This application is used by insurance brokers to register with Export Import Bank. The application provides Export Import Bank staff with the information necessary to make a determination of the eligibility of the broker to receive commission payments under Export Import Bank's credit insurance programs.

We have revised the following question: "Indicate (Not Required) if owned by a woman or an ethnic minority, describe"

To this question:

"Is the majority ownership of your business represented by: women or minority?"

This form can be reviewed at *http://www.exim.gov/pub/pending/EIB 92_79 Broker Registration Form.*

DATES: Comments should be received on or before May 10, 2011 to be assured of consideration.

ADDRESSES: Comments maybe submitted through *http://www.Regulations.Gov* or mailed to Judith Rivera, Export Import Bank of the United States, 811 Vermont Ave., NW. Washington, DC 20571

SUPPLEMENTARY INFORMATION: *Titles and Form Number:* EIB 92–79 Broker Registration Form.

OMB Number: 3048–0024.

Type of Review: Regular.

Need and Use: This application is used by insurance brokers to register with Export Import Bank. The application provides Export Import Bank staff with the information necessary to make a determination of the eligibility of the broker to receive commission payments under Export Import Bank's credit insurance programs.

Affected Public: This form affects entities involved in the export of U.S. goods and services.

Annual Number of Respondents: 50.

Estimated Time per Respondent: 100 hours.

Government Annual Burden Hours: 200 hours.

Frequency of Reporting or Use: Once.

Sharon A. Whitt,

Agency Clearance Officer.

[FR Doc. 2011–5598 Filed 3–10–11; 8:45 am]

BILLING CODE 6690–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that the Federal Deposit Insurance Corporation's Board of Directors will meet in open session at 10 a.m. on Tuesday, March 15, 2011, to consider the following matters:

Summary Agenda: No substantive discussion of the following items is anticipated. These matters will be resolved with a single vote unless a member of the Board of Directors requests that an item be moved to the discussion agenda.

Disposition of minutes of previous Board of Directors' Meetings.

Summary reports, status reports, and reports of actions taken pursuant to authority delegated by the Board of Directors.

Memorandum and resolution re: Final Rule Making Technical Amendments to FDIC's Anti-Money-Laundering Program and Fair Credit Reporting Rules to Update Cross-References to Treasury Regulations.

Memorandum and resolution re: Authorization to Publish Privacy Act System of Records Notice in the Federal Register.

Discussion Agenda

Memorandum and resolution re: Notice of Proposed Rulemaking regarding Priorities and Claims Process under the Orderly Liquidation Authority Provisions of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

The meeting will be held in the Board Room on the sixth floor of the FDIC Building located at 550 17th Street, NW., Washington, DC.

This Board meeting will be Webcast live via the Internet and subsequently made available on-demand approximately one week after the event. Visit *http://www.vodium.com/goto/fdic/boardmeetings.asp* to view the event. If you need any technical assistance, please visit our Video Help page at: *http://www.fdic.gov/video.html.*

The FDIC will provide attendees with auxiliary aids (*e.g.,* sign language interpretation) required for this meeting. Those attendees needing such assistance should call 703–562–2404 (Voice) or 703–649–4354 (Video Phone) to make necessary arrangements.

Requests for further information concerning the meeting may be directed to Mr. Robert E. Feldman, Executive Secretary of the Corporation, at 202–898–7043.

Dated: March 8, 2011.

Robert E. Feldman,

Executive Secretary, Federal Deposit Insurance Corporation.

[FR Doc. 2011–5730 Filed 3–9–11; 4:15 pm]

BILLING CODE P

FEDERAL ELECTION COMMISSION

Sunshine Act Notice

AGENCY: Federal Election Commission.

DATE AND TIME: Wednesday, March 16, 2011 at 10 a.m.

PLACE: 999 E Street, NW., Washington, DC (Ninth Floor).

STATUS: This meeting will be open to the public.

Items To Be Discussed

Correction and Approval of the Minutes for the Meeting of March 3, 2011

Draft Advisory Opinion 2011–03: Democratic Senatorial Campaign Committee, National Republican Congressional Committee, Republican National Committee, Democratic Congressional Campaign Committee, and National Republican Senatorial Committee by Marc E. Elias, Esq., Jessica Furst, Esq., John Phillippe, Esq., Brian G. Svoboda, Esq., and Michael E. Toner, Esq.

Proposed Final Audit Report on Hillary Clinton for President (A08–05)

Withdrawal and Resubmission of Proposed Interpretative Rule Regarding Electronic Contributor Redesignations (LRA 820)

Legislative Recommendations

Management and Administrative Matters.

Individuals who plan to attend and require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Shawn Woodhead Werth, Commission Secretary and Clerk, at (202) 694–1040, at least 72 hours prior to the hearing date.

