drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device, NOVOTFF–100A SYSTEM. NOVOTFF–100A SYSTEM is indicated for treatment of adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme (GBM), following histologically- or radiologically-confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. The device is intended to be used as a monotherapy, and is intended as an alternative to standard medical therapy for GBM after surgical and radiation options have been exhausted. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for NOVOTFF–100A SYSTEM (U.S. Patent No. 7,136,699) from Novocure Limited, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 10, 2012, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of NOVOTFF–100A SYSTEM represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that the FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for NOVOTFF–100A SYSTEM is 1,704 days. Of this time, 1,468 days occurred during the testing phase of the regulatory review period, while 236 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(g)) involving this device became effective:* August 10, 2006. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the FD&C Act for human tests to begin became effective August 10, 2006.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* August 16, 2010. The applicant claims December 30, 2009, as the date the premarket approval application (PMA) NOVOTFF–100A System] (PMA P100034) was initially submitted. However, FDA records indicate that PMA P100034 was a modular submission and the final module was received by FDA on August 16, 2010.

3. *The date the application was approved:* April 8, 2011. FDA has verified the applicant's claim that PMA P100034 was approved on April 8, 2011.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 807 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by June 2, 2014. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by September 29, 2014. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov,* Docket No. FDA 2013–S–0610. Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–07329 Filed 4–1–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Ryan White HIV/AIDS Program, Part C Early Intervention Services Grant Under the Ryan White HIV/AIDS Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of Ryan White HIV/AIDS Program Part C Early Intervention Services One-time Noncompetitive Replacement Award to Ensure Continued HIV Primary Medical Care.

SUMMARY: To prevent a lapse in comprehensive primary care services for more than 200 persons living with HIV/AIDS, HRSA will provide a one-time noncompetitive Ryan White HIV/AIDS Program Part C award to St. Luke's Hospital, Bethlehem, Pennsylvania.

SUPPLEMENTARY INFORMATION: The amount of the award to ensure ongoing HIV medical services is $294,399.

Authority: Section 2651 of the Public Health Service (PHS) Act, 42 U.S.C. 300ff–51.

CFDA Number: 93.918.

Project period: The period of support for this award is 12 months, explained below in further detail.

Justification for the Exception to Competition: The Two Rivers Health and Wellness Foundation, Easton, Pennsylvania (H76HA00774) announced the relinquishment of their Part C grant on December 27, 2013. Grant funds of $294,399 are to be awarded to St. Luke's Hospital, Bethlehem, PA, to prevent a lapse in HIV medical services. St. Luke's Hospital has been determined to be eligible to receive the Part C grant to provide interim HIV medical care. To prevent a lapse in HIV medical care,

grant funds of $294,399 are to be awarded to St. Luke's Hospital to provide interim HIV medical care. The Two Rivers Health and Wellness Foundation currently provides care to more than 200 persons living with HIV/AIDS who have no other payer source for their care. The $294,399 represents 12 months of HIV medical primary care services until the service area is competed and awarded by April 1, 2015.

FOR FURTHER INFORMATION CONTACT: John Fanning, Senior Policy Advisor, Division of Community HIV/AIDS Programs/HAB, HRSA, 5600 Fishers Lane, Rockville, MD 20857, by email at *jfanning@hrsa.gov,* or by phone at (301) 443–8367.

Dated: March 28, 2014.

Mary K. Wakefield,

Administrator.

[FR Doc. 2014–07407 Filed 4–1–14; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Recruitment and Screening for the Insight Into Determination of Exceptional Aging and Longevity (IDEAL) Study (NIA)

Summary: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute on Aging (NIA), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and for Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Luigi Ferrucci, M.D., Ph.D., NIA Clinical Research Branch, Harbor Hospital, 5th Floor 3001 S. Hanover, Baltimore, MD 21225 or call non-toll-free number (410) 350–3936 or Email your request, including your address to: *Ferruccilu@grc.nia.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: Recruitment and Screening for the Insight into Determination of Exceptional Aging and Longevity (IDEAL) Study—(0925–0631). Reinstatement with Change—National Institute on Aging (NIA), National Institutes of Health (NIH).

Need and Use of Information Collection: Longevity combined with good health and functionality at the end of life represents a common goal. Although research has examined correlates of long life and functional decline, we still know relatively little about why certain individuals live in excellent health into their eighties while others succumb to failing health at much younger ages. Understanding the mechanisms important to ideal aging may provide new opportunity for health promotion and disability prevention is this rapidly growing segment of the population.

The purpose of IDEAL (Insight into the Determinants of Exceptional Aging and Longevity) is to recruit into the Baltimore Longitudinal Study on Aging (BLSA) exceptionally long lived and healthy individuals and to learn what makes them so resilient and resistant to disease and disability, and to identify potential interventions that may contribute to the IDEAL condition. By enrolling the IDEAL cohort in the BLSA their biologic, physiologic, behavioral and functional characteristics will be evaluated using the same methods used with the current cohort who will serve as a type of control group. The first aim is to identify factors and characteristics that distinguish IDEAL from non-IDEAL individuals. We intend to compare the two groups to identify factors that discriminate IDEAL aging from non-IDEAL aging individuals. The second aim is to identify physiological, environmental and behavioral characteristics that are risk factors for losing the IDEAL condition over several years or longer. We postulate that the mechanisms of extreme longevity probably differ from those associated with delay or escape from disease and disability. As is customary in the BLSA, we plan to follow this cohort for life with yearly visits. This is a request for OMB clearance to continue to recruit and screen respondents into the Recruitment and Screening for the Insight into Determination of Exceptional Aging and Longevity (IDEAL) Study over the next 3 years.

OMB approval is requested for 3 years. There are no costs to the respondents other than their time. The total estimated annualized burden hours are 263.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Estimated annual number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
Individuals	Recruitment Phone Screen Part 1	500	1	10/60	83
Individuals	Recruitment Phone Screen Part 2	200	1	10/60	33
Individuals	Pre-Visit mailing/Consent	100	1	10/60	17
Individuals	Screening Exam Visit	65	1	2	130