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]

BILLING CODE 4160–01–S

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

account for twenty percent of primary brain tumors and fifty percent of astrocytomas. These indications are designated as rare diseases as there is an annual 2–3 newly diagnosed cases of glioblastoma per 100,000 people in the United States whereas the astrocytoma incidence rate is 1.22 cases per 100,000 for individuals aged 0–19 years in the United States.

Applications:

- Blood based diagnostic assays.
- Assay for clinicians to choose effective treatments.
- Therapy to treat human glioblastoma.

Advantages:

- Non-invasive diagnostics.
- Easy, ready to use assays.

Development Status: The technology is currently in the pre-clinical stage of development.

Market: Brain cancer market was worth an estimated $1,094 million in 2009 and expected to reach $1.3 billion by 2016.

Inventor: Zheng-gang Liu (NCI).

Patent Status: PCT Patent Application No. PCT/US2010/36394 filed 27 May 2010 (HHS Reference No. E–178–2009/0–PCT–02).

Licensing Status: Available for licensing.

Licensing Contact: Jennifer Wong; 301–435–4633; *wongje@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute, Cell and Cancer Biology Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact John Hewes, Ph.D. at 301–435–3131 or hewesj@mail.nih.gov for more information.

Inflammatory Genes and MicroRNA–21 as Biomarkers for Colon Cancer Prognosis

Description of Invention: Colon adenocarcinoma is the leading cause of cancer mortality world-wide and accounts for approximately 50,000 deaths annually in the United States. Adjuvant therapies improve survival for stage III colon cancer patients; however, it remains controversial if stage II patients should be given these therapies. Some stage II patients will benefit from therapy (such as patients with undetectable micro-metastases where surgery will not be curative); but therapy for others will harm quality of life with little therapeutic benefit (such as patients where surgery removed all cancerous tissue and therefore do not need additional therapy). Thus, there is a need to for biomarkers capable of accurately identifying high risk, stage II patients that are suitable for therapeutic intervention.

The investigators have identified an inflammatory gene and microRNA biomarker portfolio that can predict aggressive colon cancer, colon cancer patient survival, and patients that are candidates for adjuvant therapy. These biomarkers provide clinicians with a powerful tool to diagnose colon cancer patients and chose effective treatment methods.

Applications:

- Method to predict aggressive form of colon cancer, especially in stage II cancer patients.
- Method to determine appropriate colon cancer patients for adjuvant therapy.
- Diagnostic arrays.

Advantages:

- Rapid, easy to use arrays to accurately predict colon cancer and patients suitable for adjuvant therapy.
- Method to stratify colon cancer patients for adjuvant therapy to minimize negative side effects.
- Method to identify stage II patients that are likely to have undetectable micro-metastases.

Development Status: The technology is currently in the pre-clinical stage of development.

Market:

- Global cancer market is worth more than eight percent of total global pharmaceutical sales.
- Cancer industry is predicted to expand to $85.3 billion by 2010.

Inventors: Curtis C. Harris and Aaron J. Schetter (NCI).

Relevant Publication: AJ Schetter et al. MicroRNA expression profiles associated with prognosis and therapeutic outcome in colon adenocarcinoma. JAMA. 2008 Jan 30;299(4):425–436. [*PubMed:* 18230780].

Patent Status: PCT Application No. PCT/US09/058425 filed 25 Sep 2009, which published as WO/2010/036924 on 01 Apr 2010 (HHS Reference No. E–314–2008/0–PCT–02).

Licensing Status: Available for licensing.

Licensing Contact: Jennifer Wong; 301–435–4633; *wongje@mail.nih.gov.*

Collaborative Research Opportunity: The NCI Laboratory of Human. Carcinogenesis is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize cancer biomarkers and therapeutic targets. Please contact *Curtis_Harris@nih.gov* for more information.

Dated: August 11, 2010.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2010–20277 Filed 8–16–10; 8:45 am]

BILLING CODE 4140–01–P

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.

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A Novel Scaffold for Multivalent Display of Ligands

Description of Invention: Multivalent interactions are important in cell attachment, wound healing and immune responses. Such interactions are associated with cancer metastasis, blood clotting and the generation of antibodies from a vaccination. Mimicking multivalent interactions on a synthetic scaffold is challenging especially when large numbers of ligands (such as 5 or more) need to be displayed. There are numerous synthetic scaffolds that have been developed, but there are significant limitations that remain.

Scientists at the NIH have designed a novel multivalent scaffold that can display anywhere from 1 to 200 ligands. This system allows different types of ligands to be displayed in a controlled, spatially-addressable manner. This system uses peptide nucleic acids (PNAs) containing γ-substituted side