OMB No. 0920-0666

National Healthcare Safety Network

OMB 83-C SUPPORTING STATEMENT (Justification)

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Division of Healthcare Quality Promotion (DHQP), in the National Center for Preparedness, Detection, and Control of Infectious Diseases (proposed) at CDC, requests approval from OMB for revised and new data collection instruments for the data collection outlined under OMB Control Number 0920-0666 for the National Healthcare Safety Network (NHSN). The vision of NHSN is to create a knowledge system for accumulating, exchanging and integrating relevant information and resources among private and public stakeholders to support local and national efforts to protect patients and healthcare personnel by promoting healthcare safety. Specifically, the data will be used to determine the magnitude of various healthcare-associated adverse events and trends in the rates of these events among patients and healthcare personnel with similar risks or exposures.

The first component of NHSN to become functional was the Patient Safety Component. Its modules have focused on collection of outcome measures, namely rates of central line-associated bloodstream infections (CLABSIs), ventilator-associated pneumonia, catheter-associated urinary tract infections, dialysis incidents, and surgical site infection and post-procedure pneumonia,.

Several developments have led to the modifications of NHSN that are proposed. Recently, DHQP and the Healthcare Infection Control Practices Advisory Committee (HICPAC) published guidelines on public reporting of healthcare-associated outcome and process measures, partly in response to increasing consumer demand for healthcare information. The process measures included central-line insertion practices and surgical antimicrobial prophylaxis and influenza vaccination coverage among patients and healthcare personnel. The outcome measures included rates of CLABSIs, and surgical site infections following selected operations. Public reporting of healthcare performance has become mandatory in a number of states. In addition, several states have proposed to have their hospitals use NHSN as way to report their infections.

Some of the proposed modifications are prompted by the impending publication of HICPAC guidance on the control of multidrug-resistant organisms (MDROs), which includes recommendations for active surveillance for asymptomatic colonization in certain high-risk settings. DHQP has been actively collaborating with several groups of US healthcare facilities that are working together to implement these recommendations in their facilities. These facilities have expressed a desire to use NHSN to collect information on transmission of MDRO colonization and process measures including adherence to surveillance culture swabbing, hand hygiene, and contact precautions. We plan to provide these collaboratives with an opportunity to submit these data in pilot fashion using the customizable field options within the NHSN

This request for amendment of NHSN is to enable collection of process measure data related to prevention of bloodstream infections in patients with central lines, prevention of MDRO infection in hospitalized patients, and prevention and treatment of influenza in healthcare personnel. In addition, two new modules of the NHSN Patient Safety Component are proposed: Central Line Insertion Practices Adherence Monitoring and MDRO Prevention Process Monitoring. There is currently no systematic method to collect information on central line insertion practices or MDRO prevention.

To the NHSN Healthcare Personnel Safety Component, we propose adding an influenza vaccination assessment module. The reasons for the low-level of influenza vaccination coverage among healthcare personnel (HCP) are not well-described. There also is no systematic method to collect information either on adverse events related to the prevention and treatment of influenza, or on declination of influenza vaccination by HCP.

Amendments to previously approved NHSN Healthcare Personnel Safety Component forms also are requested. These changes are necessitated by the introduction of the influenza module, as well as a need to revise several of the forms to better reflect current technology and best practices and hopefully to simplify data analysis. There is an increase in the burden of data collection, attributable solely to the proposed new forms.

2. Purpose and Use of Information Collection

The proposed additional collections in the NHSN Patient Safety Component would enable participating facilities and CDC to monitor practices important for prevention of central line-associated and MDRO infections in individual patient-care units and facilities and to provide

aggregate adherence data for all participating facilities. Facilities would have the option of recording inserter-specific adherence data for catheter insertions; link gaps in recommended practice with the clinical outcome (i.e., CLABSI, MDRO infection) both in individual facilities and for all participating facilities in a group. Use of these forms will facilitate quality improvement by identifying specific gaps in adherence to recommended prevention practices to which intervention strategies for reducing CLABSI and MDRO rates can be targeted.

