sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kasey Heintz, Center for Food Safety and Applied Nutrition (HFS–255), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1376.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 2, 2016 (81 FR 35363), we published a notice announcing the availability of a draft guidance entitled, ''Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods.'' Section IV of the notice, ''Issues for Consideration,'' listed eight specific questions (or ''issues'') and provided two comment periods for the submission of comments pertaining to these issues (81 FR 35363 at 35366). The comment period for Issues related primarily to short-term goals (Issues 1 through 4) was scheduled to end on August 31, 2016, and the comment period for issues related primarily to long-term goals (Issues 5 through 8) was scheduled to end on October 31, 2016. Comments on Issues 1 through 8 will inform our final guidance on the voluntary sodium reduction goals.

We received requests for 90- and 30-day extensions of these comment periods, respectively. In general, the requests expressed concern that the current 90- and 150-day comment periods do not allow sufficient time to develop a meaningful or thoughtful response to the draft guidance. Some requests mentioned a need for companies to review the sodium concentration in their products, to consider what technology might be needed to meet the sodium reduction goals, and to address FDA requirements. The requested extensions would result in a 180-day comment period for all eight Issues for Consideration. We also received comments opposed to any extensions of the comment period related to the short-term goals. These comments expressed their view that the initial comment period provided sufficient time for stakeholders to review the draft guidance and to contribute informed comments and that it is important for FDA to move forward in finalizing the short-term goals for public health reasons.

We considered the requests and are extending the comment periods for the draft guidance as follows: For Issues 1 through 4, we are extending the comment period until October 17, 2016, and for Issues 5 through 8 we are extending the comment period until December 2, 2016. We believe that these extensions allow adequate time for interested persons to submit comments without significantly delaying finalizing the guidance.

Dated: August 25, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–20780 Filed 8–29–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; The Stem Cell Therapeutic Outcomes Database

AGENCY: Health Resources and Services Administration, HHS

ACTION: Notice

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than September 29, 2016.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: The Stem Cell Therapeutic Outcomes Database OMB No. 0915–0310—Revision.

Abstract: The Stem Cell Therapeutic and Research Act of 2005, Public Law (P.L.) 109–129, as amended by the Stem Cell Therapeutic and Research Reauthorization Act of 2015, P.L. 114–104 (the Act), provides for the collection and maintenance of human blood stem cells for the treatment of patients and research. HRSA's Healthcare Systems Bureau established the Stem Cell Therapeutic Outcomes Database. Operation of this database necessitates certain record keeping and reporting requirements to perform the functions related to hematopoietic stem cell transplantation under contract to the U.S. Department of Health and Human Services (HHS). The Act requires the Secretary to contract for the establishment and maintenance of information related to patients who received stem cell therapeutic products and to do so using a standardized, electronic format. Data is collected from transplant centers by the Center for International Blood and Marrow Transplant Research and is used for ongoing analysis of transplant outcomes. Post-Transplant Essential Data (TED) forms are being revised in this submission. The portion of the Product Form related to confirmation of human leukocyte antigen (HLA) typing has minor changes to the identification and date fields to allow this form to more flexibly capture HLA typing data for expanding indications of cellular therapy. The Pre-TED form remains unchanged from the previously approved OMB submission.

The increase in burden is due to an increase in the annual number of transplants and increasing survivorship after transplantation.

Need and Proposed Use of the Information: HRSA uses the information to carry out its statutory responsibilities. Information is needed to monitor the clinical status of transplantation and provide the Secretary of HHS with an annual report of transplant center specific survival data.

Likely Respondents: Transplant Centers.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes (1) the time needed to review instructions; (2) to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information; (3) processing and maintaining information; (4) disclosing and providing information; (5) training personnel to be able to respond to a collection of information; (6) searching data sources; (7) completing and reviewing the collection of information; and (8) transmitting or otherwise disclosing the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Baseline Pre-TED (Transplant Essential Data)	200	44	8,800	1.15	10,120
Product Form (includes Infusion, HLA, and Infectious Disease Marker inserts)	200	33	6,600	1	6,600
100-Day Post-TED	200	44	8,800	1.25	11,000
6-Month Post-TED	200	36	7,200	1.15	8,280
12-Month Post-TED	200	32	6,400	1.15	7,360
Annual Post-TED	200	110	22,000	1.15	25,300
*Total	200		59,800		68,660

*The Total of 200 is the number of centers completing the form. The same group of 200 centers completes each of the forms.

Jason E. Bennett,

Director, Division of the Executive Secretariat.

[FR Doc. 2016–20758 Filed 8–29–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

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:

Andrew R. Cullinane, Ph.D., National Institutes of Health: Based on Respondent's admission, an assessment conducted by the National Institutes of Health (NIH), and analysis conducted by ORI in its oversight review, ORI found that Dr. Andrew R. Cullinane, former postdoctoral fellow, Medical Genetics Branch, National Human Genome Research Institute (NHGRI), NIH, engaged in research misconduct in research supported by NHGRI, NIH.

ORI found that Respondent engaged in research misconduct by reporting falsified and/or fabricated data in the following two (2) publications and one (1) submitted manuscript:

- *Am. J. Hum. Genet.* 88(6):778–787, 2011 (hereafter referred to as ''Paper 1'')
- *Neurology* 86(14):1320–1328, 2016 (hereafter referred to as ''Paper 2'')
- ''*RAB11FIP1,* Mutated in HPS–10, Interacts with BLOC–1 to Mitigate Recycling of Melanogenic Proteins.'' Submitted for publication to *The Journal of Clinical Investigations, Cell, Nature Biology, Molecular Cell,* and *Nature Genetics* (hereafter referred to as ''Manuscript 1'')

ORI found that Respondent knowingly falsified and/or fabricated data and related images by alteration and/or reuse and/or relabeling of experimental data. Specifically:

- in Paper 1, Respondent falsified and/or fabricated the results in Figure 3C by using the same gel images to represent expression of PLDN in fibroblasts and melanocytes
- in Paper 2, Respondent falsified and/or fabricated the results in Figure 2A by erasure of a band in the blot image for LYST/CHD–4 that was present in the original data
- in Manuscript 1, Respondent falsified and/or fabricated the results in Western blot data by reuse and relabeling, duplication, and/or manipulation in Figures 2B, 2D, 2E, 3A–C, 4C, 4E, 4G, 5B, 6A–C, 7A, 7D, 7G, 7J, and Supplemental Figure 3, and Respondent falsified and/or fabricated the results by reuse and relabeling of centrifuge tubes to represent different experiments in Figures 1D, 7C, 7F, 7I, 7L, and Supplemental Figure 2

Dr. Cullinane has entered into a Voluntary Settlement Agreement with ORI and NIH, in which he voluntarily agreed:

(1) To have his research supervised for a period of three (3) years beginning on July 22, 2016; Respondent agreed to ensure that prior to the submission of an application for U.S. Public Health Service (PHS) support for a research project on which Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS-supported research, the institution employing him must submit a plan for supervision of his duties to ORI for approval. The plan for supervision must be designed to ensure the scientific integrity of Respondent's research contribution; Respondent agreed that he will not participate in any PHS-supported research until a plan for supervision is submitted to and approved by ORI; Respondent agreed to maintain responsibility for compliance with the agreed upon supervision plan;

(2) that for a period of three (3) years beginning on July 22, 2016, any institution employing him 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;

(3) to exclude himself 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 22, 2016; and

(4) as a condition of the Agreement, Respondent agreed to the retraction or correction of:

- *Am. J. Hum. Genet.* 88(6):778–787, 2011