PERSON TO CONTACT FOR INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Shawn Woodhead Werth,

Secretary and Clerk of the Commission.

[FR Doc. 2011–5846 Filed 3–9–11; 4:15 pm]

BILLING CODE 6715–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Cancer Therapy Evaluation Program Intellectual Property Option to Collaborator

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, Division of Cancer Treatment and Diagnosis, is announcing the final revision of the NCI Cancer Therapy Evaluation Program's Intellectual Property Option to Collaborator.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 6, 2010 (FR Vol. 65, No. 65), the National Cancer Institute, Division of Cancer Treatment and Diagnosis (DCT) issued a proposed revision to the Cancer Therapy Evaluation Program (CTEP)'s Intellectual Property Option to Collaborator. The proposed revision represents a major effort on the part of NCI CTEP to address the disposition of intellectual property (IP) related to data and Agent-treated specimens in studies where CTEP provides agents, as well as to harmonize the IP terms with standards currently used by the cancer research community. The background and description of the rationale can be found in the Background Section of the proposed revision issued April 6, 2010. The proposal called for submission of comments by May 6th, 2010. NCI CTEP received numerous comments in response to the proposed revision, many of which asserted that the proposed change would not meet its stated goals and requested NCI CTEP to reevaluate specific aspects of the proposal. CTEP agreed with some of these comments and has revised selected aspects of the proposed CTEP Intellectual Property Option to Collaborator to better reflect our stated goals.

I. Rationale for the Changes to the IP Option

The Cancer Therapy Evaluation Program (CTEP) of the National Cancer Institute's (NCI) Division of Cancer Treatment and Diagnosis (DCTD) obtains proprietary "Agents" from biotechnology and pharmaceutical companies (hereinafter "Collaborators") for use in NCI-supported clinical trials under funding agreements. As part of the arrangement with these Collaborators to use their proprietary Agents and to make conducting such clinical research possible, Collaborators will often require, as a condition of collaboration, that the NCI funded recipients receiving the Agent ("Institutions") agree to certain conditions, including the willingness to provide notice of and grant options to certain intellectual property rights arising from research involving the Agent under the scope of an NCI funding agreement. The IP Option will apply to inventions generated from clinical studies for which CTEP provided Agent(s) and for inventions generated under any other NCI CTEP-approved studies that use CTEP-provided Agent(s), non-publicly released clinical data or Agent(s)-treated specimens from those clinical studies.

The previous IP option language was silent as to the disposition of intellectual property developed from data and Agent-treated samples. As a result, both Collaborators and Institutions claimed an ownership interest in inventions generated from these data and materials. This lack of clarity has become a major impediment in NCI CTEP's ability to obtain proprietary Agents from collaborators for use in NCI CTEP-sponsored clinical studies. This has resulted in delays and threatens the continuing ability of CTEP to provide proprietary Agents to NCI-funded investigators for important clinical studies to advance the treatment of cancer. The lack of Agents for these clinical studies jeopardizes NCI CTEP's ability to support these research activities. The revised CTEP IP Option and Institution Notification is intended to offer appropriate incentives and assurance for both Collaborators and Institutions to participate in CTEP-sponsored clinical studies.

II. The Proposed Revision to the CTEP Intellectual Property Option to the Collaborator

The following is the proposed revision to the CTEP IP Option that was published in the **Federal Register** on April 6th:

The Cancer Therapy Evaluation Program (CTEP) of the National Cancer Institute's (NCI) Division of Cancer Treatment and Diagnosis (DCTD) obtains "Agents" from biotechnology and pharmaceutical companies (hereinafter "Collaborators") through Cooperative Research and Development Agreements ("CRADAs") and other means, for use in NCI-funded research conducted via extramural funding agreements. As part of the arrangement with these Collaborators to use their Agents and to make the collaborative research possible, NCI CTEP would agree not to provide Agents to Institutions unless they provide Collaborators with the IP Options and Institution Notifications described below. The specific terms of the IP Options depend on the types of inventions that arise out of the NCI CTEP funded research (Section A Inventions, Section B Inventions, or Unauthorized Inventions). NCI CTEP is requesting applicants include assurances of agreement with the terms of the IP Options and Institutional Notification described below in their funding applications to NCI CTEP.

References to "Institution" mean the funding recipient conducting the research described herein. The Intellectual Property Options (IP Options) and Institution Notification described below will apply to inventions arising from research involving the Agent(s) under the scope of an NCI CTEP funding agreement.