The proposed additional collections in the NHSN Healthcare Personnel Safety Component would enable participating facilities and CDC to monitor influenza vaccination coverage among HCP at individual facilities and to provide aggregate coverage estimates for all participating facilities; monitor progress towards attaining the Healthy People 2010 goal of 60% vaccination coverage among HCP; monitor influenza vaccination coverage by ward/unit of the facility and occupational group so that areas or groups with low vaccination can be targeted for interventions; monitor adverse reactions related to receipt of the vaccine or receipt of antiviral medications; and assess the characteristics of influenza vaccination programs pre- and post-influenza season to identify practices associated with high immunization rates.

3. Use of Improved Information Technology and Burden Reduction

The data collection described in the change request will be collected in the same manner as the previously approved data collection. The data entry and data management will be Web browser based.

4. Efforts to Identify Duplication and Use of Similar Information

The Division of Healthcare Quality Promotion staff keeps abreast of the infection control and occupational health fields by reviewing literature, participating in scientific conferences, and serving on committees of professional organizations. There is no other national database for healthcare-associated infections and related adverse events.

5. Impact on Small Businesses or Other Small Entities

Collection of the data may involve small businesses or other small entities. However, NSHN is a voluntary system in which the level of participation is determined wholly by the

healthcare institution's own needs for such information and resources available to collect the data.

6. Consequences of Collecting the Information Less Frequently

Many adverse events associated with healthcare, such as hospital-associated infections, occur in both endemic and epidemic patterns. It is in the best interest of the healthcare institution to conduct routine prospective surveillance in an ongoing manner to identify trends and outbreaks and to report data that may indicate a problem. An important purpose for conducting routine prospective surveillance is to quickly identify potential problems that need to be investigated and to institute appropriate measures early to minimize the number of affected patients or healthcare personnel. There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

Reporting data more frequently than quarterly. The healthcare institutions participating in NHSN are encouraged to report data they are collecting to the sponsoring agency in an ongoing manner. Such a schedule will not cause undue burden in most hospitals, since surveillance data are collected usually daily in most hospitals and entered into the computer for their own analysis. The data collected for NHSN will be entered into a computer program and sent electronically to the sponsoring agency via the Internet with no additional data preparation. Since monthly data analysis and reporting is the usual practice in most hospitals, it is advantageous to the sponsoring agency to maintain this frequency.

Generalizability of results. Although participation in the NHSN is voluntary and member institutions are not a probability sample of all such institutions in the United States, they are expected to be similar to mainstream institutions of that type. For example, in a 1999 survey of NNIS (one surveillance system that was incorporated in NHSN) hospitals, 86% of the 228 hospitals that responded were general medical-surgical hospitals, 6% were children's hospitals, and 8% were VA or military hospitals. The mean average daily census was 239 patients. The geographic distribution of NNIS hospitals is remarkably similar to U.S. hospitals, although there was a slight overrepresentation of hospitals located in the northeast. Approximately 58% of the NNIS hospitals have major teaching affiliation with a medical school. In comparison to all U.S. hospitals, NNIS hospitals are larger and more likely to be affiliated with a medical school and in

the northeast region. As with the NNIS system, aggregated data from NHSN will be stratified by important hospital and patient characteristics and the rates will be adjusted by exposure to procedures and therapies known to be of primary importance in increasing risk to adverse outcomes. Further, because NHSN membership will soon be open to any healthcare facility, we expect that over time the results will be more representative of all healthcare facilities and may be generalizable.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. The 60-Day and 30-Day Federal Register Notices were published under the original clearance.

9. Explanation of Any Payment or Gift to Respondents

The proposed change follows the same protocol as the previously approved data collection for incentives. No incentive is provided to NHSN participants.

10. Assurance of Confidentiality Provided to Respondents

An Assurance of Confidentiality has been granted for all data collected under NHSN. Accordingly, "the information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with Sections 304, 306, and 308(d) of the Public Health Services Act (42 USC 242b, 242k, and 242m(d))". Published data will not identify individual facilities without permission from the institution. Collaborators at the participating institution may publish data collected from their institution and may identify themselves as an NHSN participant.

This data collection effort is consistent with the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPPA), which expressly permits disclosures without individual authorization to public health authorities authorized by law to collect or receive the information for the purpose of preventing or controlling disease, injury, or disability, including but not limited to public health surveillance, investigation, and intervention.

