TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Reporting Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Designation Request	64	1.28	77	60	4,620
Premeeting Packages	54	1.11	60	100	6,000
Total					10,620

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

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: April 29, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–9882 Filed 5–5–08; 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.

Human Papillomavirus microRNA Diagnostics and Therapeutics

Description of Technology: Available for licensing and commercial development are patent rights that cover the uses of a p53 specific microRNA (miRNA). It has been reported that the tumor suppressive mRNA miR–34a (a downstream target of p53) is downregulated in HPV-infected primary keratinocytes. miR–34a arrests the cell cycle at G2 phase and promotes apoptosis. Therapeutic restoration of normal expression levels of miR–34a and/or simultaneous stabilization of p53 (inhibited by HPV E6) induces miR–34a accumulation in G0/G1 phase and can arrest tumor growth. Neoplasia and cancer cell progression has also been associated with p18Ink4c overexpression which can be regulated with the introduction of a therapeutic amount of miR–34a. Tumor reduction/suppression by down regulating p18Ink4c is also a therapeutic benefit provided by this invention.

Applications: Cervical cancer; Human papillomavirus; Therapeutics.

Inventors: Zhi-Ming Zheng and Xiaohong Wang (NCI).

Publications:

1. WO Lui *et al.* Patterns of known and novel small RNAs in human cervical cancer. Cancer Res. 2007 Jul 1;67(13):6031–6043.

2. I Martinez *et al.* Human papillomavirus type 16 reduces the expression of microRNA–218 in cervical carcinoma cells. Oncogene 2007 Nov 12; Advance online publication, doi:10.1038/sj.onc.1210919.

Patent Status:

U.S. Provisional Application No. 60/983,368 filed 29 Oct 2007 (HHS Reference No. E–029–2008/0–US–01).

U.S. Provisional Application No. 61/041,842 filed 02 Apr 2008 (HHS Reference No. E–029–2008/1–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Michael A. Shmilovich, Esq.; 301–435–5019; *shmilovm@mail.nih.gov*.

Collaborative Research Opportunity: The National Cancer Institute HIV and AIDS Malignancy Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize HPV-induced aberrant expression of microRNAs for cervical cancer diagnostics and therapeutics. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Microarray Binding Sensors Using Carbon Nanotube Transistors

Description of Technology: Available for licensing and commercial development are: (a) An apparatus containing microarray binding sensors having biological probe materials and carbon nanotube transistors (CNTs) and (b) various methods of using the highly sensitive CNTs for the electronic detection of nucleic acid hybridization for performing microarray gene expression experiments and detection of DNA–DNA, DNA–RNA, Peptide Nucleic Acid (PNA) –DNA, PNA–RNA, DNA-protein or PNA-protein binding. By analogy to the microarray concept, each transistor is associated with a distinct probe oligonucleotide. Each transistor is operated as a field effect transistor (FET) and the transconductance between the source and drain electrodes is measured before and after a hybridization event. The expected advantages are, besides higher sensitivity and ease of use, the elimination of chemical labeling and enzymatic manipulation and the further miniaturization. The unique distinction of this design over other CNT-based biomolecular sensing schemes is the complete isolation of the CNTs from chemical reactions concomitant with probe immobilization and target capture, and the CNTs functioning only as charge sensors. In contrast, current methods rely on enzymatic amplification of nucleic acids, fluorescent labeled targets, hybridization, amplification of signal and detection by optical scanners, which are time consuming and have limited sensitivity.

Applications: The apparatus and method can be used for numerous applications, among them: High-throughput monitoring of genome-wide

DNA, mRNA copy number changes; sequencing of DNA; miRNA levels in cancer; or identifying targets of transcription factors.

Furthermore, given the intensity of effort in linking gene expression with diseases, it is only a matter of time before diagnosis and prognosis of certain ailments can be performed on the basis of gene expression. At the present, most such analyses require costly apparatus and labor-intensive laboratory procedures.

Development Status: In the process of developing prototypes.

Inventors: Javed Khan (NCI) *et al.*

Publications:

1. H Pandana, KH Aschenbach, D Lenski, M Fuhrer, J Khan, RD Gomez. A versatile biomolecular charge based sensor using oxide-gated carbon nanotube transistor arrays. IEEE Sens J., Special Issue, July 2008, in press.

2. K Aschenbach, H Pandana, J Lee, J Khan, M Fuhrer, D Lenski, RD Gomez. Detection of nucleic acid hybridization via oxide gated carbon nanotube field effect transistors (invited). Proceedings of SPIE MEMS and Nanotechnologies, Volume 6959 (2008), in press.

