Supporting Statement A for

Application for Collaboration with the Therapeutic Development Branch (TDB), Division of Preclinical Innovation (DPI), National Center for Advancing Translational Sciences (NCATS)

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0925-0658, Expiration Date 06/30/2015--EXTENSION

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Abstract

This is an extension of a currently approved information collection request. The mission of the National Center for Advancing Translational Sciences (NCATS) is to translate fundamental research into patient treatments by establishing creative partnerships and developing innovative approaches to advance the science of drug discovery and development. The Therapeutic Development Branch (TDB) (1) is an intramural organization, and (2) solicits collaborators in the NIH-novel area of preclinical drug development. The TDB will use the data collected to determine the suitability of Principal Investigators / Research Scientists (applicants) for collaboration with TDB staff and programs.

A.1 Circumstances Making the Collection of Information Necessary

The mission of the National Center for Advancing Translational Sciences (NCATS) is to translate fundamental research into patient treatments by establishing creative partnerships and developing innovative approaches to advance the science of drug discovery and development. The Therapeutic Development Branch (TDB) (1) is an intramural organization, and (2) solicits collaborators in the NIH-novel area of preclinical drug development.

The legal authorities under which the information is requested include: Public Health Service Act, TITLE 42, CHAPTER 6A, SUBCHAPTER III, Part E, Subpart 1, § 287, National Center for Advancing Translational Sciences.

A.2 Purpose and Use of the Information Collection

TDB will use the data collected to determine the suitability of the Principal Investigators / Research Scientists (applicants) for collaboration with TDB staff and programs. As the program is resource limited, TDB must select which Principal Investigators / Research Scientists (applicants) offer the best potential for a program to reach the clinic or the patient population. The application forms provide the specific information so that staff and reviewers can evaluate the applicants' projects. Under the Therapeutics for Rare and Neglected Diseases (TRND) program, successful applicants perform collaborative research with intramural NIH drug development scientists. Under the Bridging Interventional Development Gaps (BrIDGs) program, successful applicants receive access to specific critical resources necessary for the development of therapeutic agents. Applicants would apply to either TRND or BrIDGs, depending upon the resources and scope of assistance needed to advance their particular project. Since 2012, this data collection has enabled the TDB to evaluate approximately 250 proposals, resulting in selection and implementation of 20 highly-meritorious collaborative research and development projects addressing significant unmet medical needs.

A.3 Use of Information Technology and Burden Reduction

The TDB forms are electronic, and are unique to these programs. The online submission ensures no copying or mailing are needed. All correspondence with applicants is managed electronically as well, reducing burden and increasing efficiency of communication. A Privacy Impact Assessment has been completed for this request.

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

The TDB is a unique program, which currently collects data through the use of these approved, specialized electronic forms. Due to the nature of the drug development projects TDB seeks for partnership, similar information does not exist elsewhere. There will be no unnecessary duplication of information.

A.5 Impact on Small Businesses or Other Small Entities

TDB programs accept collaboration applications from many partners, including small businesses and other small entities. The design of the TDB form specifically limits data collection to the minimum necessary to make a decision.

A.6 Consequences of Collecting the Information Less Frequently

Research and development projects in the public and private sector are continually progressing towards stages where they are appropriate for access to TDB resources as part of a collaboration. Currently, TDB is able to undertake annual solicitations for new collaborative partners. This frequency allows TDB programs to offer partners the ability to collaborate and move their projects forward, without an undue waiting period. If this information collection were not conducted, TDB would be unable to assess which potential collaborative projects offer the best potential for a program to reach the clinic or the patient population, and TDB would fail to fulfill its mission of forming novel partnerships that leverage basic research in support of translational science for the benefit of human health.

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

There are no special circumstances that require collection of information inconsistent with these guidelines. The project forms fully comply with 5 CFR 1320.5.

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

A 60-Day notice for public comment was published in the *Federal Register* (Vol. 79, No. 225, Pg. 69499) on November 21, 2014. No public comments were received.

The NCATS Therapeutics for Rare and Neglected Diseases Trans-NIH Advisory Group (TAG) was consulted, and has been actively in discussion since the conception of the program. The role of the TAG (Attach 6) is as follows:

- Provide insight and advice on scientific and programmatic issues related to drug discovery and development
- Identify areas and projects of common interest for leveraging and prevention of duplication
- Help assess potential projects
- Help program implementation by providing contacts, identifying collaborators
- Receive information and updates from TDB management

A.9 Explanation of Any Payment of Gift to Respondents

This information collection does not provide any payment or gift to respondents.

