

**Proposed Project: Maternal and Child Health Bureau Performance Measures for Discretionary Grants (OMB No. 0915-0298): Revision**

The Maternal and Child Health Bureau (MCHB) intends to continue to collect performance data for Special Projects of Regional and National Significance (SPRANS), Community Integrated Service Systems (CISS), and other grant programs administered by MCHB.

The Health Resources and Services Administration (HRSA) proposes to

continue using reporting requirements for SPRANS projects, CISS projects, and other grant programs administered by MCHB, including national performance measures, previously approved by OMB, and in accordance with the "Government Performance and Results Act (GPRA) of 1993" (Public Law 103-62). This Act requires the establishment of measurable goals for Federal Programs that can be reported as part of the budgetary process, thus linking funding decisions with performance. Performance measures for MCHB discretionary grants were initially

approved in January 2003. Approval from OMB is being sought to continue the use of these measures. Some of these measures are specific to certain types of programs, and will not apply to all grantees. Furthermore, these measures are based primarily on existing data, thereby minimizing the response burden consistent with program administration and management needs. Through the experience of utilizing these measures, we are enhancing them to better reflect program goals.

The estimated response burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Burden hours per response	Total burden hours
Grant Report .....	898	1	898	6	5,388

E-mail comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Reports Clearance Officer, Room 10-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: November 24, 2008.

**Alexandra Huttinger**,  
Director, Division of Policy Review and Coordination.

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U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, e-mail [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

**Proposed Project: Maternal and Child Health Services Title V Block Grant Program Guidance and Forms for the Title V Application/Annual Report (OMB No. 0915-0172): Revision**

The Health Resources and Services Administration (HRSA) proposes to revise the *Maternal and Child Health Services Title V Block Grant Program—Guidance and Forms for the Application/Annual Report*. The guidance is used annually by the 50 States and 9 jurisdictions to apply for Block Grants under Title V of the Social Security Act, and in preparing the required annual report. The proposed revisions follow and build on extensive consultation received from a workgroup convened to provide suggestions to improve the guidance and forms.

The changes in this edition of the Maternal and Child Health Services Title V Block Grant Program Guidance and Forms for the Title V Application/Annual Report are primarily revisions to Section II—Needs Assessment. The purpose of these revisions is: (1) To provide more complete information on the Background and Conceptual Framework for the Needs Assessment Process (Part A); (2) to clarify what State grantees are to include in the Five Year Needs Assessment Document (Part B); (3) to better explain the information to include in the Annual Needs Assessment Summary/Update, both in the year when the five year Needs Assessment is conducted and in interim years (Part C); and (4) to update Figure 2, the Needs Assessment diagram, to reflect all aspects of the Needs Assessment process. In addition, other minor changes and clarifications are included throughout the document to make the instructions clearer for the respondent. Such changes include the clarification of headings and the types of information that States may want to include in a particular section.

The estimated average annual burden is as follows:

Reporting document	Number of respondents	Responses per respondent	Total responses	Burden per response	Total burden hours	Cost per hour	Total hour cost
Application and Report without Needs Assessment (2009 & 2011) .....	59	1	59	270	15,930	\$30	\$477,900
Application with Needs Assessment (2010) .....	59	1	59	378.5	22,332	30	669,960
Total Average Annual Burden .....	59	.....	59	306	18,064	30	541,920

The total estimate of annual burden is the average for the next three year period of Application submissions in which a Needs Assessment will be required once. The Application submissions (with and without the Needs Assessment) are based on the calendar year.

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to OIRA [submission@omb.eop.gov](mailto:submission@omb.eop.gov) or by fax to 202-395-6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: November 24, 2008.

**Alexandra Huttinger,**

Director, Division of Policy Review and Coordination.

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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.

#### Method for Detection of Cancer Based on Spatial Genome Organization in the Cell Nucleus

*Description of Technology:* The successful treatment of cancer is correlated with the early detection of the cancerous cells. Conventional cancer diagnosis is largely based on qualitative morphological criteria, but more accurate quantitative tests could greatly increase early detection of malignant cells. It has been observed that the spatial arrangement of DNA in the nucleus is altered in cancer cells in comparison to normal cells. Therefore,

it is possible to distinguish malignant cells by mapping the position of labeled marker genes in the nucleus.