A. The IP Option described in this Section A would apply to inventions that use or incorporate the Agent(s) and that are conceived or first actually reduced to practice pursuant to NCI CTEP-funded clinical or non-clinical studies utilizing the Agent(s) ("Section A Inventions"):

Institution agrees to grant Collaborator(s): (i) A royalty-free, worldwide, non-exclusive license for commercial purposes; and (ii) a time limited first option to negotiate an exclusive, or co-exclusive, if applicable, world-wide, royalty bearing license for commercial purposes, including the right to grant sub licenses, subject to any rights of the Government of the United States of America, on terms to be negotiated in good faith by the Collaborator(s) and Institution. If Collaborator accepts the non-exclusive commercial license, the Collaborator agrees to pay all out of pocket patent prosecution and maintenance costs which will be pro-rated and divided equally among all licensees. If Collaborator obtains an exclusive commercial license, in addition to any other agreed upon licensing arrangements such as royalties and due diligence requirements, the Collaborator agrees to pay all out of pocket patent prosecution and maintenance costs. Collaborator(s) will notify Institution, in writing, if it is interested in obtaining a commercial license to any Section A Invention within three (3) months of Collaborator's receipt of a patent application or six (6) months of receipt of an invention report notification of such Section A Invention. In the event Collaborator fails to so notify Institution, or elects not to obtain an exclusive license, then Collaborator's option expires with respect to that Section A Invention, and Institution will be free to dispose of its interests in accordance with its policies. If Institution and Collaborator fail to reach agreement within ninety (90) days, (or such additional period as Collaborator and Institution may agree) on the terms for an exclusive license for a particular Section A Invention, then for a period of three (3) months thereafter Institution agrees not to offer to license the Section A Invention to any third party on materially better terms than those last offered to Collaborator without first offering such terms to Collaborator, in which case Collaborator will have a period of thirty (30) days in which to accept or reject the offer. If Collaborator elects to negotiate an exclusive commercial license to a Section A Invention, then Institution agrees to file

and prosecute patent application(s) diligently and in a timely manner and to give Collaborator an opportunity to comment on the preparation and filing of any such patent application(s). Notwithstanding the above, Institution is under no obligation to file or maintain patent prosecution for any Section A Invention.

For all Section A Inventions, regardless of Collaborator's decision to seek a commercial license, Institution agrees to grant Collaborator a paid-up, nonexclusive, royalty-free, world-wide license for research purposes only. Institution retains the right to make and use any Section A Invention for all non-profit research, including for educational purposes and to permit other educational and non-profit institutions to do so.

B. The IP Option described in this Section B would apply to inventions that do not use or incorporate the Agent(s) but that are conceived or first actually reduced to practice pursuant to NCI CTEP clinical or non-clinical studies utilizing the Agent(s). It also applies to inventions that are conceived or first actually reduced to practice pursuant to NCI CTEP studies utilizing clinical data or specimens from patients treated with the Agent (including specimens obtained from NCI CTEP-funded tissue banks) ("Section B Inventions"):

Institution agrees to grant to Collaborator(s): (i) A paid-up nonexclusive, nontransferable, royalty-free, world-wide license to all Section B Inventions for research purposes only; (ii) a time-limited first option to negotiate a non-exclusive, exclusive, or co-exclusive, if applicable, world-wide royalty-bearing license for commercial purposes, including the right to grant sub-licenses, subject to any rights of the Government of the United States of America, on terms to be negotiated in good faith by the Collaborator(s) and Institution; and (iii) a nonexclusive, royalty-free, world-wide license either to (a) disclose Section B Inventions to a regulatory authority when seeking marketing authorization of the Agent, or (b) disclose Section B Inventions on a product insert or other promotional material regarding the Agent after having obtained marketing authorization from a regulatory authority. Collaborator will notify Institution, in writing, of its interest in obtaining an exclusive commercial license to any Section B Invention within one year of Collaborator's receipt of a patent application or eighteen months of receipt of an invention report notifying Collaborator of such Section B Invention(s). In the event that Collaborator fails to so notify Institution, or elects not to obtain an exclusive license, then Collaborator's option expires with respect to that Section B Invention, and Institution will be free to dispose of its interests in such Section B Invention in accordance with Institution's policies. If Institution and Collaborator fail to reach agreement within ninety (90) days, (or such additional period as Collaborator and Institution may agree) on the terms for an exclusive license for a particular Subject B Invention, then for a period of six (6) months thereafter Institution agrees not to offer to license the Section B Invention to any third party on materially better terms than those last offered to Collaborator without first offering such terms to Collaborator, in which case Collaborator will have a period of thirty (30) days in which to accept or reject the offer. Institution retains the right to make and use any Section B Inventions for all non-profit research, including for educational purposes and to permit other educational and non-profit institutions to do so. If Collaborator elects to negotiate an exclusive commercial license to a Section B Invention, then Institution agrees to file and prosecute patent application(s) diligently and in a timely manner and to give Collaborator an opportunity to comment on the preparation and filing of any such patent application(s). Notwithstanding the above, Institution is under no obligation to file or maintain patent prosecution for any Section B Invention.