A.10 Assurance of Confidentiality Provided to Respondents

The NIH Privacy Officer has reviewed the NCATS submission to OMB, which proposes to determine the suitability of Principal Investigators / Research Scientists for collaboration with TDB staff and programs to advance the science of drug discovery (Attach 8).

The Privacy Act will apply to this data collection which involves the collection of personally identifiable information (PII) in the form of client and applicant name, company affiliation, scientific role, e-mail address, phone number, biological/disease expertise, intellectual property (patents issued/pending), bio-sketches, and the actual proposal. This information is needed to contact successful applicants. Selected applications and award data and files will be sent to designated sponsors (e.g., small businesses, entities and partners from the government, non-profit and private grant-making organizations).

The proposals will be collected from applicants and stored in an electronic application, review, and extramural award management system developed under contract by Altum, Inc. The system, called proposalCENTRAL, is a database and e-grantmaking website designed for the benefit of clients (e.g., grantors, grant applicants, and proposal reviewers) to partner drug development scientists with collaborators on therapeutics for rare and neglected diseases. The proposals of the clients, applicants, and awardees will be tracked in the system by ID #. Grant application, review, and award data is maintained on the Altum network and stored in separate databases for each client. Clients will have access to data relevant to the proposals submitted by the client as well as access to applicant profiles relevant to the proposals submitted to the client. A copy of Altum's security FAQ is located in the attachments (Attach 7).

A.11 Justification for Sensitive Questions

This data collection is covered by NIH Privacy Act Systems of Record 09-25-0036, "Extramural Awards and Chartered Advisory Committees (IMPAC 2), Contract Information (DCIS), and Cooperative Agreement Information, HHS/NIH" (http://oma.od.nih.gov/ms/privacy/pa-files/0036.htm).

There are no sensitive questions included in this collection effort. TDB requests only name and contact information so that successful applicants may be contacted.

A.12 Estimates of Hour Burden Including Annualized Hourly Costs

12-1. In-house testing was performed by TDB staff to determine the average time required for completing the proposed solicitation. The results of this test indicate an estimated public reporting burden for this collection of information as an average 1 hour per response form. This includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The respondents for all of the surveys are Principal Investigators and Research Scientists.

A.12-1 - Estimates of Hour Burden

Forms	Number of Respondents	Number of Responses per Respondent	Average Burden Hours Per Response	Total Annual Burden Hours
TDB Project Information Template	170	1	1	170
Online Collaborator Solicitation (TRND)	100	1	1	100
Online Collaborator Solicitation (BrIDGs)	70	1	1	70
Solicitation Instructions (TRND)	100	1	1	100
Solicitation Instructions (BrIDGs)	70	1	1	70
Total				510

12-2. The mean hourly wage rate for Medical Scientists (OES code 19-1042) is estimated as $43.38, obtained from the May 2013 Department of Labor Occupational Employment Statistics program (http://www.bls.gov/oes/current/oes191042.htm). The annualized cost burden based on the respondents' time to complete the submission process is estimated to be $22,125.

A.12-2 - Annualized Cost to Respondents

Forms	Total Annual Burden Hours	Hourly Wage Rate	Total Annual Response Cost
TDB Project Information Template	170	$43.38	$7,375

Online Collaborator Solicitation (TRND)	100	$43.38	$4,338
Online Collaborator Solicitation (BrIDGs)	70	$43.38	$3,037
Solicitation Instructions (TRND)	100	$43.38	$4,338
Solicitation Instructions (BrIDGs)	70	$43.38	$3,037
TOTAL			$22,125

A.13 Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no additional costs other than the respondent's time.

A.14 Annualized Cost to the Federal Government

This data collection is estimated to cost the Federal Government $24,890 annualized.

A.14 - Annualized Cost to the Federal Government	
	Total Cost
Annual Cost for Use of Altum / proposalCENTRAL System	$15,000
NCATS Project Manager, GS 13-4 (10% effort)	$9,890
TOTAL	$24,890

A.15 Explanation for Program Changes or Adjustments

This is an ongoing collection of information, already in OMB's inventory of approved projects. There are no program changes or adjustments to the annual burden on respondents.

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

TDB application data is collected for internal review only. There are no plans for publication of any statistical analyses based on the information collected and applications are not published.

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

The expiration date for OMB approval will be displayed.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to the certification are requested.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

This collection does not employ statistical methods.