For the participating healthcare institutions, data are collected in this project for the purposes of local surveillance and program evaluation. DHQP aggregates the data for surveillance and program evaluation purposes. No research will be conducted as part of this data collection effort and no patient consent forms will be used. Even though not a research project, this Protocol was submitted for ethical review to the CDC Institutional Review Board (IRB) and was approved (Protocol #4062, exp. 05/18/05.) A request for amendment and continuation was recently approved, expiring 05/18/07 (Attachment A). The IRB amendment addresses all changes proposed in this OMB amendment request with the exception of the MDRO module for which approval is being requested.

11. Justification for Sensitive Questions

The reporting of adverse events associated with healthcare can be sensitive unless the institution is assured that the data aggregating organization will provide security for the data and maintain their confidentiality. As discussed in item 10 above, NHSN is authorized to assure confidentiality to its participating individuals and institutions.

12. Estimates of Annualized Burden Hours and Costs

The following table of estimates of burden hours summarizes the burden hours only for` the proposed new forms as the proposed changes to previously approved forms will not change their burden hours.

Table 1. Estimated national annual burden in number of hours to collect and report data, by form, for proposed new forms.

Form No.	Title	No. of Respondents	No. of Responses/ Respondent Annually	Total No. of Responses Annually	Average Burden/ Response (hrs)	Total Burden (hrs)
57.75FF	Healthcare Worker Influenza Vaccination	90	500	45,000	10/60	7,500
57.75GG	Healthcare Worker Influenza Antiviral Medication Administration	90	50	4,500	10/60	750
57.75HH	Pre-season Survey on Influenza Vaccination Programs for Healthcare Workers	90	1	90	10/60	15

Form No.	Title	No. of Respondents	No. of Responses/ Respondent Annually	Total No. of Responses Annually	Average Burden/ Response (hrs)	Total Burden (hrs)
57.75II	Post-season Survey on Influenza Vaccination Programs for Healthcare Workers	90	1	90	10/60	15
57.75JJ	Central Line Insertion Practices Adherence Monitoring	100	100	10,000	5/60	833
57.75LL	MDRO Prevention Process Monitoring	100	100	10,000	10/60	1,667
Total						10,780

The number of respondents is unchanged from the original OMB application. (Nevertheless, the number of respondents is different for each form, although the maximum number of respondents, 350 are unchanged.) The change in total burden hours from what was originally approved is attributable totally to the proposed new forms. The new burden will be 10,780 higher than the previously approved burden hours to 76,597, due solely to the new forms: influenza module forms, central line insertion practices adherence monitoring and MDRO prevention process monitoring forms.

B. Estimates of annualized cost to respondents for the new hour burdens summarized in Table 1 above, for collection of information, identifying and using appropriate wage rate categories are summarized in Table 2 below.

Table 2. Estimated national annual cost burden to collect and report data, by form

Form No.	Title	Average Hourly Salary of Respondent	Total Burden (hrs)	Total Burden (dollars)
57.75FF	Healthcare Worker Influenza Vaccination	30.62	7,500	229,650
57.75GG	Healthcare Worker Influenza Antiviral Medication Administration	30.62	750	22,965
57.75HH	Pre-season Survey on Influenza Vaccination Programs for Healthcare Workers	30.62	15	459

57.75II	Post-season Survey on Influenza Vaccination Programs for Healthcare Workers	30.62	15	459
57.75JJ	Central Line Insertion Practices Adherence Monitoring	30.62	833	25,506
57.75LL	MDRO Prevention Process Monitoring	30.62	1,667	51,044
Total		30.62	10,780	330,083

The estimated annual cost burden has increased by $330,083, attributable to the cost of completing proposed new forms in NSHN. The average salaries of the professional disciplines most frequently involved in performing surveillance have been used in the calculations and they are based on data from the Department of Labor, Bureau of Labor Statistics**.** All costs related to salary are the hourly salary in 2004 by occupation. The disciplines currently most often involved in healthcare-associated infections surveillance are the following along with their average hourly salary in 2004: infection control/occupational health professional $30.23, staff registered nurse $26.61, all healthcare providers $30.62. The last figure, $30.62 was used as the average salary for the different occupations of those entering data in NHSN.

13. Estimates of Other Total Annual Cost Burden to Respondents or Recordkeepers

There is no additional annual cost burden to respondents or recordkeepers for this proposed modification to NHSN.

