Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed information collection request 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 functions; (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.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, email your request, including your address, phone number and the document identifier OS–0955–0002, to *Information.Collection Clearance@hhs.gov* or call the Information Collection Clearance Office on (202) 690–6162. Comments and recommendations for the proposed information collection must be received within 60 days of the issuance of this notice.

Proposed Project: Facts for Consumers about Health IT Service Providers (Revision)—OMB No. 0955–0002–OS/Office of the National Coordinator for Health Information Technology

Abstract: ONC is proposing to revise current OMB approved Facts for Consumers about Health IT Service Providers. The current OMB approval is applicable through September 30, 2012. It includes iterative rounds of in-depth consumer testing to assess and analyze consumer understanding and input about a model privacy notice for personal health records (PHRs). ONC intends to revise the project to use the same focus group and cognitive usability interview testing process for the development of a model notice of privacy practices (NPP). 45 CFR 164.520 requires covered entities to make available a NPP for protected health information to their patients or health plan members. The notice must, among other things, outline the purposes for which the covered entity is permitted to use and disclose health information, the rights of individuals with respect to their health information, the entities' duties to protect that information, and the process for filing a complaint concerning possible violations of the HIPAA Privacy Rule, such as an improper use or disclosure of information. 45 CFR 164.520 requires that the notice be written in plain language, but studies have shown that these notices are often difficult for patients to understand due to their length and complexity.

The Federal Health IT Strategic Plan identifies the Fair Information Practice Principles (FIPPS) an important guidepost in the development of privacy policies and programs. Openness and Transparency is a key principle of fair information practices. The NPP is an important component of fulfilling this principle. If patients cannot adequately understand the notice because of its length or complexity, then the use and disclosure of their health information is not open and transparent.

In addition, each participant will have been recruited through a 15-minute screening interview. The participants will be recruited according to U.S. census statistics for race/ethnicity, age, marital status, gender, and income.

ESTIMATED ANNUALIZED BURDEN TABLE

Forms (if necessary)	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Cognitive Testing Screening	General Public	84	1	15/60	21
Cognitive Testing	General Public	42	1	90/60	63
Total		126			84

Keith A. Tucker,

Information Collection Clearance Officer, Department of Health and Human Services.

[FR Doc. 2012–21103 Filed 8–27–12; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Shane Mayack, Ph.D., Joslin Diabetes Center: Based on the report of an investigation conducted by the Joslin Diabetes Center (Joslin) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Shane Mayack, former postdoctoral fellow, Department of Developmental and Stem Cell Biology, Joslin, engaged in research misconduct in research supported by National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH), grants T32 DK07260–29 and P30 DK036836 and the 2008 NIH Director's New Innovator Award Program grant DP2 OD004345–01.

ORI found that Respondent engaged in research misconduct involving two (2) published papers:

- Mayack, S.R., Shadrach, J.L., Kim, F.S., & Wagers, A.J. ''Systemic signals regulate ageing and rejuventation of blood stem cell niches.'' *Nature* 463:495–500, 2010.
- Mayack, S.R., & Wagers, A.J. ''Osteolineage niche cells initiate hemotopoietic stem cell mobilization.'' *Blood* 112:519–531, 2008.

As a result of Joslin's investigation, both *Nature* 463:495–500, 2010 (hereafter referred to as the ''*Nature* paper'') and *Blood* 112:519–531, 2008 (hereafter referred to as the ''*Blood* paper'') have been retracted by the corresponding author.

Specifically, ORI found that:

• Respondent falsely represented von Kossa-stained bone nodule images in two (2) published papers:

a. Figure 2B in the *Blood* paper was copied from an unrelated published experiment in Figure 3, *J Orth Surg Res* 1:7, 2006, and was used to falsely represent Respondent's own experiment for bone nodules formed in cultured osteoblastic niche cells.

b. Figure S2c in the *Nature* paper was copied from an online image for an unrelated experiment (at *http://skeletalbiology.uchc.edu/30_ResearchProgram/304_gap/3042_Lineage%20in%20Vitro/3042_01_aCellCult.htm#mCOB*) and was

used to falsely represent Respondent's own experiment for bone nodules formed in osteoblastic niche cells from young and aged mice.

