consider to be CBI or otherwise protected through *www.regulations.gov* or e-mail. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *www.regulations.gov* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the U.S. EPA Region 4 office located at 61 Forsyth Street, SW., Atlanta, Georgia 30303. Regional office is open from 7 a.m. until 6:30 p.m. Monday through Friday, excluding legal holidays.

Written comments may be submitted to Ms. Batchelor within 30 calendar days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: Paula V. Batchelor at 404/562–8887.

Dated: October 11, 2007.

Rosalind H. Brown,

Chief, Superfund Enforcement & Information Management Branch, Superfund Division.

[FR Doc. E7–21094 Filed 10–25–07; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Protection of Human Subjects: Categories of Research That May Be Reviewed by the Institutional Review Board Through an Expedited Review Procedure

AGENCY: Department of Health and Human Services, Office of the Secretary.

ACTION: Notice.

SUMMARY: The Office for Human Research Protections (OHRP) is requesting written comments on a proposed amendment to item 5 of the categories of research that may be reviewed by the institutional review board (IRB) through an expedited review procedure, last published in the **Federal Register** on November 9, 1998 (63 FR 60364). On that date, the Office for Protection from Research Risks (OPRR), now OHRP, and the Food and Drug Administration (FDA) simultaneously published identical lists of categories of research activities involving human subjects which may be reviewed by the IRB through an expedited review procedure. It has come to OHRP's attention that there has been confusion in the research community about expedited review category 5. OHRP is proposing to amend expedited review category 5 to clarify that the category includes research involving materials that were previously collected for either nonresearch or research purposes, provided that any materials collected for research were not collected for the currently proposed research. Expedited review category 5 also includes research involving materials that will be collected solely for nonresearch purposes.

In addition, OHRP is requesting comments on the entire expedited review list that was last published in the **Federal Register** on November 9, 1998 (63 FR 60364) to determine if other changes are needed.

As part of its charge to provide expert advice and recommendations to the Secretary of Health and Human Services (the Secretary) and the Assistant Secretary for Health on issues and topics pertaining to or associated with the protection of human research subjects, the Secretary's Advisory Committee on Human Research Protections (SACHRP), through its Subcommittee on Subpart A, considered whether the current expedited review categories should be modified. On March 14, 2007, SACHRP submitted recommendations regarding expedited review to the Secretary, and on June 18, 2007, the Secretary sent a letter to the SACHRP chairperson, stating that HHS would give serious consideration to these recommendations. In regard to the current expedited review categories, SACHRP recommended that expedited review category 7 should be revised as described in Section V below. Therefore, in addition to requesting comments on the entire expedited review list that was published in the **Federal Register** on November 9, 1998 (63 FR 60364), OHRP is also specifically requesting comments on SACHRP's recommended revision of expedited review category 7.

As required under 21 CFR 56.110(a), FDA also will publish in the **Federal Register** a list of categories of research that may be reviewed by the IRB through an expedited review procedure. FDA intends to issue the list concurrently with OHRP's issuance of its final notice, and in compliance with 21 CFR 10.115 (good guidance practice regulations). This approach maintains FDA's practice of moving in tandem on this issue with OHRP.

DATES: Submit written or electronic comments by December 26, 2007.

ADDRESSES: Submit written comments to EXPEDITED REVIEW, Office for Human Research Protections, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Comments also may be sent via e-mail to *expeditedreviewohrp@hhs.gov*, or via facsimile at 301–402–2071. Comments received within the comment period, including any personal information provided, will be made available to the public upon request.

FOR FURTHER INFORMATION CONTACT: Mr. Glen Drew, Office for Human Research Protections, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, 1–866–447–4777 or by e-mail to: *glen.drew@hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Expedited Review Procedures

The Department of Health and Human Services (HHS) human subjects protection regulations at 45 CFR 46.110 permit expedited review procedures for certain kinds of human subjects research that have been found by an IRB to involve no more than minimal risk to research subjects, or for minor changes in previously IRB-approved research during the period (of one year or less) for which approval is authorized. An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB, in

accordance with the requirements at 45 CFR 46.110.

The HHS regulations at 45 CFR 46.110 also give the Secretary the authority to amend and republish the list of research categories that may be reviewed by the IRB through an expedited review procedure, after consultation with other departments and agencies. This same section of the HHS regulations also requires that an amended expedited review list be published by the Secretary in the **Federal Register**.

As required by HHS regulations at 45 CFR 46.110, this proposed amendment of expedited review category 5 was developed after consulting with the other Federal departments and agencies that have promulgated the Federal Policy for the Protection of Human Subjects.

II. Background on the Expedited Review List

The first expedited review list was published by the Secretary in 1981 (46 FR 8392). On November 10, 1997, OPRR, now OHRP, and FDA published identical proposed revisions to the 1981 expedited review list (published for OPRR at 62 FR 60607). The category of research in question, expedited review category 5, was addressed in the proposed categories 4 and 5 in the November 10, 1997 **Federal Register** Notices requesting public comment. In those Notices, proposed categories 4 and 5 were presented as follows:

> (4) Research involving existing identifiable data, documents, records, or biological specimens (including pathological or diagnostic specimens) where these materials, in their entirety, have been collected prior to the research, for a purpose other than the proposed research.
>
> (5) Research involving solely (a) prospectively collected identifiable residual or discarded specimens, or (b) prospectively collected identifiable data, documents, or records, where (a) or (b) has been generated for nonresearch purposes.

