Therefore, selection of potential facilities will be based on the coordination of CBER's priorities for staff training as well as the limited available resources for this program. In addition to logistical and other resource factors to consider, a key element of site selection is a successful compliance record with FDA or another Agency with which we have a memorandum of understanding. If a site visit involves a visit to a separate physical location of another firm under contract to the applicant, the other firm also needs to agree to participate in the program, as well as have a satisfactory compliance history.

III. Requests for Participation

Identify requests for participation with the docket number found in brackets in the heading of this document. Received requests are available for public examination in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: *February 10, 2015.*

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–03117 Filed 2–13–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Start-up Evaluation License for the Development of Theranostic Kits for Taxane-based Chemotherapy

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant to Taxor Diagnostics, LLC of an exclusive evaluation option license to practice the inventions embodied in the following US Patent, US Patent Application, and International Patent Application (and all foreign counterparts): US Patent No. 8,546,091, issued 01 October 2013, entitled, ''Akt Phosphorylation at SER473 as an Indicator for Taxane-based Chemotherapy'' [HHS Ref. E–191–2009/0–US–07]; US Patent Application serial no. 14/031,699, of the same name, filed 19 September 2013 [HHS Ref. E–191–2009/0–US–08]; and International (PCT) Patent Application no. PCT/US2010/035816, of the same name, filed 21 May 2010 [HHS Ref. E–191–2009/0–PCT–02]. The patent rights in this invention have been assigned to the Government of the United States of America.

The prospective exclusive evaluation option license territory may be worldwide, and the field of use may be limited to:

1. Exclusive use of the Licensed Patent Rights to develop a test kit approved by the FDA as a Class III medical device under the Premarket approval (PMA) process, such test kit to be distributed in commerce for the purpose of identifying subgroups of breast cancer, colorectal cancer, and non-small cell lung cancer patients that may benefit from treatment with a taxane therapy; and

2. Non-exclusive use of the Licensed Patent Rights to develop a test kit for which the FDA issues an order, in the form of a letter, which finds Licensee's device to be substantially equivalent to one or more similar legally marketed devices, and states that the Licensee's device can be marketed in the U.S. (*i.e.,* 510(k) cleared), such test kit to be distributed in commerce for the purpose of identifying subgroups of breast cancer, colorectal cancer, and non-small cell lung cancer patients that may benefit from treatment with a taxane therapy.

Upon the expiration or termination of the exclusive evaluation option license, Taxor Diagnostics, LLC will have the exclusive right to execute an exclusive commercialization license which will supersede and replace the exclusive evaluation option license with no greater field of use and territory than granted in the exclusive evaluation option license.

DATES: Only written comments or applications for a license (or both) which are received by the NIH Office of Technology Transfer on or before March 4, 2015 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive evaluation option license should be directed to: Patrick McCue, Ph.D., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–5560; Facsimile: (301) 402–0220; Email: *mccuepat@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: The technology describes a method of identifying cancer patients that will respond favorably to and benefit from treatment with taxane-based therapy depending on the phosphorylation status of protein Akt-Serine 473 in patient's tumor biopsy sample.

The prospective exclusive evaluation license is being considered under the small business initiative launched on 1 October 2011, and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive evaluation option license, and a subsequent exclusive commercialization license, may be granted unless the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404 within fifteen (15) days from the date of this published notice.

Complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive evaluation option license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: February 9, 2015.

Richard U. Rodriguez,

Acting Director, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2015–03088 Filed 2–13–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; 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 Institute of Environmental Health Sciences Special Emphasis Panel; Worker Health and Safety Training Review.

Date: March 9–10, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Chapel Hill Hotel, One Europa Drive, Chapel Hill, NC 27517.