14. Annualized Cost to the Government

The estimated cost of this amendment to NHSN to the government is based on expenses incurred in the following categories: personnel, programming contracts, and computer resources. The items included in each category and their costs relevant to the proposed modifications to NHSN are shown in Table 3 below. The total cost to the government in 2006 is estimated to be $ $1,490,440. In subsequent years there could be changes in programming contract costs as additional modules are added.

Expense Item	Description	Estimated Annual Cost
Personnel	A total of 3.5 FTE/contractor personnel Will be actively involved in the development and deployment of the NHSN. The personnel categories and their FTE contributions are as follows:	Their annual compensation in 2006 will be $361,440

Expense Item	Description	Estimated Annual Cost
	Medical epidemiologist – 0.5 Statistician – 0.5 Epidemiologist – 1.0 Computer Programmer – 0.5 Database Analyst – 0.5 Business analyst – 0.5	
Programming contracts	Design, develop, and deploy amendments to NHSN	$1,027,000
Computer resources	Servers, software licenses (e.g., SAS), Internet access	$102,000
Total		$1,490,440

15. Explanation for Program Changes or Adjustments

As noted in the terms of clearance, the changes to NHSN are requested to add additional forms that will enable the collection of process measures as well as outcomes by the system. In addition, proposed modifications to the already approved forms were made either to simplify data analysis or to accommodate the new data collection elements. The burden change of 10,780 additional burden hours will increase the burden hours from 65,817 to 76,597. There will be no change to the number of respondents and the number of responses will increase from 174,395 to 244,075, which is a difference of 69,680.

16. Plans for Tabulation and Publication and Time Schedule

NHSN is an ongoing data collection system and as such, does not have an annual timeline. The data are reported on a continuous basis by participating institutions and the data are aggregated by the sponsoring agency into a national database that are analyzed for two main purposes: To describe the epidemiology of healthcare-associated adverse events, and to provide comparative process measure and comparative rates in populations with similar risks. Comparative rates can be used by participating and also by non-participating healthcare institutions that collect their data using NHSN methodology.

The reporting institutions will be able to access at any time their own data and analyze them through the Internet. Reports containing aggregated data will be produced annually and posted on the Internet similar to the NHSN member's page, which is, http://www.cdc.gov/ncidod/hip/nhsn/members/members.htm, as well as on CDC's DHQP web

page (http://www.cdc.gov/ncidod/dhqp/nnis_pubs.html). The report will also be published annually in a scientific journal and on the Internet to make NHSN data widely available. Results of in-depth analysis of data from the NHSN will be published in peer-reviewed journals, and presented at scientific and professional meetings. The proposed modifications to NHSN will not alter the plans for tabulation, publication, nor the time schedule.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Expiration date display exemption does not apply to the NHSN.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

This is usually not applicable to this request for amendment.

B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

NHSN is an ongoing surveillance system that does not employ probability sample methods for selecting participating hospitals. Participation in NHSN is voluntary and is open to all healthcare institutions with patient population groups that are addressed by the NHSN modules. Participating institutions have complete autonomy on choice of modules to use and the period of data collection, as long as 6 months of data collected under one or more NHSN modules are reported each year. This is unchanged from the original application for OMB approval of NHSN.

Summary of requested changes

I. The first of three proposed collections to be added to NHCSN is the Influenza Module, which would enable participating facilities and CDC to:

a. Monitor influenza vaccination coverage among healthcare personnel at individual facilities and to provide aggregate coverage estimates for all participating facilities.
b. Monitor progress towards attaining the Healthy People 2010 goal of 60% vaccination coverage among healthcare personnel.
c. Monitor influenza vaccination coverage by ward/unit of the facility and occupational group so that areas or groups with low vaccination can be targeted for interventions.
d. Monitor adverse reactions related to receipt of the vaccine or receipt of antiviral medications.
e. Assess the characteristics of influenza vaccination programs pre- and post-influenza season to identify practices associated with high immunization rates

In order to facilitate this additional collection of data, four new forms are proposed:

1. Healthcare Worker Influenza Vaccination (CDC 57.75FF) (This form is a modification of CDC 57.75Y.)
2. Healthcare Worker Influenza Antiviral Medication Administration (CDC 57.75 GG*)*
3. Pre-season Survey on Influenza Vaccination Programs for Healthcare Workers (CDC 57.75HH)
4. Post-season Survey on Influenza Vaccination Programs for Healthcare Workers (CDC 57.75 II)

Modifications to the currently approved forms are being proposed to provide additional information relevant to influenza vaccination:

