NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION

REQUEST FOR DETERMINATION OF RESEARCH STATUS

To be completed by the NCCDPHP 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 NCCDPHP staff .**
(3) **Be sure to complete all applicable items, obtain appropriate signatures and submit this form for approval.**

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

Date submitted: *5/11/2004*
Title of Project : *Assessment and monitoring of breastfeeding-related maternity care practices in the United States*

Dates for project period:
Beginning: *9/2004*
Ending: *9/2008*

Dates for funding (if applicable):
Beginning: *9/2004*
Ending: *9/2007*

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**
____**Continuation, without revision(s)**
____**Revision**
____**Continuation, with revision(s)**

Lead NCCDPHP staff member:
Name: *Paulette Murphy*
User ID: *pem1*
Scientific Ethics number: *2772*

Contact information:
Division: *DNPA*
Telephone: *4/498 1721*
Mailstop: *K-25*

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)?**
X **YES** ____**NO**

If YES, list those activities which are research: *Primary purpose is surveillance of practices within facilities routinely providing intrapartum care; potential future analyses include associations and relationships between characteristics and practices within facilities and corresponding breastfeeding rates. We do not anticipate "research" component to begin until 2006.*

2. **Is this CDC project research or public health practice (check all that apply)?**
X **Research**
Check one:
____**Human subjects involved**
X **Human subjects not involved**
____**Public health practice**
Check all that apply:
____**Emergency Response**
____**Program evaluation**
____**Surveillance**
____**Other (please explain)** _____

3. **If RESEARCH 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. *X* NOT APPLICABLE – NO HUMAN SUBJECTS INVOLVED

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
_____	_____	_____
_____	_____	_____

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 instructional techniques, curricula or classroom management methods)?**
____YES ____NO

Research Involving Surveys, Interview Procedures (including Focus groups), Observations 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 to 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)**
____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 participation 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.**

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

	Site name and Location	Assurance Number (FWA, MPA or SPA) if applicable
Primary Site	Not yet identified	
Site 2		
Site 3		
Site 4		
Site 5		

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, position and title)	Date	Research Determination / Remarks
Paulette Murphy Paulette Murphy, MLIS Deputy Branch Chief, Maternal and Child Nutrition Branch NCCDPHP staff member completing this form	5/11/04	___ Public health practice *X* 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 approval required ___ CDC Exemption approval or IRB approval required Comments:
[signature] Branch Chief or Human Subjects Contact	5/12/04	___ Public health practice *X* 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 approval required ___ CDC Exemption approval or IRB approval required Comments:

Deb Dalusta Division ADS or Human Subjects Contact		___ Public health practice X 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 approval required ___ CDC Exemption approval or IRB approval required Comments:
[signature] NCCDPHP ADS, Deputy ADS, or Human Subjects Contact	5/19/04	___ Public health practice X 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 approval required ___ CDC Exemption approval or IRB approval required Comments:

7. Please prepare and attach a short summary paragraph (< 1 page)

The Department of Health and Human Services (DHHS) Healthy People 2010 calls for increased breastfeeding initiation, exclusivity, and duration among infants in the United States, establishing breastfeeding protection, promotion, and support as national policy. The DHHS Blueprint for Action on Breastfeeding further specifies this need, highlighting the intrapartum hospital stay as a uniquely influential experience relative to breastfeeding.

This project seeks to establish a mechanism to estimate prevalence of breastfeeding-related practices at the hospital level. Although a few small studies have been done in individual states and within individual facilities, it is currently not possible to assess and monitor breastfeeding-related hospital practices across the United States. In October, 2003, CDC convened an expert panel of researchers with specific experience in surveillance and monitoring of hospital practices related to breastfeeding. The Expert Panel's recommendation was to establish an ongoing, national system to monitor and evaluate hospital practices related to breastfeeding among all facilities that routinely provide intrapartum care in the United States. This project will be a survey of all facilities routinely providing intrapartum care to assess their practices. A long-term goal of the project is to establish systematic assessment and monitoring of these practices.

Ten specific hospital practices have been identified by the World Health Organization/United Nations Children's Fund (WHO/UNICEF) as the *Ten Steps to Successful Breastfeeding*. The survey instrument will be designed to capture information primarily about Baby Friendly hospital practices. Respondents to the survey will be hospitals and other facilities (such as free-standing birth centers) that routinely provide intrapartum care. Although a hospital employee will complete the survey, s/he will be responding on behalf of the facility, rather than as an individual. The survey instrument will be mailed and/or administered via Internet, and will contain no individual patient information. The individual completing the instrument will provide no identifiable or personal data.

CDC staff and contractors will be involved in all steps of this project, include study design, instrument design, data collection, analysis, and dissemination. Because this project does not include human subjects, there will be no access at any point to identifiable or personal data.

This project is research not involving human subject. The unit of analysis for this project will be the hospital, rather than an individual person. None of the information provided via the survey instrument will relate to a particular individual. All of the items in the survey instrument will inquire about the presence of a particular practice (eg.: existence of a breastfeeding policy), prevalence of a particular practice (eg.: proportion of staff receiving standardized training on breastfeeding management) or characteristics of a particular practice (eg.: general indications for providing pacifiers to breastfed infants).