Inventions arising more than five years after the release of data on the primary end point of the NCI CTEP clinical trial that generated the clinical data and/or specimens will not be subject to the Section B(ii) IP Option.

C. The IP Option described in this Section C would apply to inventions made by Institution's investigator(s) or any other employees or agents of Institution, which are or may be patentable or otherwise protectable, as a result of research utilizing the Agent(s) outside the scope of the NCI CTEP funding agreement (Unauthorized Inventions):

Institution agrees, at Collaborator's request and expense, to grant to Collaborator a royalty-free exclusive or co-exclusive license to Unauthorized Inventions.

D. Institution Notification

Institution agrees to promptly notify NCI CTEP (*NCICTEPpubs@mail.nih.gov*) and Collaborator(s) in writing of any Section A Inventions, Section B Inventions, and Unauthorized Inventions upon the earlier of: (i) Any submission of any invention disclosure to Institution of a Section A, Section B, or Unauthorized Invention, or (ii) the filing of any patent applications of a Section A, Section B, or Unauthorized Invention. Institution agrees to provide a copy of either the invention disclosure or the patent application to the Collaborator and to NCI CTEP which will treat it in accordance with 37 CFR part 401. These requirements do not replace any applicable reporting requirements under the Bayh-Dole Act, 35 U.S.C. 200–212, and implementing regulations at 37 CFR part 401.

III. Comments on the Proposed Revision and NCI CTEP's Response and Modifications to the Proposed Option Based on Feedback

The NCI CTEP received 24 responses to the proposed revision to the CTEP Intellectual Property Option. Comments were received from pharmaceutical and biotechnology companies, diagnostic companies, industry groups, the cooperative groups, universities, hospitals and the Council on Government Relations.

To make it easier to identify comments and our responses, the word "Comment" in parentheses, appears before the comment's description and the word "Response," in parentheses, appears before our response. Similar comments are grouped together under the same number. Due to the detail of some responses as well as space and time limitations, we will not address every point brought up by every Commenter, but will focus on major concerns expressed by a variety of Commenter's and the issues that were addressed in the final version of the CTEP IP Option. We have condensed some responses into topic areas, especially areas where there were a wide range of conflicting suggestions. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance or the order in which it was received. For ease of use comments will be divided by Section and follow a generalized order of the proposed Option itself:

1. Overall Scope of the IP Option and Situations in Which the IP Option Would Be Applied

(Comment) A recurring issue among many respondents was that the document itself was unclear as to the scope of the IP Option, specifically to which studies the IP Option must be applied.

(Response) NCI has endeavored to properly clarify the scope in the final revision. The NCI CTEP IP option will

apply to inventions generated from: (a) Clinical studies for which CTEP provided Agent(s), (b) other NCI CTEP-approved studies that use CTEP–Provided Agent(s), and (c) non-publicly released clinical data or Agent(s)-treated specimens from those clinical studies.

2. The Definition of Inventions, Was too Vague and Ambiguous in Both Sections A and B

(Comment) Many respondents from all groups commented that the definition of inventions as those that "use or incorporate" Agent was too vague. Several respondents offered suggestions as to language that would clarify the intended meaning and narrow the scope.

(Response) NCI concurs that this language was vague, and in the final Option has modified the language to more appropriately clarify the scope. The final Option replaces "use or incorporates" with the statement that the Option will apply to "inventions that would be described in patent disclosures that claim the use and/or the composition of the Agent(s)."

3. Invention Language Should State That the Scope Should Cover Inventions That Are "Conceived AND Reduced to Practice" Under the Clinical Studies as Opposed to "Conceived OR Reduced to Practice"

(Comment) Several respondents suggested altering this language based on the following reasoning: While this language is consistent with the Bayh-Dole Act scope of "subject inventions" for Federal funding purposes, Bayh-Dole only speaks to the rights to inventions provided to funding recipients and the government. The IP option, however applies to rights that funding recipients grant to third party Collaborators, therefore the Bayh-Dole scope does not apply to theses inventions. Since the Bayh-Dole scope does not apply this language should not be considered. Use of "OR" language was purported to have substantial risk to create conflicting obligations, as the Collaborator would have rights to prior conceptions (that are reduced to practice under the clinical study) and future reductions to practice (of conceptions made under this clinical study). This would require institutions to carefully monitor and possibly restrict other agreements and funding related to follow on research.

(Response) NCI CTEP finds this argument unpersuasive. While it may not be necessary to apply the Bayh-Dole scope to the inventions covered under this Option, NCI CTEP feels that there is value in maintaining a consistent standard that reflects the intent of Bayh-Dole. This language is also consistent with the terms offered to collaborators under Federal Cooperative Research and Development Agreements. More importantly this change would be inconsistent with programmatic policy and the manner in which clinical studies are reviewed and approved. Many of the clinical study proposals are in response to an NCI CTEP-solicitation that has been formulated with the Collaborator so it would be difficult for the investigator to have "conceived" the invention. However, the investigator could be the first to "reduce it to practice." "Conceived or reduced to practice" benefits the investigators submitting unsolicited proposals since, even if the Collaborator disapproved a proposal, the investigator would still have "conceived" the invention.

In regards to future reductions to practice, NCI CTEP wants to reinforce that the Section A is only applicable to studies wherein CTEP provides Agent, which limits the application of this clause sufficiently that future reductions are not a concern. If an Institution is utilizing NCI CTEP provided agent, any invention generated is by definition not a future reduction to practice, but rather part of an ongoing study.

4. The Section A and B Licenses Should be an Assignment of all Intellectual Property (Including Copyright and Trademarks) to the Collaborator, With an Offer to Provide an Automatic Non-Exclusive Research Use License Back to the Inventing Institution

(Comment) Several respondents felt that an outright assignment of all intellectual property to collaborators would provide a better incentive for participation in NCI CTEP clinical studies.

(Response) NCI believes that while this would provide greater incentives for participation on the part of Industry, such assignment would have a chilling effect on the participation of academic researchers and on the business model of downstream diagnostic companies. In addition, NCI CTEP feels that the rights offered in the CTEP IP Option should pertain solely to patents.

5. The Section A Non-Exclusive Royalty Free Commercialization License Should be Sub-Licensable

(Comment) Several respondents felt that the Section A non-exclusive license needed to be sub-licensable in order to have any real value. In today's market place, collaborators often partner with several other entities when undertaking development efforts, so the non-exclusive license is effectively worthless without the ability to sub-license.

(Response) NCI believes that there is merit to this position; however we are cognizant that an unfettered right to sub-license would destroy all value for inventing institutions. NCI CTEP has included new language indicating that the Section A license is sublicensable, however it may only be sub-licensed to affiliates or Collaborators for the purposes of development.

6. Patent Expenses Related to all Licensing Options

(Comment) There were several distinct and competing views in the comments related to the disposition of patent expenses. Some respondents felt that it was inappropriate for the Institutions to receive reimbursement of any patent expenses for non exclusive licenses. Conversely, other respondents felt that the Option should clearly state that the Collaborator is responsible for all patent expenses, including expenses associated with the exclusive licensing option.

(Response) NCI believes that the proposed IP option strikes an appropriate balance in regards to patent expenses. Since the proposed option represents an expansion of rights relative to the current option, NCI believes it is entirely appropriate for Collaborators to shoulder patent expenses (in a pro-rated manner) if they wish to exercise their option to the NERF or the Exclusive licensing option in Section A. If Collaborator is not interested in shouldering patent expenses related to Section A inventions, they are in no way obligated to and will still receive a research use license.

In regard to Section B inventions, NCI CTEP feels that the granted licenses are sufficiently narrow in scope and consistent with the free research use license of Section A. NCI CTEP will remain silent in regard to any exclusive or non-exclusive licenses that parties may wish to negotiate in addition to the licenses described in this section. The Institution and the Collaborator are in the best position to determine the most appropriate terms for an exclusive or a non exclusive license on any Section B invention, should they decide to negotiate such a license. While it is a standard convention in exclusive licensing negotiations for the licensee to cover the cost of patents, there may be instances, particularly with regard to smaller companies participating in the program, where it would be to the benefit of both the Institution and the Collaborator to have the flexibility to negotiate other licensing terms.

7. Time Frames On Negotiation of Section A Exclusive Licensing Options as Well as Most-Favored Nation Period

(Comment) This was an area of broad discussion where comments varied substantially based on the position of the commenter. In general Industry responders felt the time period for negotiation and most favored nation status was too short, and asked for a time frame double what the proposed Option provided. Arguments focused on the difficulty of properly valuating the IP in such a short time frame. Conversely, Institutions and diagnostic company respondents felt the time frame for negotiation was too long, and that the most favored nation provisions should be removed entirely. Arguments focused on the delay that these terms engender and the ability of a Collaborator to use them to "halt" development of associated technologies.

(Response) NCI believes that the current time frame for negotiation of Section A inventions appropriately balances the concerns expressed by both Collaborators and Institutions. While neither side is completely satisfied with the time frames, they are consistent with previous policy, and our experience indicates they are at the very least functional.

8. Section B Inventions: Clarity Regarding the Scope of Data to Which the Option Will Apply

(Comment) Several respondents felt that the description of data in Section B was ambiguous and overly broad, and that it could be interpreted to apply to data that had been published or had otherwise entered the public domain.

(Response) NCI CTEP agrees that the language in this Section B pertaining to data required more clarity. We have added language specifying that it only applies to confidential data from clinical studies that used NCI CTEP-provided Agent or data from such studies that has not yet been published. The Option is not intended to read on publicly available or published data.