In addition, a chart included in OPRR's and FDA's November 10, 1997 **Federal Register** Notices, comparing the proposed expedited review list with the 1981 list, indicated that the proposed category 4 (see above) was intended to replace expedited review category 8 on the 1981 list. Category 8 on the 1981 list stated, ''the study of existing data, documents, records, pathological specimens, or diagnostic specimens.''

The comments received on OPRR's and FDA's November 10, 1997 **Federal Register** Notices overwhelmingly supported the proposed revision to the expedited review list. With minor modifications to the 1997 proposed expedited review list, on November 9, 1998, OPRR and FDA simultaneously published identical revised lists of categories of research activities that may be reviewed by the IRB through the expedited review procedure (published for OPRR at 63 FR 60364, and for FDA at 63 FR 60353). In regard to expedited review category 5, the OPRR and FDA November 9, 1998 **Federal Register** Notices described this category of research as:

> (5) Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

The preamble of the OPRR November 9, 1998 **Federal Register** Notice explained that:

> Categories four (4) and five (5) on the proposed list have been combined into one new category five (5) on the 1998 list. This new section is added in response to comments that raised questions about the relationship of proposed categories four (4) and five (5) to exempt research and about separating out existing and prospectively collected materials. The term ''nonresearch purposes'' was maintained in new category five (5) to describe the origins of the research material * * *

Similarly, the FDA November 9, 1998 **Federal Register** Notice explained that:

> Categories four and five on the proposed list have been combined into one new category, category five, addressing research involving materials collected or which will be collected solely for nonresearch purposes. This new category five was formed in response to comments that raised questions about why the two categories separated out existing and prospectively collected materials. The term ''nonresearch purposes'' was maintained in new category five to describe the origins of the research materials.

III. Clarification on the Scope of Expedited Review Category Five (5) Needed

The description of expedited review category 5 and the preamble language as published in the November 9, 1998 OPRR and FDA **Federal Register** Notices has caused confusion in the research community about whether this expedited review category includes research involving materials that were originally collected for either nonresearch or research purposes, or is limited to research involving materials that were originally collected solely for nonresearch purposes.

As evidence of this confusion, in their 1999 report, *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance,* the National Bioethics Advisory Commission (NBAC) stated:

> NBAC finds that there is no need to distinguish between collections originally created for clinical purposes and those created for research purposes. In both cases, research on the collected materials should be eligible for expedited review if the research presents no more than a minimal risk to the study subjects.

As a result of this finding, NBAC recommended that ''OPRR should revise its guidance to make clear that all minimal-risk research involving human biological materials—regardless of how they were collected—should be eligible for expedited IRB review.'' In response to NBAC's 1999 report, HHS convened a multi-agency Working Group to analyze the appropriateness, feasibility, and practical implications of implementing NBAC's recommendations and to develop a set of proposed HHS activities to enhance the protection of human subjects in research involving human biological materials. In regard to the NBAC recommendation above, the HHS Working Group stated:

> The Working Group concurs with Recommendation 2 and agrees with NBAC that, for purposes of determining eligibility for expedited IRB review, it is not necessary to draw a distinction between samples originally collected for clinical purposes and those obtained for research purposes. The Working Group also agrees with NBAC's observation that current guidance regarding the types of research that IRBs may review through expedited procedures (63 FR 60364 [HHS] and 60353 [FDA], November 9, 1998) appears to exclude research utilizing existing specimens previously collected for research purposes. It is the understanding of the Working Group that this apparent exclusion is not intentional but rather resulted from a copy editing oversight * * *

IV. OHRP Assessment

After reviewing OPRR's and FDA's 1997 and 1998 **Federal Register** notices concerning revisions to the 1981 expedited review list, NBAC's recommendation, and the HHS Working Group's response, OHRP has concluded that expedited review category 5 was intended to, and should, include research involving existing information or specimens that were previously collected for *nonresearch* purposes, as well as research involving existing information or specimens that were previously collected for *research* purposes—provided they were not collected for the currently proposed research.

OHRP notes that neither OPRR's nor FDA's November 10, 1997 **Federal Register** Notice indicated that the proposed expedited review category 4

was intended to narrow category 8 on the 1981 list to exclude existing specimens that were collected for research purposes, provided the materials were collected for a research purpose other than the proposed research. Because proposed category 4 would have applied to research involving existing identifiable information or specimens that had been previously collected for *either research or nonresearch purposes,* provided they were not collected for the currently proposed research, OHRP has concluded that the term ''nonresearch purposes'' was retained in the final version of category 5 to describe the origins of the prospectively collected material only, not the origins of the previously collected material. However, this intent was not made clear in either OPRR's or FDA's November 9, 1998 **Federal Register** Notice.

V. OHRP Request for Comments

For the reasons described in Section IV, OHRP is proposing to revise expedited review category 5 as set forth below.

