

revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Clinical Mytheries: A Video Game About Clinical Trials. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* New England Research Institutes as a contractor for the National Heart Lung and Blood Institute is planning to create an engaging, informational “serious video game” for adolescents about clinical studies which: (1) Incorporates core learning objectives; and (2) dispels misconceptions. Two types of information collection are planned:

- Usability testing to understand game-play/usability. This information will be collected by focus group and will be digitally recorded 90 minute groups.
- A pre/post randomized trial to measure change in knowledge. This information will be collected electronically through on-line questionnaire.

The game will be incorporated with a larger initiative to provide information about clinical research (<http://www.nhlbi.nih.gov/childrenandclinicalstudies/index.php>). *Frequency of Response:* Once. *Affected Public:* Individuals. *Type of Respondents:* Adolescents—aged 8–14.

The annual reporting burden is as follows: *Estimated Number of Respondents:* 280; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours per Response:* Wave 1—90/60 (1.5 hours), Wave 2—80/60 (1.33 hours); and *Estimated Total Annual Burden Hours Requested:* 378. The annualized cost to respondents is estimated at: \$3,783. There are no Capital Costs to report. The Operating Costs to collect this information is estimated at \$42,425.00.

Note: The following table is acceptable for the Respondent and Burden Estimate information, if appropriate, instead of the text as shown above.

Form name	Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Qualitative Focus Group Discussion Guide and screener.	Adolescents—Wave one	30	1	90/60 (1.5 hours) ..	45
Screen pre post eval	Adolescents—Wave two	250	1	80/60 (1.33 hours)	333
Total		280			378

Request For Comments: 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.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Victoria Pemberton, RNC, MS, CCRC, National Heart, Lung and Blood Institute, 6701

Rockledge Drive, Rm. 8109, Bethesda, MD 20892, or call non-toll-free number (301) 435-0510 or Email your request, including your address to: pembertonv@mail.nih.gov

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: February 8, 2013.

Michael Lauer,

Director, Division of Cardiovascular Diseases, National Heart, Lung, and Blood Institute, NIH.

Dated: February 12, 2013.

Lynn Susulski,

NHLBI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2013-04547 Filed 2-26-13; 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.

FOR FURTHER INFORMATION CONTACT:

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.

Java Software for Investigational Drug Clinical Research

Description of Technology: A Java based software application available for academic use and on a royalty-bearing basis for commercial licensing. The Investigational Drug Management System (IDMS) supports the operational needs of the investigation drug section of a pharmacy providing inventory management functions which fulfill the recordkeeping requirements defined in the Code of Federal Regulations related to the storage, labeling, handling, and dispensing of investigational drugs. The internet/browser based application interfaces with the Computerized Provider Order Entry (CPOE) system for

tracking patients and prescriptions for investigational drugs. The IDMS supports the prescription filling process by capturing real-time data during the dispensing activity where automated safety checks are performed, ensuring the “five rights” of medication use are satisfied. The system supports randomized double-blind clinical trials by generating complex, multi-tiered randomization schemes that produce patient-specific treatment assignments along with industry standard labels containing barcodes. IDMS serves as the book of record providing end-to-end traceability for the receipt of raw materials from their source to the dispensing of finished pharmaceutical dosage forms to patients.

Potential Commercial Applications:

- Clinical data management
- Clinical Trials
- Investigational new drug trials

Competitive Advantages:

- Web based
- User friendly
- Data portability
- Randomization tables

Development Stage:

- Prototype
- Clinical

Inventors: Richard O. DeCederfelt, George J. Grimes, Stephen M. Bergstrom, Jon W. McKeeby (all of NIH-CC).

Intellectual Property: HHS Reference No. E-063-2013/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Contact: Michael Shmilovich; 301-435-5019; shmilovm@mail.nih.gov.

Software To Improve the Quality of Microscopy Images

Description of Technology: Available for licensing and commercial use is software based on an iterative deconvolution procedure that recovers images that have been blurred by a known point spread function. The software provides superior results when multiple independent observations of the same specimen are obtained. An example of such observations might be the multiple views of a specimen collected by a selective illumination plane microscope (SPIM). By using the blurring function and observations (raw images) corresponding to each view in sequential order through the iteration loop, the resulting output contains higher resolution, contrast, and signal than would result if any single observation alone was used, or if the output from single deconvolution operations on each image are combined, e.g. by averaging. In its current form, the software has been tested on the

Richardson-Lucy deconvolution (RLD) procedure. Preliminary data indicate that the algorithm provides an isotropic resolution of 350 nm, greatly improving the raw data (lateral resolution 0.5 microns, axial resolution 1.5 microns) on nematode embryos. In vivo data illustrating the power of the algorithm are available upon request.

