Dated: August 10, 2010.

Elaine Parry,

Director, Office of Program Services.

[FR Doc. 2010–20262 Filed 8–16–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

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

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Proposed Project: Multiplier Surveys—NEW

While all SAMHSA programming is intended to support the SAMHSA vision of a life in the community for everyone, and its strategic goals of accountability, capacity, and effectiveness, there has been little systematic investigation of the long-range impact of different categories of discretionary programs. The Multiplier Surveys will inform SAMHSA policy and budget development by determining which types of investments are most appropriate for achieving different policy objectives, including sustainability of the program or its intended outcomes after Federal funding ends. It also seeks to determine which program types or factors are best at achieving certain objectives after the conclusion of Federal funding, such as capacity improvement, system change, sustainability and influence on other programs. Findings will be used to make recommendations to SAMHSA management to better inform policy and budget development and to determine which types of investments are most appropriate for achieving different policy objectives.

To achieve the goals of the Multiplier Surveys four programs have been chosen from each of SAMHSA's three Centers. Four Project Directors from each of the 12 programs (48 respondents in all), whose Federal funding ended no later than September 30, 2008 will be interviewed by telephone to determine how the project was sustained after Federal funding ended and what factors contributed to its sustainability.

In addition, all grantees from each of the 12 selected programs meeting inclusion criteria will be invited via e-mail to complete a short on-line survey about their project and how/if it was sustained after Federal funding ended. A 20 percent response rate or about 100 respondents to the on-line survey is expected.

The estimated response burden is as follows:

Information source	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hours
Project Director	48	1	48	1.25	60
Web-based Survey	100	1	100	.75	75
Total	148	.....	148	.....	135

Written comments and recommendations concerning the proposed information collection should be sent by September 16, 2010 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202–395–5806.

Dated: August 10, 2010.

Elaine Parry,

Director, Office of Program Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0418]

Agency Information Collection Activities; Proposed Collection; Comment Request; Institutional Review Boards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the recordkeeping requirements for institutional review boards (IRBs).

DATES: Submit either electronic or written comments on the collection of information by October 18, 2010.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane., rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., Pl50–400B, Rockville, MD 20850, 301–796–3792, e-mail: *Elizabeth.Berbakos@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520) Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c)

and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Institutional Review Boards—21 CFR 56.115 (OMB Control Number 0910–0130)—Extension

When reviewing clinical research studies regulated by FDA, IRBs are required to create and maintain records describing their operations, and make the records available for FDA inspection when requested. These records include: Written procedures describing the structure and membership of the IRB and the methods that the IRB will use in performing its functions; the research protocols, informed consent documents, progress reports, and reports of injuries to subjects submitted by investigators to the IRB; minutes of meetings showing attendance, votes, and decisions made by the IRB, the number of votes on each decision for, against, and abstaining, and the basis for requiring changes in research or for disapproving research; records of continuing review activities; copies of all correspondence between investigators and the IRB; statement of significant new findings provided to subjects of the research; and a list of IRB members by name, showing each member's earned degrees, representative capacity, and experience in sufficient detail to describe each member's contributions to the IRB's deliberations, and any employment relationship between each member and the IRB's institution. This information is used by FDA in conducting audit inspections of IRBs to determine whether IRBs and clinical investigators are providing adequate protections to human subjects participating in clinical research.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
56.115	2,500	14.6	36,500	100	3,650,000
Total					3,650,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The recordkeeping requirement burden is based on the following: The burden for each of the paragraphs under 21 CFR 56.115 has been considered as one estimated burden. FDA estimates that there are approximately 2,500 IRBs. The IRBs meet on an average of 14.6 times annually. The agency estimates that approximately 100 hours of person-time per meeting are required to meet the requirements of the regulation.

Dated: August 11, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–20273 Filed 8–16–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; *telephone:* 301/496–7057; *fax:* 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Glioblastoma Diagnostics and Therapeutics

Description of Invention: Investigators at the NIH have discovered an Anti-TNF Induced Apoptosis (ATIA) protein, which protects cells against apoptosis. ATIA is highly expressed in glioblastoma and astrocytomas and its inhibition results in increased cell sensitivity to TNF-related apoptosis-inducing ligand induced cell death. Hence, ATIA assays may enable clinicians to effectively stratify patients for appropriate treatment. ATIA exists in a soluble form that can be detected in culture medium of ATIA expressing cells indicating it could be used to develop a non-invasive, blood based diagnostic test such as an ELISA. Glioblastomas and astrocytomas can be diagnosed via MRI and CT scans; however, these scans cannot detect tumor type, *i.e.* glioblastoma vs. medulloblastoma. The investigators found that ATIA is induced in cells under hypoxia conditions. More importantly, knockdown of ATIA in human glioblastoma cells renders cells to apoptosis under hypoxia conditions. Therefore, ATIA is a potential novel therapeutic target for treating human glioblastoma.

Glioblastoma arise from astrocytes, cells that provide neurons structural and metabolic support. Glioblastomas