Remove (5) in its entirety, and add, in its place:

(5) Research involving materials (data, documents, records, or specimens) that

(a) have previously been collected for nonresearch purposes;

(b) have previously been collected for research purposes, provided the materials were not collected for the currently proposed research; or

(c) will be collected solely for nonresearch purposes.

Note: Some research under section (a) or (b) of this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.

OHRP is also requesting comments on the entire expedited review list that was last published in the **Federal Register** on November 9, 1998 (63 FR 60364) to determine if other changes are needed. The following is the current expedited review list, as published in the **Federal Register** on November 9, 1998:

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children,[2] considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) Hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

(8) Continuing review of research previously approved by the convened IRB as follows:

(a) Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) where no subjects have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

In addition to requesting comments on all of the expedited review categories listed above, OHRP specifically requests comments on a recommendation by SACHRP to revise expedited review category 7 as follows:

Research (a) on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, affective states, interpersonal relationships, identity, language, communication, cultural beliefs or practices, and social behavior); or (b) employing methods commonly used in social, behavioral, epidemiologic, health services and educational research (including, but not limited to, survey, interview, oral history, participant observation, ethnographic, focus group, program evaluation, human factors evaluation, or quality assurance methods). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Dated: October 22, 2007.

Ivor A. Pritchard,

Acting Director, Office for Human Research Protections.

[FR Doc. E7–21126 Filed 10–25–07; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number NIOSH–091]

Notice of Public Meeting

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the following meeting on updating the NIOSH publication ''Occupational Exposure Sampling Strategies Manual''.

The document can be found at *http://www.cdc.gov/niosh/docs/77–173/* .

Instructions are provided for submitting comments.

Public Meeting Dates and Times: November 8, 2007, 8:30 a.m. to 4:30 p.m. EST and November 9, 2007, 8:30 a.m. to 12 p.m. EST.

Place: Washington Court Hotel, 525 New Jersey Avenue, NW., Washington, DC 20001.

Purpose of Meeting: To obtain input from stakeholders on their needs for information and guidance to be included in a revision of the ''Occupational Exposure Sampling Strategies Manual'' (OESSM), which is sometimes referred to as ''Leidel, Busch and Lynch'' or ''The NIOSH Yellow Book'' [*http://www.cdc.gov/niosh/77–173.html*].

Status: The forum will include scientists and representatives from various government agencies, industry, labor, and other stakeholders, and is open to the public, limited only by the space available. Persons wanting to attend and contribute comments at the meeting are requested to register at *http://www.team-psa.com/niosh-OESSM07/home.asp* no later than November 1, 2007. Unreserved walk-in attendees will be accommodated on the day of the meeting if space is available.

The meeting has several scheduled presentations and panels that will include time for questions and answers. In addition, two breakout sessions will be held to solicit discussion and input on specific occupational exposure issues.

Presentations, questions, and oral comments given at the meeting will be recorded and included in the docket. Written comments will also be accepted at the meeting. Written comments may also be submitted to Diane Miller, Robert A. Taft Laboratories, 4676 Columbia Parkway, MS C–34, Cincinnati, Ohio 45226, telephone 513/533–8611. All material submitted to the Agency should reference docket number NIOSH–091 and must be submitted by November 30, 2007 to be considered by the Agency. All electronic comments should be formatted as Microsoft Word. Please make reference to docket number NIOSH–091.

NIOSH seeks to obtain materials, including published and unpublished reports and research findings, relevant to the current practice, limitations, and needs for development of occupational exposure assessment practices and policies.

NIOSH will use this information to assess the needs and scientific basis for revisions to its guidance and recommendations in occupational exposure assessment.

Contact Person for Technical Information: Paul Middendorf, telephone (513)533–8606, M/S C–9, Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

Contact Person for Submitting Comments/Meeting Attendance: Diane Miller, Robert A. Taft Laboratories, 4676 Columbia Parkway, MS C–34, Cincinnati, Ohio 45226, telephone 513/533–8611. All material submitted to the Agency should reference docket number NIOSH–091.

All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

Dated: October 18, 2007.

James D. Seligman,

Chief Information Officer, Centers for Disease Control and Prevention.

[FR Doc. E7–21078 Filed 10–25–07; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–2088–92 and CMS–10244]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Agency: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Outpatient Rehabilitation Provider Cost Report; *Use:* In accordance with sections 1815(a), 1833(e) and 1861(v)(1)(A)(ii) of the Social Security Act, providers of service in the Medicare program are required to submit annual information to achieve reimbursement for health care services rendered to Medicare beneficiaries. Section 42 CFR 413.20(b) requires that cost reports be required from providers on an annual basis. Such cost reports are required to be filed with the provider's fiscal intermediary. The CMS 2088–92 cost report is needed to determine the amount of reimbursable cost that is due these providers for furnishing medical services to Medicare beneficiaries. *Form Number:* CMS–2088–92 (OMB#: 0938–0037); *Frequency:* Reporting—Yearly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 623; *Total Annual Responses:* 623; *Total Annual Hours:* 62,300.

2. *Type of Information Collection Request:* New Collection; *Title of*