Patent Status:

U.S. Patent Application No. 60/743,524 filed 17 Mar 2006 (HHS Reference No. E–056–2007/0–US–01).

PCT Application No. PCT/US2007/06809 filed 19 Mar 2007, which published as WO 2007/109228 on 27 Sep 2007 (HHS Reference No. E–056–2007/0–PCT–02).

U.S. Patent Application No. 11/723,369 filed 19 Mar 2007 (HHS Reference No. E–056–2007/0–US–03).

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

Licensing Contact: Cristina Thalhammer-Reyero, Ph.D., M.B.A.; 301–435–4507; *thalhamc@mail.nih.gov*.

Collaborative Research Opportunity: The Oncogenomics Section, Center for Cancer Research, National Cancer Institute, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize electrical detection of nucleic acid and protein levels. Please contact Javed Khan, M.D. at 301–435–2937 or *khanjav@mail.nih.gov* for more information.

Segmenting Colon Wall Via Level Set Techniques

Description of Technology: Virtual Colonoscopy (VC) has become a more prevalent and accepted method of colorectal cancer diagnosis. An essential element for detecting cancerous polyps using VC, in conjunction with computer-aided detection, is the accurate segmentation of the colon wall. While the inner boundary of the colon wall, the lumen-mucosal boundary, has often been the focus of previous segmentation work, detection of the outer wall, the serosal tissue boundary, allows for the segmentation of the colon wall, which is useful in determining potential polyps, muscular hypertrophy, and diverticulitis of the colon. Unfortunately, automatic determination of the outer colon wall position often is difficult due to the low contrast between CT attenuation values of the colon wall and the surrounding fat tissue. This invention is a level set based method to determine, from a CT colonography (CTC) scan, the location of the colon serosal tissue boundary. After determining this location, the algorithm segments the entire colon wall at subvoxel accurate precision.

In this algorithm, the loops in the colon caused by over-distention are detected and removed when the centerline calculation is performed. Also, a newly developed method for the detection and segmentation of the outer wall of the colon is used to connect collapsed portions where the lumen segmentation failed to produce a connected centerline. These two methods allow for a complete and accurate centerline to be calculated in uniformly distended colons as well as colons containing segments which are over and/or under-distended.

Applications: Diagnostics.

Inventors: Robert L. Van Uitert, Ronald M. Summers, Ingmar Bitter (CC).

Publications:

1. R Van Uitert, I Bitter. Subvoxel precise skeletons of volumetric data based on fast marching methods. Med Phys. 2007 Feb;34(2):627–638.

2. RL Van Uitert, RM Summers. Automatic correction of level set based subvoxel precise centerlines for virtual colonoscopy using the colon outer wall. IEEE Trans Med Imaging. 2007 Aug;26(8):1069–1078.

3. RM Summers, J Yao, PJ Pickhardt, M Franaszek, I Bitter, D Brickman, V Krishna, JR Choi. Computed tomographic virtual colonoscopy computer-aided polyp detection in a screening population. Gastroenterology. 2005 Dec;129(6):1832–1844.

4. R Van Uitert, I Bitter, RM Summers, JR Choi, PJ Pickhardt. Quantitative assessment of colon distention for polyp detection in CT virtual colonoscopy. Proc SPIE Int Soc Opt Eng. (2006) 6143,61431B:451–457; published online 13 Mar 2006, doi 10.1117/12.653205.

5. R Van Uitert, I Bitter, RM Summers. Detection of colon wall outer boundary and segmentation of the colon wall based on level set methods. Conf Proc IEEE Eng Med Biol Soc. 2006;1:3017–3020.

6. G Iordanescu, RM Summers. Benefits of centerline analysis for CT colonography computer-aided polyp detection. Proc SPIE Int Soc Opt Eng. (2003) 5031:388–397; published online 02 May 2003, doi:10.1117/12.485797.

7. G Iordanescu, RM Summers. Automated centerline for computed tomography colonography. Acad Radiol. 2003 Nov;10(11):1291–1301.

Patent Status: U.S. Patent Application No. 11/810,704 filed 05 Jun 2007 (HHS Reference No. E–298–2006/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Michael A. Shmilovich, Esq.; 301–435–5019; *shmilovm@mail.nih.gov*.

Dated: April 28, 2008.

Steven M. Ferguson,

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

[FR Doc. E8–9871 Filed 5–5–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; The Colon Cancer Family Registry.

Date: May 29, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Courtyard Gaithersburg Washingtonian Ctr, 204 Boardwalk Place, Gaithersburg, MD 20878.

Contact Person: Gerald G. Lovinger, PhD, Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Blvd., Room 8101, Bethesda, MD