Potential Commercial Applications:

- Image Resolution
 - Sub-micron microscopy
- Competitive Advantages:*
- Enables isotropic resolution
 - Iterative deconvolution algorithm that can readily be applied to SPIM datasets

Development Stage:

- Prototype
- In vitro data available
- In vivo data available (animal)

Inventors: Hari Shroff, Andrew York, Yicong Wu (all of NIBIB).

Publications:

1. Swoger J, et al. Multi-view image fusion improves resolution in three-dimensional microscopy. *Opt Express*. 2007 Jun 25;15(13):8029–42. [PMID 19547131]
2. Verveer PJ, et al. High-resolution three-dimensional imaging of large specimens with light sheet-based microscopy. *Nat Methods*. 2007 Apr;4(4):311–3. [PMID 17339847]

Intellectual Property: HHS Reference No. E-062-2013/0—Software Tool. Patent protection is not being pursued for this technology.

Licensing Contact: Michael Shmilovich; 301-435-5019; shmilovm@mail.nih.gov.

Collaborative Research Opportunity:

The NIBIB Section on High Resolution Optical Imaging is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize our algorithm, especially with respect to multiview microscopes. For collaboration opportunities, please contact Hari Shroff at hari.schroff@nih.gov.

Background-Free Fluorescent Nanodiamond Imaging

Description of Technology: Available for licensing and commercial development are intellectual property rights covering a method of imaging a biological specimen (e.g., human tissue) using fluorescent nanodiamonds implanted into the subject of interest, applying a magnetic field to said subject and producing a resultant image by a net juxtaposition of a second acquired image. This process suppresses the background and permits selective imaging of the nanodiamonds in the

presence of background fluorescence that exceeds the signal from the nanodiamonds. Another aspect of the invention provides an imaging method in which the resulting image is acquired by applying time-varying magnetic fields using one or more secondary image averaged against the first. The technique relies on imposing a small (~100 Gauss) magnetic field on the sample of interest during optical imaging combined with post-processing of the acquired images to remove the background. This technology can readily be added onto any commercial optical imaging platform to achieve background-free images of the nanodiamonds in a biological specimen.

Potential Commercial Applications:

- In vitro and in vivo optical imaging and diagnostics
- MRI imaging

Competitive Advantages:

- Improved resolution through composite imagery
- Background elimination
- Indefinite tracking due to the exceptional stability of the fluorescent nanodiamonds
- Wide excitation band (~500–600 nm)
- Broad-band Near IR emission (600–700 nm)
- Nanodiamonds are stable in aqueous solution
- In related technologies we have developed a method to specifically coat and functionalize nanodiamonds for targeting and labeling applications

Development Stage:

- Prototype
- In vitro data available
- In vivo data available (animal)

Inventors: Susanta Sarkar, Ambika Bumb, Keir Neuman (all of NHLBI).

Intellectual Property: HHS Reference No. E-261-2012/0—US Provisional Application No. 61/711,702 filed 09 Oct 2012.

Related Technology: HHS Reference No. E-175-2012/0—US Provisional Application No. 61/672,996 filed 18 Jul 2012, “Method of Preparing Silica-coated Nanodiamonds.”

Licensing Contact: Michael Shmilovich; 301-435-5019; shmilovm@mail.nih.gov.

Collaborative Research Opportunity:

The NHLBI Laboratory of Single Molecule Biophysics is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize background-free imaging of fluorescent nanodiamonds for in vivo and in vitro applications. For collaboration opportunities, please contact Keir C. Neuman, Ph.D. at neumankc@mail.nih.gov or 301-496-3376.

Silica-Coated Nanodiamonds for Imaging and the Delivery of Therapeutic Agents

Description of Technology: NIH investigators invented a robust and easily implemented method of synthesizing silica-coated nanodiamonds for imaging and therapeutic applications. A patent estate covering these methods is offered for licensing to commercial entities. The method generally includes coating nanodiamonds with a silica precursor, e.g., tetraethylorthosilicate (TEOS), inside liposomes. The liposomes are then removed to yield a final product that is stable, monodisperse, and easy to functionalize.

Potential Commercial Applications:

- Imaging
- Drug delivery

Competitive Advantages:

- Small size
- Physiologically inert carrier
- Monodisperse
- Stable in aqueous solution
- Readily functionalized

Development Stage: Prototype.