This NIH invention provides methods of detecting abnormal cells in a sample using the spatial position of one or more genes within the nucleus of a cell, as well as a kit for detecting abnormal cells using such methods. The invention also provides methods of identifying gene markers for abnormal cells using the spatial position of one or more genes within the nucleus of a cell.

*Applications:* Diagnostic for cancer from tumor biopsies after non-invasive techniques such as a mammogram or PSA assay have suggested cancer.

*Advantages:*

- Sensitive detection of cancer.
- Very small sample (100-200 cells) reduces the need for invasive procedures.

- Does not require mitotic chromosomes.

- Applicable to solid tumors and blood cancers.

- Single cell assay allows analysis of subpopulations from biopsy.

- Probes to all genomic regions are available.

- Alternative or complementary to conventional diagnostics.

- Measures metastatic potential of cancer cells.

- Determination of tumor type.

*Market:*

- This novel in vitro diagnostic test for cancer has use in oncology laboratories of hospitals and commercial clinical laboratories.

- In the United States, almost 1.5 million new cancer cases are expected to be diagnosed in 2008.

*Development Status:* Presently in the process of validating the assay using a larger set of tumor samples.

*Inventors:* Tom Misteli and Karen Meaburn (NCI).

*Publication:* KJ Meaburn and T Misteli. Locus-specific and activity-independent gene repositioning during early tumorigenesis. *J Cell Biol.* 2008 Jan 14;180(1):39-50.

*Patent Status:* U.S. Provisional Application No. 61/094,318 filed 04 Sep 2008 (HHS Reference No. E-283-2008/0-US-01).

*Licensing Status:* Available for exclusive or non-exclusive licensing.

*Licensing Contact:* Whitney Hastings; 301-451-7337; [hastingw@mail.nih.gov](mailto:hastingw@mail.nih.gov).

*Collaborative Research Opportunity:* The National Cancer Institute, Cell Biology of Genomes Group, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize diagnostic methods for detection of cancer using spatial genome

organization. Please contact John D. Hewes, Ph.D. at 301-435-3121 or [hewes@mail.nih.gov](mailto:hewes@mail.nih.gov) for more information.

#### A Novel, Non-Invasive and Therapeutically Useful High Throughput Technique To Isolate Highly Enriched Tumor Reactive Lymphocytes From Peripheral Blood-Potential Use in Adoptive Immunotherapy

*Description of Technology:* The adoptive transfer of autologous antigen reactive lymphocytes has been shown to mediate significant tumor regression in some patients with metastatic cancer. However, the isolation of these T lymphocytes requires invasive surgery, which can lead to post-operative complications and delays in initiating adoptive immunotherapy with T cells.

This technology is directed to the use of a novel high throughput technique to isolate highly enriched tumor reactive lymphocytes in a non-invasive manner from the peripheral blood of cancer patients for the purpose of cancer immunotherapy. The technique utilizes a highly sensitive PCR based screening assay.

*Applications:* The isolated T lymphocytes can be used in adoptive immunotherapy for the treatment of metastatic cancer.

*Advantages:*

- A rapid and non-invasive high throughput method of isolating tumor reactive T cells, which is otherwise difficult with conventional peripheral blood isolating techniques.

- The method is easy to use and based on a highly sensitive PCR based screening assay.

- The method can detect the presence of extremely rare T cells in a bulk population of peripheral blood cells.

*Development Status:* The method of isolating tumor reactive T lymphocytes has been established. The method was successfully used to isolate tumor reactive T cells from peripheral blood of cancer patients.

*Inventor:* Udai S. Kammula (NCI).

*Patent Status:* U.S. Patent Application No. 61/027,623 filed 11 Feb 2008 (HHS Reference No. E-003-2008/0-US-01).

*Licensing Status:* Available for exclusive or non-exclusive licensing.

*Licensing Contact:* Sabarni K. Chatterjee, PhD; 301-435-5587; [chatterjeesa@mail.nih.gov](mailto:chatterjeesa@mail.nih.gov)

*Collaborative Research Opportunity:* The National Cancer Institute, Surgery Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this high throughput T