REQUEST FOR DETERMINATION OF RESEARCH STATUS

To be completed by the staff member with lead responsibility for the project and approved by branch chief (if applicable) and Division ADS. A separate PGO funding memo is required if project is research and involves human subjects regardless of the CDC staff role.

Instructions: **(1) Use this form to declare: (a) the research status of any project, (b) role or roles of CDC staff**

(2) A short summary should be attached offering specific details about the project and the role of staff.

(3) Be sure to complete all applicable items, obtain appropriate signatures and submit this form for approval.

Tracking Number: TBD/TBD

(Use PGO number if cooperative agreement, grant, etc.)

Date submitted: 02/02/2017

Title of Project: Assessment and Monitoring of Breastfeeding-related Maternity Care Practices in the U.S. (Maternity Practices in Infant Nutrition and Care – 2020 and 2022 mPINC survey)

Dates for project period:

Beginning: 09/25/2017

Ending: 12/31/2022

Dates for funding (if applicable):

Beginning:

Ending:

Project is (choose one):

NOTE: Revision, as used below, refers to any substantive change made to the project including scope of project, funding restrictions, personnel, role of CDC staff member, determination of research status, etc.

[X] **New** [ ] **Revision**

[ ] **Continuation, without revision(s)** [ ] **Continuation, with revision(s)**

Lead staff member:

Name: Daurice Grossniklaus

User ID: DTG3

Scientific Ethics number: 1761

Contact information:

Division: DNPAO

Telephone: 770-488-5249

Mailstop: F77

Please indicate your role(s) in this project:

[ ] **Project officer** [X] **Technical monitor**

[ ] **Principal investigator** [ ] **Investigator**

[ ] **Consultant** [ ] **Other (please explain)**

1. Are any or all of the activities within this project DESIGNED to contribute to generalizable knowledge (i.e., research)?

[ ] **YES** [X] **NO**

If YES, list those activities which are research:

2. Is this CDC project research or public health practice (check all that apply)?

[ ] **Research**

Check one:

[ ] **Human subjects involved**

[ ] **Human subjects not involved**

[X] **Public health practice**

Check all that apply:

[ ] **Emergency Response** [X] **Surveillance**

[ ] **Program evaluation** [ ] **Other (please explain)**

3. If RESEARCH involving human subjects, has the project or research activities been reviewed by the CDC IRB for human subjects protection?

a. [ ] **NO, New project, not yet reviewed**

b. [ ] **NO, Existing project, not ready to submit**

c. [ ] **NO, Submitted for approval**

d. [ ] **YES, Reviewed and approved by CDC**

If YES, please list protocol number and expiration date

e. [ ] **NO, RESEARCH, no CDC investigators (CDC IRB not required)**

f. [ ] **N/A (Not Applicable)**

If RESEARCH, list any other CDC staff involved in this project, please include the name, role, and scientific ethics number

Name	Role (project officer, investigator, consultant, etc.)	Scientific ethics number Prin
Daurice Grossniklaus		1761

IF YOU THINK THE RESEARCH PROJECT MIGHT QUALIFY AS EXEMPT RESEARCH (as identified in 45CFR46.101), PLEASE ANSWER questions 4-6, OTHERWISE SKIP TO question 7.

4. Does the proposed research involve prisoners?

[ ] **YES** **If YES, this research cannot be exempted and must be reviewed by an IRB (skip to question 7).**

[ ] **NO**

5. Does the proposed research involve fetuses, pregnant women, or human in vitro fertilization as targets (such that Subpart B would apply)?

[ ] **YES** **If YES, this research cannot be exempted and must be reviewed by an IRB (skip to question 7).**

[ ] **NO**

Educational Research

6.1 Is this research conducted in established or commonly accepted educational settings, AND does the research involve normal educational practices (e.g., research on regular and special education strategies or research on the effectiveness of, or comparison among instrucational techniques, curricula or classroom management methods)?

[ ] **YES** [ ] **NO**

Research Involving Surveys, Interview Procedures (including Focus groups), Observation of Public Behavior, or Educational Tests

6.2 Will this research use educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior?

[ ] **YES** [ ] **NO** **If NO skip 6.3**

Will children (<18 years of age) be research subjects?

[ ] **YES** **If YES, this research cannot be exempted and must be reviewed by an IRB (skip to item 7)**

[ ] **NO**

6.2.1 Is the information obtained recorded in such a manner that human subjects can be identified directly or indirectly through identifiers (such as a code) linked to the subjects;

[ ] **YES** [ ] **NO**

6.2.2 Will any disclosure of the human subjects' responses outside of the research setting have the potential to place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability or reputation? (Examples here may include: the collection of sensitive data regarding the subjects' (or relatives' or associates') possible substance abuse, sexuality, criminal history or intent, medical or psychological condition, financial status, or similarly compromising information).

[ ] **YES** [ ] **NO**

6.3 Will this research use educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior but the research is not exempt under paragraph 6.2 of this section:

[ ] **YES** [ ] **NO** **If NO skip to 6.4**

6.3.1 Will this research involve human subjects that are elected or appointed public officials or candidates for public office?

[ ] **YES** [ ] **NO**

6.3.2 Does federal statute(s) require(s) without exception that confidentiality of the personally identifiable information will be maintained throughout the research and thereafter? (Note: CDC can use this exemption criterion only in the case where a 308(d) Assurance of Confidentiality has been obtained to cover the research).

[ ] **YES** [ ] **NO**

Existing Data Which Is Publicly Available or Unidentifiable

6.4 Does this research involve only the collection or study of existing* data, documents, records, pathological or diagnostic specimens? (* 'existing' means existing before the study begins)?