1. Healthcare Personnel Safety Reporting Plan (CDC Form 57.75B)
2. Healthcare Worker Demographic Data (CDC Form 57.75X)
3. Healthcare Personnel Safety Component Facility Survey (CDC Form 57.75Z)

II. The second of three proposed collections to be added to NHSN is Central Line Insertion Practices Adherence Monitoring, which would enable participating facilities and CDC to do the following:
    a. Monitor central line insertion practices in individual patient care units and facilities and to provide aggregate adherence data for all participating facilities. Facilities have the option of recording inserter-specific adherence data.
    b. Link gaps in recommended practice with the clinical outcome (i.e., CLABSI) both in individual facilities and for all participating facilities.
    c. Facilitate quality improvement by identifying specific gaps in adherence to recommended prevention practices, thereby helping to target intervention strategies for reducing CLABSI rates.

In order to facilitate this additional collection of data, one new form is proposed:
Central Line Insertion Practices Adherence Monitoring Form (CDC 57.75JJ).

III. The third of three proposed collections to be added to NHSN is MDRO Prevention Process Monitoring, which would enable participating facilities and CDC to do the following:
    a. Monitor processes and practices in individual patient care units and facilities and to provide aggregate adherence data for all participating facilities.
    b. Link gaps in recommended practice with the clinical outcome (i.e., MDRO infection) both in individual facilities and for all participating facilities.
    c. Facilitate quality improvement by identifying specific gaps in adherence to recommended prevention practices, thereby helping to target intervention strategies for reducing MDRO infection rates.

In order to facilitate this additional collection of data, one new form is proposed:
MDRO Prevention Process Monitoring Form, (CDC 57.75LL).

A change to Form 5: Patient Safety Monthly Reporting Plan has been proposed to include monitoring of insertion line practices under the Device-associated Module. Participating facilities may indicate in the Plan their intention to monitor adherence to Central Line Insertion Practices for the time period covered by the Plan.

Several options have also been modified under Procedure-associated module. The modified choices are intended to help clarify the selection of procedure monitoring areas (inpatient vs. outpatient).

IV. Amendments to several forms that comprise the Healthcare Personnel Safety Component portion of NHSN are proposed.

CDC Form 57.75W: "Healthcare Worker Postexposure Prophylaxis"

* PEP ID# field renamed to "MedAdminID"

* One field added to request clarification on which infectious agent the prophylaxis was intended for.

* Text field "Indication: Prophylaxis" added to clarify that the drugs entered were indicated for prophylaxis.

* Instruction box removed from bottom of form and moved next to Initial PEP and PEP Change fields for clarity.

CDC Form 57.75V: "Exposures to Blood/Body Fluids"

* Form was numbered with Section numbers and question numbers to clarify skip patterns.

Section I: General Exposure Information (formerly General Exposure Information).

-Clarifications about location of exposure made.

-Skip patterns modified for "Skin exposure"

-For fluid/tissue and body site of exposure, option to specify "Other" exposure added

Section II: Percutaneous Injury (formerly Section I: Percutaneous Injuries)

* Options/questions from page 2 and 4 of previous version have been incorporated in Questions 7,8, 9 in the modified version
* Page 3 questions were renumbered, additional fields added to specify "other" objects.
*Wording changed to "Manufacturer and Model" from "Brand name of device"
* Option for "Mylar wrapping/plastic" safety feature added
* Removal of last question on page 3
* Page 4: First question is now Section II, Question 6 in new form. The rest of the options on page 4 have been incorporated into Questions 7, 8 and 10 in section II.

Section III: Mucous Membrane and/or Skin Exposure (former Section II with same title)

* Page 5, first question removed (it is asked on page 1, Question 7c in new form)
* All other questions retained, with some of the options reordered

Section IV: Bite (Page 5 on old form) (former Section III with same title):

* Second question options were reordered.

Section V: Source information (formerly Source Information):

* Page 6, third question, word change. Added "Not tested" option to table

Section VI: For HIV Infected Source (formerly For HIV Infected Source):

Numbering and format changes only.

Section VII: Initial Care Given to Healthcare Worker (formerly Follow-up Care Given to Healthcare Worker): Numbering and format changes only.