Inventors: Ambika Bumb (NHLBI), Susanta Kumar Sarkar (NHLBI), Keir Neuman (NHLBI), Martin Brechbiel (NCI).

Publications:

1. Yu SJ, et al. Bright fluorescent nanodiamonds: no photobleaching and low cytotoxicity. *J Am Chem Soc.* 2005 Dec 21;127(50):17604–5. [PMID 16351080]
2. Wilson RM. Nanodiamonds are promising quantum probes of living cells. *Phys Today* 2011 Aug;64(8):17. [doi 10.1063/PT.3.1204]
3. Chow EK, et al. Nanodiamond therapeutic delivery agents mediate enhanced chemoresistant tumor treatment. *Sci Transl Med.* 2011 Mar 9;3(73):73ra21. [PMID 21389265]
4. Krueger A. New carbon materials: biological applications of functionalized nanodiamond materials. *Chemistry* 2008;14(5):1382–90. [PMID 18033700]

Intellectual Property: HHS Reference No. E-175-2012/0—US Provisional Application No. 61/672,996 filed 18 Jul 2012.

Related Technology: HHS Reference No. E-261-2012/0—US Provisional Application No. 61/711,702 filed 09 Oct 2012, “Imaging Methods and Computer-Readable Media for Background-Free imaging of Fluorescent Nanodiamonds.”

Licensing Contact: Michael Shmilovich; 301-435-5019; shmilovm@mail.nih.gov.

Collaborative Research Opportunity: The NHLBI Laboratory of Single Molecule Biophysics is seeking statements of capability or interest from

parties interested in collaborative research to further develop, evaluate or commercialize fluorescent nanodiamonds for use as in vivo and in vitro optical tracking probes. For collaboration opportunities, please contact Keir C. Neuman, Ph.D. at neumankc@mail.nih.gov or 301-496-3376.

Dated February 20, 2013.

Richard U. Rodriguez,

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

[FR Doc. 2013-04443 Filed 2-26-13; 8:45 am]

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Chimeric Antigen Receptors to CD22 for Treating Hematological Cancers

Description of Technology: Chimeric antigen receptors (CARs) are hybrid proteins consisting of an antibody binding fragment fused to protein signaling domains that cause T-cells which express the CAR to become cytotoxic. Once activated, these cytotoxic T-cells can selectively eliminate the cells which they recognize via the antibody binding fragment of the CAR. Thus, by engineering a T-cell to

express a CAR that is specific for a certain cell surface protein, it is possible to selectively target those cells for destruction. This is a promising new therapeutic approach known as adoptive cell therapy.

CD22 is a cell surface protein that is expressed on a large number of B-cell lineage hematological cancers, such as leukemia and lymphoma. Several promising therapies are being developed which target CD22, including therapeutic antibodies and immunotoxins. This technology concerns the use of a high affinity antibody binding fragment to CD22 (known as m971), as the targeting moiety of a CAR. The resulting CAR can be used in adoptive cell therapy treatment for cancer.

Potential Commercial Applications:

- Treatment of diseases associated with increased or preferential expression of CD22
 - Specific diseases include hematological cancers such as chronic lymphocytic leukemia (CLL), hairy cell leukemia (HCL) and pediatric acute lymphoblastic leukemia (ALL)
- Competitive Advantages:**
- High affinity of the m971 antibody binding fragment increases the likelihood of successful targeting
 - Targeted therapy decreases non-specific killing of healthy, essential cells, resulting in fewer non-specific side-effects and healthier patients
 - Hematological cancers are susceptible to cytotoxic T-cells for treating because they are present in the bloodstream
 - Expression of CD22 only on mature cells allows the avoidance of stem cell elimination during treatment

Development Stage: Pre-clinical.

Inventors: Rimas J. Orentas et al. (NCI).

Intellectual Property: HHS Reference No. E-291-2012/0—US Provisional Application No. 61/717,960 filed 24 Oct 2012.

Related Technology: HHS Reference No. E-080-2008/0—U.S. Patent Application No. 12/934,214 filed 23 Sep 2010.

Licensing Contact: David A. Lambertson, Ph.D.; 301-435-4632; lambertsond@mail.nih.gov.

Modified Peptide Nucleic Acids (PNAs) for Detection of DNA or RNA and Identification of a Disease or Pathogen

Description of Technology: The NIH announces a novel method for fast, simple, and accurate detection of nucleic acids outside the modern laboratory. Nucleic acid testing is highly specific and often provides definitive