevention and control. A surveillance system includes a functional capacity for data collection, analysis, and dissemination linked to public health programs." (CDC 1986)

Program evaluation is the systematic collection of information about the activities, characteristics, and outcomes of programs to make judgments about the program, improve program effectiveness, and/or inform decisions about future program development. Program evaluation should not be confused with ***treatment efficacy*** which measures how well a treatment achieves its goals which can be considered as research. CDC guidance on research/non-research http://www.cdc.gov/od/science/regs/hrpp/researchDefinition.htm

For easy access to HHS human subjects regulations, see http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm
For guidance on differentiating research from nonresearch, see http://www.cdc.gov/od/science/regs/hrpp/researchDefinition.htm
For guidance on engagement of institutions in research, see http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html

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Attach protocol or project description (standard format at end of this form) in enough detail to justify the proposed category. Submit through division ADS/Director.

☒ Check here if an OMB determination form has been completed for this project.

☐ Check here 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.

Brief Description of change/modification:

Approval initials & printed name: Nancy Andrews 1/31/2013 Margaret Daniels 1-31-13
Branch Chief Date Division ADS or Division Director Date

Division Notes/Comments:

Project Title:

LSPPPO ADS Review **Date received in LSPPPO ADS office:**

☒ **Concur; project does not require human subject research review beyond LSPPPO at this time**

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

Comments/Rationale for Determination:

Signed: Shannon Gibbons 01/31/2013
Name Date
Associate Director for Science, LSPPPO

NOTE: This page is an outline for a proposal to ensure all required information is included for review and approval. You may submit a proposal following the outline provided below, or a full protocol that includes information pertaining to all applicable elements.

PROJECT TITLE: Cytology Workload Assessment and Measure

1. Principal Investigator(s): MariBeth Gagnon

2. CDC Project Officer(s) including roles and responsibilities: MariBeth Gagnon, collaborate with awardee

3. Other participants in research: N/A

4. Sponsoring institution(s): CDC/OSELS/LSPPPO/DLSS

5. Project Goals: Provide information on cytology workload assesment and measures to HHS agencies responsible for the Clinical Laboraotry Improvement Amendment (CLIA) program to determine appropriate gynecologic cytology screening workload maximums using semi-automated screening devices.

6. Project Objectives: 1) Conduct an assessment of practice related to cytology workload for cytotechnologists and 2) measure the amount of time spent by cytotechnologsits screening Pap test glass slides using an automated review microscope with the two FDA approved semi-autoamted screening systems.

7. Program needs to be addressed: Provide information on cytology workload assesment and measures to HHS agencies responsible for the Clinical Laboraotry Improvement Amendment (CLIA) program to determine appropriate gynecologic cytology screening workload maximums using semi-automated screening devices.

8. Populations to be studied: CLIA-certified cytology laboratories in the US

9. Methods: survey and time study

10. Sampling Methodology: 100 participants will be selected to include a mix of different types of laboratories (independent and hospital), different sizes of laboratories (small, medium, and large) and include individuals that screen slides at various speeds.

11. Incentives to be provided: N/A

12. Plans for data collection and analysis: To be determined in collaboration with contract awardee

13. Confidentiality protections: No confidential infomration will be collected.

14. Other ethical concerns/issues: N/A

15. Projected time frame for the project: August 31, 2013 - August 30, 2015

16. Plans for publication and dissemination of the project findings: Results will be published in a peer-reviewed journal

17. Appendices - including informed consent documents, data collection instruments, focus group guides, flyers, etc: Survey will be developed and cleared through OMB

18. References: ASC's Workload Recommendation for Automated Pap Test Screening.
http://www.cytopathology.org/website/download.asp?id=6429

February 2012 CLIAC Summary, see section on Semi-Automated Cytology Workload, http://wwwn.cdc.gov/cliac/cliac0212.aspx
September 2010 CLIAC Summary, see section on Workload Recording for Semi-automated Cytology Screening Devices (FDA) under Cytology Proficiency Testing, http://wwwn.cdc.gov/cliac/cliac0910.aspx
BD FocalPoint™ GS Imaging System Product Insert, http://www.bd.com/tripath/downloads/msds_pi/focalpoint/focalpoint_gs_pi.pdf
Thin Prep Imaging product insert, http://www.thinprep.com/pdfs/thinprep_package_insert.pdf