• Respondent falsely represented eight (8) flow cytometry contour plots as different experimental results by using identical plots but with different labels and different numerical percentages. Specifically, the following contour plots in the *Blood* paper, the *Nature* paper, an earlier version of the *Nature* paper submitted to *Science* (hereafter referred to as the ''*Science* manuscript''), and a July 2008 PowerPoint presentation were identical but were labeled differently:

a. Panels 4 and 2 in Figure 6C, *Blood* paper, and panels 1 and 2, respectively, in supplementary Figure 3b, *Nature* paper
b. Panel 3 in Figure 6C, *Blood* paper, and panel 1 in Figure 2, July 2008 PowerPoint presentation
c. Panels 1 and 2, Figure 2b, *Science* manuscript, and panels 2 and 3, respectively, in Figure 2, July 2008 PowerPoint presentation
d. Panels 2, 3, and 4, supplemental Figure 4A, *Blood* paper, and panels 3, 1, and 2, respectively, in Figure 4B, *Science* manuscript

Both the Respondent and HHS want to conclude this matter without further expenditure of time or other resources and have entered into a Voluntary Settlement Agreement to resolve this matter. Respondent neither admits nor denies ORI's finding of research misconduct. This settlement does not constitute an admission of liability on the part of the Respondent. Dr. Mayack has voluntarily agreed:

(1) If within three (3) years from the effective date of the Agreement, Respondent does receive or apply for U.S. Public Health Service (PHS) support, Respondent agrees to have her research supervised for a period of three (3) years beginning on the date of her employment in a research position in which she receives or applies for PHS support and to notify her employer(s)/institution(s) of the terms of this supervision; Respondent agrees that prior to the submission of an application for PHS support for a research project on which the Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of Respondent's duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of Respondent's research contribution; Respondent agrees that she shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agrees to maintain responsibility for compliance with the agreed upon supervision plan;

(2) If within three (3) years from the effective date of the Agreement, Respondent does receive or apply for PHS support, Respondent agrees that any institution employing her shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract; and

(3) To exclude herself voluntarily from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of three (3) years, beginning on July 27, 2012.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8800.

John Dahlberg,

Director, Division of Investigative Oversight, Office of Research Integrity.

[FR Doc. 2012–21236 Filed 8–27–12; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10003]

Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB); Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Correction of notice.

SUMMARY: This document corrects a technical error in the notice [Document Identifier: CMS–10003] entitled ''Notice of Denial of Medical Coverage (or Payment)'' that was published in the July 6, 2012 (77 FR 40064) **Federal Register**.

FOR FURTHER INFORMATION CONTACT: William Parham, (410) 786–4669.

SUPPLEMENTARY INFORMATION:

I. Background

In the FR Doc. 2012–16514 of July 6, 2012 (77 FR 40064), we published a Paperwork Reduction Act notice requesting a 60-day public comment period for the document entitled ''Notice of Denial of Medical Coverage (or Payment).''

In the July 6, 2012 notice, we listed the incorrect contact information. Therefore, we are correcting that error in this notice.

II. Correction of Error

In FR Doc. 2012–16514 of July 6, 2012 (77 FR 40064), make the following correction:

On page 40068, first column, fourth full paragraph, on the fifteenth line in the paragraph beginning with ''(For policy questions regarding, '' and ending with, ''410–786–0273),'' is corrected to read as follows.

''(For policy questions regarding this collection contact Kathryn McCann Smith at 410–786–7623.)''

Dated: August 22, 2012.

Martique Jones,

Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2012–21076 Filed 8–23–12; 11:15 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–E–0102]

Determination of Regulatory Review Period for Purposes of Patent Extension; TORISEL

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for TORISEL and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.