9. Section B(ii) Inventions (ii): Exclusive Licensing Option

(Comment) In general the inclusion of the Section B(ii) exclusive licensing option was the source of greatest controversy within the proposed Option. Institutions and diagnostic company respondents felt strongly that the proposed B(ii) exclusive licensing option:

a. Was overly broad and included reach-through that would stifle the development of Inventions that are critical to the treatment of cancer patients. In particular the Option would make it difficult, if not impossible, for diagnostic companies to develop companion diagnostics to a particular treatment in a timely manner.

b. Had time frames for negotiation of these licenses that were overly generous and needed to be reduced.

c. Should not have a 5 year time limitation as this was both overly long and logistically impractical to implement.

d. Was fundamentally unfair, would constrain the ability of Institutions to collaborate on diagnostics, and thus, it would have a chilling effect on participation in CTEP studies.

(Response) NCI believes that Institution, and particularly Diagnostic company respondents made a compelling argument for the removal of this clause from the proposed option. The NCI's goal in promulgating the revision was to encourage participation in CTEP studies by ensuring that Collaborators receive enough rights to protect their ability to successfully manufacture and commercially market any therapeutic they supply to the CTEP program (freedom to operate).

The NCI believes that freedom to operate is protected by the more narrowly tailored Section B(iii) option, and that the B(ii) option as presented in the proposed option is overbroad and unnecessary to achieve NCI's goals. In response, the NCI has removed the Section B(ii) option in its entirety from the final Option.

10. Section B(iii) Inventions Use of "and" Instead of "or"

(Comment) Several respondents felt that it was unclear whether Collaborators would receive both the right to use Invention data for regulatory purposes and the right to include Invention data on product insert information.

(Response) NCI agrees that this language was unnecessarily vague. The intent was for Collaborator to have both rights and as such the wording has been amended to replace "or" with "and."

11. Section C Inventions: Recommendations That the NCI Remain Silent on Unauthorized Inventions

(Comment) Several respondents felt that that section was unduly harsh and should be removed altogether, with any action regarding unauthorized use to be left for the parties to resolve. Respondents also felt that this language may be in conflict with the Bayh-Dole Act.

(Response) The NCI finds this argument unpersuasive. The removal of this section would effectively make it more attractive to develop an invention outside the scope of approved studies than under the scope and would provide a strong incentive for participants to breach the agreement. The NCI feels that there must be some form of penalty for breaching the agreement in order to maintain our ability to obtain proprietary Agents for clinical studies.

In regards to Bayh-Dole, NCI has discussed this with our legal counsel at OGC. These unauthorized studies are, by definition, not done under the scope of a government funding agreement (the party is in fact in breach of a government funding agreement) therefore Bayh-Dole does not apply to these inventions. This language provides consequences in the event that a party steps outside of the agreed upon scope of work.

12. Section C Inventions: Recommendation That the NCI include a Non-Exclusive Research Use License Back to the Inventing Institution

(Comment) Several respondents felt that while the unauthorized use language was appropriate, the institution should retain a license to use any inventions generated, including those through unauthorized use, for internal research purposes.

(Response) The NCI believes that this argument has merit and has included this language in the final Option. While we do not believe it is appropriate for Institutions to benefit from misuse of Agent, data or Agent-treated samples, we feel that we also have an obligation to support the scientific endeavor and avoid blocking important research in the case of inadvertent breach.

IV. The Final Revision to the CTEP IP Option

The following is the revision in its final form, with alterations made based on comments received to the April 6th **Federal Register** notice:

The Cancer Therapy Evaluation Program (CTEP) of the National Cancer Institute's (NCI) Division of Cancer Treatment and Diagnosis (DCTD) obtains "Agents" from biotechnology and pharmaceutical companies (hereinafter "Collaborators") through Cooperative Research and Development Agreements ("CRADAs") and other means, for use in NCI-funded research conducted via extramural funding agreements. As part of the arrangement with these Collaborators to use their Agents and to make the collaborative research possible, NCI CTEP would agree not to provide Agents to Institutions unless they provide Collaborators with the IP Options and

Institution Notifications described below. The specific terms of the IP Option depend on the types of inventions that arise out of the studies wherein Agent is supplied by NCI CTEP pursuant to an agreement with a Collaborator (Section A Inventions, Section B Inventions, or Unauthorized Inventions). NCI CTEP is requesting that applicants include assurances of agreement with the terms of the IP Options and Institutional Notification described below in applicable funding applications to NCI.

References to "Institution" mean the funding recipient conducting the research described herein. The Intellectual Property Options (IP Options) and Institution Notification described below will apply to inventions arising from research involving the Agent(s) under the scope of an NCI funding agreement.

A. The IP Option described in this Section A would apply to inventions that would be described in patent disclosures that claim the use and/or the composition of the Agent(s) and that are conceived or first actually reduced to practice pursuant to clinical or non-clinical studies utilizing the NCI CTEP provided Agent(s) ("Section A Inventions"):

Institution agrees to grant to Collaborator(s): (i) a royalty-free, worldwide, non-exclusive license for commercial purposes with the right to sub license to affiliates or collaborators working on behalf of Collaborator for Collaborator's development purposes; and (ii) a time limited first option to negotiate an exclusive, or co-exclusive, if applicable, world-wide, royalty bearing license for commercial purposes, including the right to grant sub licenses, subject to any rights of the Government of the United States of America, on terms to be negotiated in good faith by the Collaborator(s) and Institution. If Collaborator accepts the non-exclusive commercial license, the Collaborator agrees to pay all out-of-pocket patent prosecution and maintenance costs which will be pro-rated and divided equally among all licensees. If Collaborator obtains an exclusive commercial license, in addition to any other agreed upon licensing arrangements such as royalties and due diligence requirements, the Collaborator agrees to pay all out-of-pocket patent prosecution and maintenance costs. Collaborator(s) will notify Institution, in writing, if it is interested in obtaining a commercial license to any Section A Invention within three (3) months of Collaborator's receipt of a patent application or six (6) months of receipt of an invention report notification of such a section A invention. In the event that Collaborator fails to so notify Institution, or elects not to obtain an exclusive license, then Collaborator's option expires with respect to that Section A Invention, and Institution will be free to dispose of its interests in accordance with its policies. If Institution and Collaborator fail to reach agreement within ninety (90) days, (or such additional period as Collaborator and Institution may agree) on the terms for an exclusive license for a particular Section A Invention, then for a period of three (3) months thereafter Institution agrees not to offer to license the Section A Invention to any third party on materially better terms than those last offered to Collaborator without first offering such terms to Collaborator, in which case Collaborator will have a period of thirty (30) days in which to accept or reject the offer. If Collaborator elects to negotiate an exclusive commercial license to a Section A Invention, then Institution agrees to file and prosecute patent application(s) diligently and in a timely manner and to give Collaborator an opportunity to comment on the preparation and filing of any such patent application(s). Notwithstanding the above, Institution is under no obligation to file or maintain patent prosecution for any Section A Invention.

For all Section A Inventions, regardless of Collaborator's decision to seek a commercial license, Institution agrees to grant Collaborator a paid-up, nonexclusive, royalty-free, world-wide license for research purposes only. Institution retains the right to make and use any Section A Invention for all non-profit research, including for educational purposes and to permit other educational and non-profit institutions to do so.

B. The IP Option described in this Section B would apply to inventions not covered by Section A, but are nevertheless conceived or first actually reduced to practice pursuant to clinical or non-clinical studies utilizing the CTEP-provided Agent(s). It also applies to inventions that are conceived or first actually reduced to practice pursuant to NCI CTEP-approved studies that use non-publicly available clinical data or specimens from patients treated with the CTEP-provided Agent (including specimens obtained from NCI CTEP-funded tissue banks) ("Section B Inventions"):

Institution agrees to grant to Collaborator(s): (i) a paid-up nonexclusive, nontransferable, royalty-free, world-wide license to all Section B Inventions for research purposes only; and (ii) a nonexclusive, royalty-free, world-wide license to (a.) disclose Section B Inventions to a regulatory authority when seeking marketing authorization of the Agent, and (b.) disclose Section B Inventions on a product insert or other promotional material regarding the Agent after having obtained marketing authorization from a regulatory authority. Notwithstanding the above, Institution is under no obligation to file or maintain patent prosecution for any Section B Invention.

C. The IP Option described in this Section C would apply to inventions made by Institution's investigator(s) or any other employees or agents of Institution, which are or may be patentable or otherwise protectable, as a result of research utilizing the CTEP-provided Agent(s), unreleased or non-publicly available clinical data or Agent treated specimens outside the scope of approval granted by the NCI CTEP (Unauthorized Inventions):

Institution agrees, at Collaborator's request and expense, to grant to Collaborator a royalty-free exclusive or co-exclusive license to Unauthorized Inventions. Institution will retain a non-exclusive, non-sub-licensable royalty free license to practice the invention for research use purposes.

D. Institution Notification

Institution agrees to promptly and confidentially notify NCI CTEP (*NCICTEPpubs@mail.nih.gov*) and Collaborator(s) in writing of any Section A Inventions, Section B Inventions, and Unauthorized Inventions upon the earlier of: (i) Any submission of any invention disclosure to Institution of a Section A, Section B, or Unauthorized Invention, or (ii) the filing of any patent applications of a Section A, Section B, or Unauthorized Invention. Institution agrees to provide a copy of either the invention disclosure or the patent application to the Collaborator and to NCI CTEP which will treat it in accordance with 37 CFR Part 401. These requirements do not replace any applicable reporting requirements under the Bayh-Dole Act, 35 U.S.C. 200–212, and implementing regulations at 37 CFR part 401.