[ ] **YES** [ ] **NO** **If NO skip to 7**

6.4.1 Is this material or information publicly available?

[ ] **YES** [ ] **NO**

6.4.2 Is this material or information recorded in such a manner by the investigator that the subjects cannot be identified directly or indirectly through identifiers linked to the subjects?

(Note: If a link is created by an investigator even temporarily, for research purposes, this criterion is not met. If a temporary link is created by clinical staff who already have access to the data, this criterion is met).

[ ] **YES** **(there are no identifying information and no unique identifiers or codes)YES**

[ ] **NO** **(there are identifiers (including codes))**

7. Please prepare and attach a short summary paragraph (<1 page); if this is new:

a. Be sure to include the purpose of the project, specific details about the project and the role of the CDC staff member (s) in the project. In explaining one's role as a consultant be particularly careful to identify involvement in things like: study design decisions, oversight of protocol development, participation in review of data collection procedures, and particpation in data analysis and/or manuscript preparation, as well as whether there will be access to identifiable or personal data.

b. Explain your project status selection (research--non-exempt, exempt, no CDC investigator or not involving human subjects; public health practice). If you selected research not involving human subjects be sure to indicate if the data includes any personal information (e.g., name, SSN), linkable study identification numbers or codes, or geographical information.

7a. The purpose of this project is to track the maternity care practices that support breastfeeding in hospitals. Since 2007, CDC has administered the national survey of maternity care practices related to breastfeeding, known as the Maternity Practices in Infant Nutrition and Care (mPINC) Survey on a biennial basis in order to monitor and examine changes in these practices over time. The mPINC survey uses a census design and is administered to every facility in the US that routinely provides maternity care services. A staff person completes the mPINC survey on behalf of his or her institution in their capacity as the person most knowledgeable about the relevant practices. The first survey in 2007 established a measure of the prevalence of specific breastfeeding-related maternity care practices at maternity care facilities across the United States and Territories at that point in time and the extent to which these practices vary by state. In addition to providing prevalence measures at subsequent points in time, biennial analyses of data from the 2009 - 2015 surveys provide important information about changes and trends in practices since the initial baseline assessment. The current RFTP is intended to continue work similar to that of the previous surveys. The 2020 mPINC survey is intended to be completed within the scope of the Information Collection Review (ICR) currently being submitted to cover the mPINC 2018 administration or under a new ICR to be submitted prior to the 2020 mPINC administration. Access to data, processes, surveys, and reports on previous mPINC surveys is available at www.cdc.gov/mpinc and http://www.reginfo.gov/ (search "OMB Control Number: 0920-0743" for complete records of 2007-2016 OMB activity related to this project). CDC staff monitor the contract and conduct analyses on data from the survey. Analyzed data will be linked to hospital identification number, hospital name and hospital address in order for the Contractor conducting the survey to disseminate hard copy and/or electronic versions of hospital-specific benchmark reports. The web survey will include an item for the survey recipient's permission to retain their title, hospital affiliation, and hospital email address so that an electronic copy of the hospital-specific benchmark report can be emailed to the survey recipient in lieu of a paper copy.

7b. This project is public health practice. The data collected are part of an ongoing surveillance system tracking hospital practices that support breastfeeding. Although the data has the potential to be used for research, the primary purpose of the data collection is for surveillance and monitoring. No human subject research will be conducted under this request. If human subject research is conducted a new Research Determination will be submitted.

8. Please list the primary project site and all collaborating site(s).

Explanation of project components:

9. If project involves research that is funded extramurally, list amount of award that should be restricted pending IRB approval and describe which project components will be affected, if known:

Approvals (signature and position title)	Date	Research Determination / Remarks
Latetia Moore Freeman - Deputy Associate Director for Sc	02/03/2017	[X] Public health practice [ ] Research not involving human subjects [ ] Research involving human subjects, no CDC investigators [ ] Research involving human subjects, CDC investigators, exempt [ ] Research involving human subjects, CDC investigators, not exempt (check if applicable) [ ] Local IRB [ ] CDC Exemption [ ] CDC IRB
staff member completing this form		Comments: LV Moore reviewed and approves

Deborah Galuska - ASSOCIATE DIRECTOR SCIENCE Team Lead	02/03/2017	[X] Public health practice [ ] Research not involving human subjects [ ] Research involving human subjects, no CDC investigators [ ] Research involving human subjects, CDC investigators, exempt [ ] Research involving human subjects, CDC investigators, not exempt (check if applicable) [ ] Local IRB [ ] CDC Exemption [ ] CDC IRB Comments:
Deborah Galuska - ASSOCIATE DIRECTOR SCIENCE Division ADS	02/03/2017	[X] Public health practice [ ] Research not involving human subjects [ ] Research involving human subjects, no CDC investigators [ ] Research involving human subjects, CDC investigators, exempt [ ] Research involving human subjects, CDC investigators, not exempt (check if applicable) [ ] Local IRB [ ] CDC Exemption [ ] CDC IRB Comments:
Joan Redmond Leonard - PUBLIC HEALTH ANALYST CUC ADS, Deputy ADS, or Human Subjects Contact	02/21/2017	[X] Public health practice [ ] Research not involving human subjects [ ] Research involving human subjects, no CDC investigators [ ] Research involving human subjects, CDC investigators, exempt [ ] Research involving human subjects, CDC investigators, not exempt (check if applicable) [ ] Local IRB [ ] CDC Exemption [ ] CDC IRB Comments: