Supporting Statement A For:

National Cancer Institute (NCI) Cancer Nanotechnology Platform Partnership Scientific Progress Reports

June, 2013

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LIST OF ATTACHMENTS

Attachment 1: Proposed information collection instrument "Cancer Nanotechnology Platform Partnerships (CNPP; U01) Guidelines for CNPP Annual and Interim Reports"

Attachment 2: Privacy Act Memo

The National Institutes of Health grantees are required to submit interim and final progress reports and other post-award documents associated with the monitoring, oversight, and closeout of an award.   This submission represents a request for OMB to approve new program specific progress report guidelines for Cancer Nanotechnology Platform Partnerships (CNPP) awarded by the National Cancer Institute (NCI). The CNPPs are part of the Alliance for Nanotechnology in Cancer, a network of awards funded by NCI to promote the application of nanotechnology to cancer research and care. The proposed guidelines request information about award performance related to trans-Alliance collaboration, scientific milestones, progress towards clinical translation and technology commercialization, and education and outreach efforts. The Alliance supports a Nanotechnology Characterization Laboratory and a public database of nanomaterials (caNanoLab) that members are expected to utilize as necessary; these activities are reported through the proposed guidelines. The report also gathers information on leveraged funding, patents and publications. The information is gathered every six months. This information is needed to monitor the performance of this special program within NCI, funded through Requests for Applications (RFA CA-09-013, released May 29, 2009) using the cooperative agreement mechanism (U01). The information will be used to monitor individual award performance and the effectiveness of the program as a whole. The respondents are the Principal Investigators of the awards, along with their institutional business officials. The awards are administered by and the reports reviewed by the Office of Cancer Nanotechnology Research (OCNR), part of the Center for Strategic Scientific Initiatives within NCI.

A.   JUSTIFICATION

A.1   Circumstances Making the Collection of Information Necessary

The Cancer Nanotechnology Platform Partnerships (CNPP) are part of the National

Cancer Institute's (NCI) Alliance for Nanotechnology in Cancer. The Alliance is a network of

awards established to promote the development of nanotechnology for the study and treatment of

cancer by supporting multi-disciplinary research focused on cancer biology, diagnosis and

therapy. The network has a unique focus on the clinical translation and commercialization of

new technologies, and a goal to increase awareness of and use of nanotechnology to solve

problems in cancer care. Within the Alliance, the CNPPs are expected to address major barriers

and/or fundamental questions in cancer using innovative nanotechnology solutions, populating

the early stages of a cancer nanotechnology clinical development pipeline. The CNPP awards

were made in response to Request for Funding Applications (RFA) CA-09-013 and are expected

to take advantage of Alliance infrastructure and collaborate with Alliance funded Centers of Cancer Nanotechnology Excellence (CCNEs). Each CNPP award includes funds restricted for use on trans-Alliance "Challenge Projects." Additional collaboration with Alliance training and career development awards, including participation in workshops and seminar series, is encouraged, and CNPP investigators are invited to participate in thematic scientific working groups coordinated by the Alliance program office. The Alliance also supports the Nanotechnology Characterization Laboratory (NCL), which supports the preclinical characterization of nanomaterials intended for use as cancer therapeutics or diagnostic agents, and caNanoLab, a database of nanomaterials developed for biomedical applications. Alliance members, including CNPP investigators, are encouraged to use these resources. In keeping with the Alliance emphasis on outcomes and translation, each CNPP has a set of timed milestones in addition to specific aims that they are responsible for meeting. Progress in these areas (collaboration, education, outreach, clinical translation and commercialization), in addition to scientific achievement as measured by progress towards specific aims, is monitored through the use of program specific progress report guidelines.

NCI typically approves research awards for five years, including budgets and research specific aims for all five years. However, funds are dispensed to awardees on a yearly basis, following programmatic and administrative review and approval of annual progress reports submitted by awardees. NIH uses PHS 2590 form for progress reports and now has transitioned to the Research Performance Progress Report (RPPR) (OMB No. 0925-0002, Expiration Date 8/31/2015). The Cancer Nanotechnology Platform Partnerships (CNPPs, U01 mechanism) were not awarded through the Streamlined Non-Competing Awards Process and therefore continue to use PHS 2590 for yearly reporting. Additionally, the CNPP program requires progress reports to

be filed every six months, and the RPPR system does not currently support reporting filed with frequency greater than once a year. This necessitates the use of the attached program specific progress report guideline to collect information on award performance, including the program specific information outlined above.

The PHS 2590 form requests detailed budget and budget justification information, personnel reports, and a Progress Report Summary (Form Page 5). A complete Form Page 5 includes information on:

A. Specific Aims

B. Studies and Results

C. Significance

D. Plans

E. Publications

F. Project-Generated Resources

The "Cancer Nanotechnology Platform Partnerships (CNPP; U01) Guidelines for CNPP Annual and Interim Reports" report takes the place of A-D of the Progress Report Summary (Form Page 5) of the PHS 2590 annual report. For annual reports, all other components of the PHS 2590 are filed in accordance with the instructions and guidelines available at http://grants.nih.gov/grants/funding/2590/2590.htm. The report outlined in the attached guideline contains all the information gathered during the mid-year report; that is, no budget or personnel information is requested for the mid-year report. The mid-year report allows program staff to track the scientific progress of individual awards and the strength of the larger collaborative network the CNPPs are part of.

Alliance awards, including CNPPs, are made through the RFA mechanism, meaning they are funded by set-aside funds that are separate from the general pool of research program grant (RPG) funds used to support investigator initiated research at NIH. The use of the set-aside indicates that the area is a programmatic priority for NCI/NIH and reflects programmatic interest beyond that for a typical RPG award, as does the use of U01 NIH cooperative agreement activity code. The Alliance is overseen by the Office of Cancer Nanotechnology Research within the Center for Strategic Scientific Initiatives in the Office of the Director, NCI. Program staff in this office review Alliance progress reports.

Section 410 of the Public Health Service Act (42 USC § 285), authorizes collection of this information, as outlined in Special Authorities of the Director – Sec. 413. [285a-2]. Section 413 authorizes the NCI Director to collect and disseminate (including through publications) to clinicians and the general public information on cancer research, diagnosis, prevention and treatment.

Monitoring progress and network activity is necessary to ensure that awardees are on track to reach program goals and that the intent and requirements of the RFA are being met. Evidence that program goals aren't being met (e.g., missed milestones or a lack of trans-Alliance collaboration) are used by program staff to open discussions with investigators on how to adjust their research or collaboration plans to improve performance in these areas. Reporting every six months allows these adjustments to be made quickly enough to prevent serious shortcomings. Strong performance by awardees is used to inform best practices and identify areas that could benefit from shared activities. Close scientific engagement with awardees is a feature of cooperative agreements and enables program staff to identify research areas or issues of shared difficulty or high potential reward. Program staff can then organize discussions or projects to

confront or exploit these areas, through the Alliance working groups or other program activities. Up-to-date knowledge of difficulties in the development of cancer nanotechnology based diagnostic and therapeutic agents is also crucial to fulfilling the programmatic goal of accelerating translation of these new technologies to clinical application.

The information collected in the progress report guideline can also be used for program evaluation and performance analysis. Although no formal evaluation components currently exist, program performance, including success of the network model and progress on clinical translation and technology commercialization, will be assessed prior to the end of the program, as part of institute deliberations on the continuation of the special set-aside for the CNPPs.

A.2   Purpose and Use of the Information

The current proposal is for the collection of information to monitor progress by investigators funded through the NCI's Alliance for Nanotechnology in Cancer CNPP program. Each report will be prepared by the principal investigator of the CNPP award. The report consists of information already known to the investigator, which has not previously been gathered and submitted to the program office or made public. Much of the information is specific to the requirements of this program (e.g., progress on milestones, Challenge projects, submissions to NCL and caNanoLab).

 Information to be collected:

- Key achievements

- Project summary – narrative entailing progress towards specific aims during reporting period, development of new collaborations within and outside the Alliance, indications of meeting milestones or failure to meet them, anticipated changes in milestones, plans for following six months and any red flags towards meeting project goals.

- Challenge Projects – narrative entailing progress on Challenge projects and plans for following six months

- Evidence of Community Building and Interaction Within the Alliance – list of new collaborations (within and outside the Alliance), Challenge projects associated with CNPP, lists of data submissions to caNanoLab and materials submissions to NCL

- Progress Towards Clinical Translation – narrative describing progress

- Progress Towards Technology Transfer and Commercialization – narrative describing progress

- Education/Training Activities – narrative or list of activities

- New Funding Opportunities Which Leveraged CNPP Work – list of funding opportunities

- Publications and Patents – list of publications and patents

Review and Use of Submitted Information

The currently proposed progress report guidelines are intended to monitor performance in those areas that the NCI program office considers to be of greatest importance in building and sustaining a successful network of awards and for successful clinical translation. Comparing responses to these reports to other measures of performance will provide some indication of the value of these components. For example, the program office encourages awardees to use the Nanotechnology Characterization Laboratory (NCL) for preclinical studies of the nanomaterials they develop, along with using the caNanoLab database to deposit the results of studies. Over time, by comparing the reported use of these resources with actual progress in clinical translation, the program office will gain better understanding of the value of these resources to investigators. The reports will also help us understand how investigators use these resources, so that we can better design programs around these resources in the future. Similarly, investigator experiences with the trans-Alliance Challenge projects (e.g., the ease with which they were able to form collaborations to pursue these projects, the strength of research results from these projects) will provide important information on ways the program office can most effectively

encourage collaboration between awards. Promotion of successful collaboration is a particular priority for multi-disciplinary research programs. In addition, program staff maintains a database of publications gathered from reports; this publication database can be compared to publication reports returned from public databases such as PubMed to gauge compliance with NIH public access policies. This curated publication and patent data can also be used as input for program evaluation studies.

Progress reports are reviewed by Alliance program staff. Once they have reviewed the reports, program staff contacts investigators with questions or comments regarding scientific details or programmatic matters. Examples include asking investigators about a change in proposed drug to be encapsulated in a nanoparticle vehicle, providing help to an investigator in identifying and contacting potential collaborators on Alliance Challenge projects and having discussions on amendments to specific aims or milestones in response to unexpected scientific developments or difficulties in performing experiments. These interactions between program staff and investigators also allow investigators to better leverage the shared body of knowledge existing in the Alliance network. For example, reported difficulties in performing experiments related to hyperthermia treatments of cancer in one of the Alliance Center grants led to a teleconference between members of the Alliance working in this area. The discussion led to another Alliance investigator sharing materials and performing experiments with the center.

A.3   Use of Improved Information Technology and Burden Reduction

The interim reports are PDF'd by the principal investigators then sent, via e-mail, to the program office for review and eventual submission to NIH E-grants for electronic entry. In keeping with NIH guidelines for non-SNAP awards, the annual report filed in June will be part of the paper PHS 2590 submission (OMB No. 0925-0002, Expiration Date: 08/31/2015); the

PDF of the report will be included as an attachment to the PHS 2590. As mentioned in Section A.1, the fully automated RPPR system for report filing is not yet available for use with twice yearly reports filed by non-SNAP awards. The proposed guidelines for the report will be posted on the Alliance website, allowing investigators easy access to the guidelines as they prepare their report. No automated or dedicated IT system will be used for these reports.

The NCI Privacy Act Coordinator has been consulted and has determined that since there is no IT system for the report, a Privacy Impact Assessment (PIA) is not needed.

A.4   Efforts to Identify Duplication and Use of Similar Information

Typically NIH awardees file progress reports only once a year. The interim report proposed here will not duplicate any existing information collection, since this collection doesn't occur now. For the annual report, the proposed guidelines take the place of and provide greater detail for one section of the PHS 2590. This section, the Progress Report Summary (Form Page 5), is for collection of scientific progress information. This information will be included in the proposed guidelines, along with additional information specific to the Alliance program (e.g. Challenge project participation) that is otherwise not collected; this information is not publicly available and cannot be gathered from other sources. The program office has consulted the PHS 2590 and the PRA liaison office at NIH, and the information to be gathered through the proposed guidelines is not collected in existing reports and cannot be collected in a twice-yearly basis using the currently existing NIH reporting tools.

A.5   Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this information collection.

A.6   Consequences of Collecting the Information Less Frequently

The proposed information collection will occur twice a year. Information is collected on that time table to allow the program office to monitor and adequately manage performance in individual awards and interactions between awards. In particular, these awards include milestones in addition to specific aims, and progress towards milestones is monitored closely. In the absence of the information provided by the reports, the program office will not be able to judge progress towards milestones or assist in overcoming difficulties in meeting them. Inability to collect this information will also hamper the program office's ability to maintain a functional network of awards that strongly promote the development and translation of cancer nanotechnology. This includes monitoring collaborations and assisting investigators in identifying potential collaborative project topics and partners and assisting investigators in submission of materials to NCL and caNanoLab.

A.7   Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

None of the special circumstances relating to the guidelines of 5 CFR 1320.5 apply to this information collection, and the proposed guidelines fully comply with 5 CFR 1320.5.

A.8   **Comments in Response to the Federal Register Notice and Efforts to Consult**
Outside the Agency

The 60-Day <u>Federal</u> <u>Register</u> notice soliciting comments on this project prior to initial submission to OMB was published on May 13, 2013, Vol. 78, P. 27974. No public comments were received.

There have been no efforts to consult outside the agency.

A.9   Explanation of Any Payment or Gift to Respondents

There will be no payments or gifts to respondents.

A.10   Assurance of Confidentiality Provided to Respondents

Personally identifiable information will be collected. Information related to awardees' scientific progress, interactions with other awardees or for-profit partners, and success in leveraging their awards to raise additional funds will be included in the report. Information will be collected by and seen only by members of the program office and the NCI Office of Grants Administration. Information in reports will not be shared with anyone outside of NIH, and physical copies of reports will be kept in NIH secured storage areas. Electronic files will be kept on password protected government computers, secure NCI servers and on the NIH's secure grants database system. The data collection is covered by NIH Privacy Act Systems of Record Notice (SORN) #09-25-0036, "Extramural Awards and Chartered Advisory Committees (IMPAC 2), Contract Information (DCIS), and Cooperative Agreement Information, HHS/NIH" (**Attachment 2**). This SORN was published in Federal Register on 9/26/2002, Vol. 67, p. 60742.

A.11   Justification for Sensitive Questions

Personally identifiable information will be collected in the form of key achievements, education and training activities, publications and patents. However, there are no sensitive questions included in the proposed guidelines.

A.12   Estimates of Annualized Burden Hours and Costs

The three hour per report estimate includes time to gather information, most of which should already exist (e.g., publication lists kept by investigators for their CVs) but some of which may be collected from other members of their labs (e.g., images for the scientific narrative section). The estimate is based on the time necessary to create the three page narrative project and challenge project summaries (Items 2 and 3 of proposed guidelines) and to format the

responses to Items 4-8, (Item 4 consists of two lists, Items 5-8 are brief narratives). In many cases, we expect the time to prepare to be significantly shorter, since similar narratives will be prepared by the investigators for grant applications, research group homepages and internal reports, but the estimates given should be sufficient even for a report that does not copy narrative from other sources. The annualized estimate of respondent burden is 72 hours to complete the report twice a year for 12 respondents (Table A.12-1). This amounts to a total of 216 hours over three years of information collection.

The annualized cost to the respondents is $3,240, using an estimated value of the principal investigators' time of $45/hr, which amounts to a total of $9,720 over three years (Table A.12-2).

A.12 - 1 Estimates of Annual Burden Hours				
Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Time per Response (in hours)	Total Annual Burden Hours
Principal Investigators	12	2	3	72
Total				72

A.12 - 2 Annualized Cost to Respondents				
Type of Respondents	Number of Respondents	Total Annual Burden Hours	Hourly Wage Rate	Total Annual Respondent Cost
Principal Investigators	12	72	$45.00	$3,240.00
Total				$3,240.00

A.13   Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no direct costs to respondents other than their time to participate.

A.14 Annualized Cost to the Federal Government

The cost of this information collection to the federal government arises entirely from the labor of program staff spent on the development of the guidelines and then on the review of the reports. Review includes time spent reading the report, following up on information contained in the report (e.g., additional literature searches) and possible follow up contact with investigators regarding red flags, collaborations or materials submission described in the report. Although data from the reports will be used in program evaluations, program evaluation will occur whether or not this information is collected, and use of the reports in evaluation studies will not result in additional costs to the government. In fact, the collation of information in reports will decrease the cost of gathering data for use in evaluations. There will be a small amount of additional labor arising from curation of the report data into databases (e.g., publications, patents, NCL submissions) for use by program staff to monitor and evaluate program activities and the addition of the reports to the internal NCI database of grant information (i.e., eGrants).

We estimate that all work on the review and storage of reports submitted in response to the proposed guidelines will require the effort of 0.06 FTE, spread over 5-6 program officials and a corresponding number of grants management specialists in NCI's Office of Grants Administration. The bulk of this effort will be by the program officials, at a GS12 level or above, so that this data collection will result in an estimated cost of $6,000/year for each of the three years we expect to gather the information.

Table 14-1 Annual Cost to the Federal Government		
	TOTAL	**ANNUAL AVERAGE**
NCI Personnel	$18,000	$6,000.00
Grand Total	$18,000	$6,000.00

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A.15   Explanation for Program Changes or Adjustments

This is a new information collection.

A.16   Plans for Tabulation and Publication and Project Time Schedule

Statistical analysis is not planned for the information collected in these reports. Since the primary purpose of this information collection is program monitoring and evaluation, data from these reports will not be used for publications. Statistical analysis of award publications will be done using information from the publicly available PubMed database, for the purpose of clean comparison to other awards and programs that will not use the proposed guidelines. Information from the reports will be used to judge the quality of the publicly available data, which may be used in publications based on network analysis of the Alliance.

Information on collaborations, network activity, leveraged funding, educational efforts, etc. will be tabulated for use in program evaluations. Informal review of the information will be done after each information collection, to monitor program progress in real time, with a formal program evaluation planned during the year following initial collection of the data. The small size of the dataset for this information precludes statistical analysis of these data. However, the information will inform design of possible surveys for use in the evaluation and will be analyzed qualitatively to compare program outcomes with goals. Network maps of Alliance collaborations (e.g. Challenge projects) will be made, although the size of the dataset precludes statistical analysis of the maps. The maps will be studied as a measure of collaborative activity and to look

for trends in collaboration, such as CNPP interaction with other CNPPs vs. CNPP interaction

with center awards. Most analysis will be simple counting, such as number of materials

submitted to NCL, number of separate information submissions to caNanoLab, number of

CNPP-CNPP Challenge projects, etc...

The annual report is filed in June and then the interim report in December. The project

time schedule (Table A.16-1) represents a 6-month time frame and then is repeated every 6

months.

Table A.16-1 Project Time Schedule				
	Months after OMB approval			
	Month 1	Month 2	Months 2-3	Months 4-6
Contact providers	██			
Obtain responses from providers		██		
Program review of responses		██	██	
Tabulation and analysis of responses			██	██
Summarize results				██

A.17   Reason(s) Display of OMB Expiration Date is Inappropriate

We are not seeking approval to not display the expiration date for OMB approval of the

information collection.

A.18   Exceptions to Certification for Paperwork Reduction Act Submissions

The proposed guidelines for program specific progress reports for NCI CNPP U01

reports do not require any exceptions to the Certification for Paperwork Reduction Act

Submissions (5 CFR 1320.9)