practices regulation (21 CFR 10.115). The draft guidance, when finalized will represent the Agency's current thinking on " Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Frequently Asked Questions." It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at http://www.regulations.gov or from the CBER Internet site at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* To receive " Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Frequently Asked Questions," you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1723 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations and guidance documents. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 809.10 have been approved under OMB control number 0910–0485; the collections in 21 CFR part 812 have been approved under OMB control number 0910–0078; and the collections of information regarding importer entry notice have been approved under OMB control number 0910–0046.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 18, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–13390 Filed 5–31–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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

Thrombolytic Temperature-Sensitive Liposomes

Description of Technology: The subject technology discloses a novel method for inducing targeted thrombolysis in blood vessels. In this technology, a thrombolytic agent is encapsulated within temperature-sensitive liposomes. This composition is administered into the patient's blood circulation. Certain clots and vulnerable atherosclerotic processes elicit an endogenous heat that facilitates local thrombolytic drug release. The thermosensitive liposome can also be exogenously heated to at least its phase transition temperature to induce the release the thrombolytic agent from the liposome at the thrombus for targeted thrombolysis. The temperature for activated release can be varied, depending on the specific composition of the liposome.

Applications: Thrombolysis of blood clots formed in blood vessels, primarily in thromboemblic diseases such as myocardial infarction and stroke, venous thromboemblic diseases such as deep vein thrombosis (DVT), and pulmonary embolism (PE).

Advantages:

• Due to the protection of the thrombolytic agent within the liposome structure until the time that release is induced, this technology provides for better stability and longer half-life of the agent.

—Enhanced efficacy compared to the currently used thrombolytic treatments.

—Decreased side effects compared to the currently used thrombolytic treatments.

—Potentially decreased immunogenicity.

• Lower treatment dose may be required compared to current methods using free thrombolytic agent.

—Increases safety profile and reduces the risk of dose-related intracranial hemorrhage in treated patients.

Development Status: Proof of principle has been demonstrated in vitro.

Inventors: Bradford Wood, Matt Dreher, *et al.* (NIHCC).

Patent Status: U.S. Provisional Application No. 61/473,665 filed 08 Apr 2011 (HHS Reference No. E–090–2011/0–US–01).

Relevant Publications:

1. Collen D. Staphylokinase: A potent, uniquely fibrin-selective thrombolytic agent. Nat Med. 1998 Mar;4(3):279–284. [PMID: 9500599]

2. Elbayoumi TA, Torchilin VP. Liposomes for targeted delivery of antithrombotic drugs. Expert Opin Drug Deliv. 2008 Nov;5(11):1185–1198. [PMID: 18976130]

3. Heeremans JL, Prevost R, Bekkers ME, *et al.* Thrombolytic treatment with tissue-type plasminogen activator (t-PA) containing liposomes in rabbits: A comparison with free t-PA. Thromb Haemost. 1995;73(3):488–494. [PMID: 7667833]

4. Tiukinhoy-Laing SD, Huang S, Klegerman M, Holland CK, McPherson DD. Ultrasound-facilitated thrombolysis using tissue-plasminogen activator-loaded echogenic liposomes. Thromb Res. 2007;119(6):777–784. [PMID: 16887172]

5. Needham D, Dewhirst MW. The development and testing of a new temperature sensitive drug delivery

system for the treatment of solid tumors. Adv Drug Deliv Rev. 2001 Dec 31;53(3):285–305. [PMID: 11744173]

6. Frenkel V, Oberoi J, Stone MJ, *et al.* Pulsed-high intensity focused ultrasound enhances thrombolysis in an in vitro model. Radiology 2006 Apr;239(1);86–93. [PMID: 16493016]

Licensing Status: Available for licensing.

Licensing Contacts:

• Uri Reichman, PhD, MBA; 301–435–4616; *UR7a@nih.gov.*

• Michael Shmilovich, Esq.; 301–435–5019; *shmilovm@mail.nih.gov.*

Collaborative Research Opportunity: The NIH Clinical Center, Interventional Radiology Section & Center for Interventional Oncology is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this novel approach to thrombolysis. Please contact Ken Rose, PhD at 301–435–3132 or *rosek@mail.nih.gov* for more information.

Methods and Devices for Transcatheter Cerclage Annuloplasty

Description of Technology: The invention relates to techniques and devices for cardiovascular valve repair, particularly annuloplasty techniques and devices in which tensioning elements are positioned to treat regurgitation of the mitral valve or tricuspid valve. More specifically, the technology pertains to a new device for myocardial septal traversal ("cerclage reentry") that also serves to capture (ensnare) and externalize the traversing guidewire. The focus of the invention is to avoid a phenomenon in cardiac surgery known as "trabecular entrapment." The device features an expandable and collapsible mesh deployed in the right ventricle to simplify capture of a reentering guidewire during transcatheter cerclage annuloplasty. The wire mesh exerts pressure against trabecular-papillary elements of the tricuspid valve to displace them against the right ventricular septal wall. By abutting the right ventricular reentry site of the cercalge guidewire, trabecular entrapment is avoided. The device comprises a shaft having a distal loop which provides a target in the interventrical myocardial septum through which a catheter-delivered tensioning system is guided. The loop ensnares the catheter-delivered tensioning system as it reenters the right ventricle or right atrium. The expandable and collapsible mesh is disposed within the right ventricle such that the catheter-delivered tensioning system is directed from the ventricular septum into the right ventricular cavity through only a suitable opening in the mesh and such that the catheter delivered tensioning system is captured or ensnared within the mesh opening.

Applications: Cardiovascular valve repair surgeries.

Features and Advantages:

• The device avoids trabecular entrapment of the cerclage guidewire during septal-perforator-to-right-ventricular myocardial guidewire traversal

• The device allows ensnarement of reentering guidewire.

• The device provides an X-ray target for guidewire reentry from the septal perforator veins.

• Collapsible transcatheter device that can be introduced from a cephalad (typically transjugular or transaxillary) or caudad (typically transfemoral) approach.

• The device is intended to allow straightforward removal from the same vascular sheath as the cerclage retrograde traversal guidewire, to allow both free ends of the guidewire to be externalized through the same sheath.

Development Status:

• Practical usefulness of the technology has been demonstrated.

• Preclinical testing of extant prototype is planned.

• Clinical development is planned.

Inventors: Robert J. Lederman and Ozgur Kocaturk (NHLBI).

Relevant Publication: Kim JH, *et al.* Mitral cerelage annuloplasty, a novel transcatheter treatment for secondary mitral valve regurgitation: initial results in swine. J Am Coll Cardiol. 2009 Aug 11;54(7):638–651. [PMID: 19660696].

Patent Status: U.S. Provisional Application No. 61/383,061 filed 15 Sep 2010 (HHS Reference No. E–108–2010/0–US–01).

Licensing Status: Available for licensing.

Licensing Contacts:

• Uri Reichman, PhD, MBA; 301–435–4616; *UR7a@nih.gov.*

• Michael Shmilovich, Esq.; 301–435–5019; *shmilovm@mail.nih.gov.*

Collaborative Research Opportunity: The National Heart, Lung, and Blood Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Peg Koelble at *koelblep@nhlbi.nih.gov* for more information.

Dated: May 25, 2011

Richard U. Rodriguez,

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

[FR Doc. 2011–13521 Filed 5–31–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

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

The meeting 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 Heart, Lung, and Blood Institute Special Emphasis Panel, Utilization of a Human Lung Tissue Resource for Vascular Research.

Date: June 23, 2011.

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

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Susan Wohler Sunnarborg, PhD, Scientific Review Officer, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7185, Bethesda, MD 20892.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: May 25, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–13523 Filed 5–31–11; 8:45 am]

BILLING CODE 4140–01–P