Section VIII: Baseline Lab Results (formerly Baseline Lab Results):

* Instructions added, stating if baseline testing performed, to continue with table. "If yes, indicate below"
* "Indeterminate" option added to 'anti-HCV EIA' test

Follow-up lab results tests have been separated out to a new form, CDC Form 57.75FF: "Laboratory Testing." (See below)

Section IX: Follow-up (formerly Follow-up):

* Word change - removed "to Employee Health".
* Added additional question regarding where follow-up would be performed.

Section X: Narrative (formerly Section V): Moved before Prevention section

Section XI: Prevention (formerly Section IV): Moved after Narrative section.

CDC Form 57.75KK: "Laboratory Testing" added. Originally baseline and follow-up data collection had been indicated using the same form. It was decided that it would be easier for the user to use a separate lab form for collecting the follow-up lab data.

CDC Form 57.75Za "Facility Survey": Added fields to capture both the total part-time and full-time personnel.

CDC Form 57.75Z "Implementation of Engineering Controls" has been replaced with a new version of the form. The same types of information will be collected (device implementation and discontinuation quarter and year, reasons, and name and codes of devices). However, the list of devices has been changed to reflect the current market in devices.

Attachments

A. IRB approval for modification (pending)

B. NHSN Management and Demographics Forms

Patient Safety Monthly Reporting Plan (CDC 57.75A)

Healthcare Personnel Safety Reporting Plan (CDC 57.75B)

C. Module-Specific Data Collection Forms

Central-Line Insertion Practices Adherence Monitoring (CDC 57.75JJ)

MDRO Prevention Process Monitoring, (CDC 57.75LL)

Healthcare Worker Influenza Vaccination (CDC 57.75FF)

Healthcare Worker Influenza Antiviral Medication Administration (CDC 57.75GG)

Pre-season Survey on Influenza Vaccination Programs for Healthcare Workers (CDC 57.75HH)

Post-season Survey on Influenza Vaccination Programs for Healthcare Workers (CDC 57.75II)

Exposures to Blood/Body Fluids (CDC 57.75V)

Healthcare Personnel Postexposure Prophylaxis (CDC 57.75W)

Healthcare Personnel Laboratory Testing (CDC 57.75FF)

Healthcare Personnel Facility Survey (CDC 57.75Za)

Implementation of Engineering Controls (CDC 57.75Z) (Formerly Part of Healthcare Personnel Facility Survey)

Attachment A. IRB approval for modification

-----Original Message-----
From: Valosen, John A. (CDC/OD/OCSO)
Sent: Tuesday, August 29, 2006 10:10 AM
To: Horan, Teresa C. (CDC/CCID/NCID)
Cc: Erickson, Lynn G. (CDC/CCID/NCID) (CTR); Kovach, Gloria (CDC/CCID/NCID) (CTR); Williamson, Dhelia (ATSDR/DHS/SRB); Campbell, Scott (CDC/OD/OCSO); Stokes, Susan (CDC/CCID/NCID)
Subject: 4062: IRB Approval of Amendment to Protocol, (Expedited)

DATE: 8/29/2006

FROM: IRB Administrator
Human Research Protection Office
Office of the Chief Science Officer, OD/CDC

SUBJECT: IRB Approval of Amendment to Protocol #4062, "The National Healthcare Safety Network" (Expedited)

TO: TERESA HORAN [TCH1]
NCPDCID/DHQP

CDC's IRB A has reviewed and approved your request to amend protocol #4062 by adding minor edits to the CDC form 57.75 (Form 3); changes made to the "Central Line Insertion Practices Adherence Monitoring Form"; the addition of extensive amendments to several forms that comprise the Healthcare Worker Safety Component portion of NHSN; and minor updates to Patient Safety forms, using the expedited review process outlined in 45 CFR 46.110(b)(2), "Minor changes in previously reviewed research during the period (of one year or less) for which approval is authorized."

Reminder: IRB approval of protocol #4062 will still expire on 5/18/2007. Any problems of a serious nature should be brought to the immediate attention of the IRB, and any other proposed changes to the protocol should be submitted as an amendment to the protocol for IRB approval before they are implemented.

If you have any questions, please contact the Human Research Protection Office at (404) 639-4721 or e-mail: huma@cdc.gov.

John A. Valosen
Administrator IRB A

cc:
Lynn Erickson
Gloria Kovach
Dee Williamson
Scott Campbell
Susan Stokes