V. Conclusion

NCI and NIH would like to offer our thanks to all respondents for their articulate and well thought out comments, and their willingness to participate in this process.

Dated: March 8, 2011.

Jeffrey Abrams,

Associate Director, Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute.

[FR Doc. 2011–5609 Filed 3–10–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: "Pilot Test of the Proposed Pharmacy Survey on Patient Safety Culture." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, A1–IRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by May 10, 2011.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by e-mail at *doris.lefkowitz@AHRQ.hhs.gov.*

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by e-mail at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Pilot Test of the Proposed Pharmacy Survey on Patient Safety Culture

As the baby boomer population ages, the general U.S. population continues to grow, and as drug therapies for the treatment of chronic diseases become more efficacious, the expected increase in the number of prescriptions and demand for pharmaceutical products is likely to increase the potential for medication errors in community/retail pharmacies. In 2007, there were about 56,000 community/retail pharmacies, including about 22,000 traditional chain pharmacy companies, nearly 17,000 independent drug stores, about 9,300 supermarket pharmacies, and about 7,700 mass merchant pharmacies. Numerous reports substantiate the presence of medication errors in pharmacies. For example, one national observational study of prescription dispensing accuracy and safety in 50 pharmacies in the U.S. found a rate of about 4 errors per day in a pharmacy filling 250 prescriptions daily. This error rate translates to an estimated 51.5 million errors occurring during the filling of 3 billion prescriptions each year.

Given the widespread impact of pharmacies on patient safety, the new Pharmacy Survey on Patient Safety Culture (Pharmacy SOPS) will measure pharmacy staff perceptions about what is important in their organization and what attitudes and behaviors related to patient safety are supported, rewarded, and expected. The survey will help community/retail pharmacies to identify and discuss strengths and weaknesses of patient safety culture within their individual pharmacies. They can then use that knowledge to develop appropriate action plans to improve their practices and their culture of patient safety. This survey is designed for use in community/retail pharmacies, which includes chain drugstores (*e.g.,* Walgreens and CVS), supermarket pharmacies, independently owned pharmacies, and mass merchant pharmacies (*e.g.,* Wal-Mart, Costco, Target), not for use in hospital pharmacies.

This research has the following goals:

(1) Cognitively test and modify as necessary the Pharmacy Survey on Patient Safety Culture Questionnaire;

(2) Pretest and modify the questionnaire as necessary;

(3) Make the final questionnaire available to the public.

This study is being conducted by AHRQ through its contractor, Westat, pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of healthcare services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

Method of Collection

To achieve the goals of this study the following activities and data collections will be implemented:

(1) *Cognitive interviews*—Two rounds of interviews will be conducted by telephone with 10 respondents each. The purpose of these interviews is to refine the questionnaire's items and composites. Each round will be conducted with a mix of pharmacists and non-pharmacist staff working in community/retail pharmacies throughout the U.S. The same interview guide will be used for each round.

(2) *Pretest*—The draft questionnaire will be pretested with all pharmacy staff in approximately 60 community/retail pharmacies. The purpose of the pretest is to collect data for an assessment of the reliability and construct validity of the survey's items and composites, allowing for their further refinement.

(3) *Pharmacy background questionnaire*—This questionnaire will be completed by the pharmacy manager in each of the 60 pretest sites to provide background characteristics of the pharmacy, such as pharmacy type (independently owned or chain), type of chain (traditional drugstore, supermarkets, mass merchant), average number of prescriptions filled weekly, average number of hours the pharmacy is open on weekdays, *etc.*

(4) *Dissemination activities*—The final questionnaire will be made available to the public through the AHRQ Web site. This activity does not impose a burden on the public and is therefore not included in the burden estimates in Exhibit 1.

The information collected will be used to test and improve the draft survey items in the Pharmacy Survey on Patient Safety Culture Questionnaire. Psychometric analysis will be conducted on the pilot data to examine item nonresponse, item response variability, factor structure, reliability, and construct validity of the items included in the survey. Because the survey items are being developed to measure specific aspects of patient safety culture in the pharmacy setting, the factor structure of the survey items will be evaluated through multilevel confirmatory factor analysis. On the basis of the data analyses, items or factors may be dropped.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the pharmacies' time to participate in this research. Cognitive interviews will be conducted with staff at 20 pharmacies (approximately 10 pharmacists and 10 nonpharmacist staff) and will take about one hour and 30 minutes to complete. 627 staff from 60 pharmacies will participate in the pretest (an average of 10.45 staff from each pharmacy). The pretest questionnaire (the Pharmacy Survey on Patient Safety Culture)