



Applying for NIH Grants by Non-US Organisations – Lessons Learnt

23rd Annual EARMA Conference Malta, April 24th-26th 2017

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Research & Innovation Management

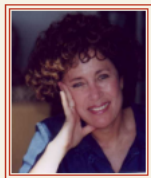
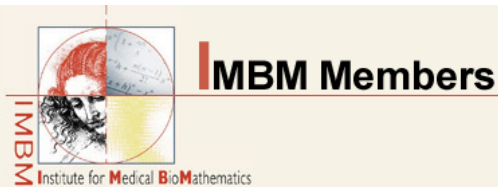
- Eligibility
- Registration
- Submission
- Main points and lessons learnt
- By this way
 - Differences between NIH to EU (H2020)
- The project was done in collaboration with Dr. Joana Rosario from US. We planned to submit this session together. She was responsible for the scientific part of this proposal.

- A Grant is a grant is a grant?
- Yes, but....
 - Similarities in the rules
 - Systems are different
 - Implementation is (very) different



EU is “closing gaps” with the US

- A word on our customer:
 - Institute for Medical BioMathematics (IMBM)
 - Private (non-profit) research institute, established in Israel
 - Mission: analytical and computational approaches for optimising the treatment of cancer and infectious diseases



Prof. Zvia Agur – President

Professor Zvia Agur is an eminent international biomathematician, who has made major contributions to the theory of disease dynamics, chemotherapy and vaccination policies optimization. Prof. Agur is founder of the Institute for Medical BioMathematics (IMBM), has been the president of the Israeli Society of Theoretical and Mathematical Biology, a member of the Board of Directors of the European Society of Mathematical and Theoretical Biology, and an editor of several professional publications. Her innovative research work has won national awards, has been published in a long line of leading scientific journals and is recognized by the academic community worldwide. Prof. Agur holds a Ph.D. from the Hebrew University in Jerusalem and the Université Libre in Brussels.

[Scientific Activities](#) [Complete List of publications](#)



The Institute for Medical BioMathematics (IMBM) is an independent research institute, acting where the most advanced science can take traditional medicine a big step forward. This is done by using analytical and computational approaches as a basis for optimizing the treatment of cancer and infectious diseases.

10 Hate'ena St., P.O.B. 282, Bene Ataroth 60991, Israel. Tel: 972-3-9734068 / 9733075 Fax: 972-3-9733410
E-mail: office@imbm.org

- Program: NIH
- Funding Opportunity Announcement (FOA)
- PA (Program Announcement), PAR/PAS

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The “Bible”
Cross-ref & linked

- Check:

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	National Cancer Institute (NCI)
Funding Opportunity Title	Development of Innovative Informatics Methods and Algorithms for Cancer Research and Management (R21)



- Check:

Activity Code	R21 Exploratory/Developmental Research Grant
Announcement Type	New
Related Notices	<ul style="list-style-type: none">• NOT-OD-16-004 - NIH & AHRQ Announce Upcoming Changes to Policies, Instructions and Forms for 2016 Grant Applications (November 18, 2015)• NOT-OD-16-006 - Simplification of the Vertebrate Animals Section of NIH Grant Applications and Contract Proposals (November 18, 2015)• NOT-OD-16-011 - Implementing Rigor and Transparency in NIH & AHRQ Research Grant Applications (November 18, 2015)
Funding Opportunity Announcement (FOA) Number	PAR-15-334
Companion Funding Opportunity	PAR-15-332, U01 Research Projects – Cooperative Agreements PAR-15-333, U24 Resource-Related Research Projects – Cooperative Agreements PAR-15-331, U24 Resource-Related Research Projects – Cooperative Agreements
Number of Applications	See Section III. 3. Additional Information on Eligibility .



- Check:

Funding Opportunity Purpose



The purpose of this Funding Opportunity Announcement (FOA) is to invite exploratory/developmental research grant (R21) applications for the development of innovative methods and algorithms in biomedical computing, informatics, and data science addressing priority needs across the cancer research continuum, including cancer biology, cancer treatment and diagnosis, cancer prevention, cancer control and epidemiology, and/or cancer health disparities. As a component of the NCI's Informatics Technology for Cancer Research (ITCR) Initiative, this FOA encourages applications focused on the development of novel computational, mathematical, and statistical algorithms and methods that can considerably improve acquisition, management, analysis, and dissemination of relevant data and/or knowledge. The central mission of ITCR is to promote research-driven informatics technology across the development lifecycle to address priority needs in cancer research. In order to be successful, the proposed informatics method or algorithm must have a clear rationale on why it is novel and how it will benefit the cancer research field. Potential applicants who are interested in more downstream tool development, from prototyping to hardening and adaptation, should consult the other companion FOAs listed above.

- Check:

Key Dates

Posted Date	August 18, 2015
Open Date (Earliest Submission Date)	October 20, 2015
Letter of Intent Due Date(s)	30 days prior to the application due date
Application Due Date(s)	<p>November 20, 2015; June 14, 2016; November 21, 2016; June 14, 2017; November 20, 2017; June 14, 2018, by 5:00 PM local time of applicant/organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on these dates.</p> <p>Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.</p>
AIDS Application Due Date(s)	Not Applicable
Scientific Merit Review	March-April 2016, October-November 2016, March-April 2017, October-November 2017, March-April 2018, October-November 2018
Advisory Council Review	May 2016, January 2017, May 2017, January 2018, May 2018, January 2019
Earliest Start Date	July 2016, April 2017, July 2017 , April 2018, July 2018, April 2019
Expiration Date	June 15, 2018



- Check:

Section I. Funding Opportunity Description

Purpose

The purpose of this Funding Opportunity Announcement (FOA) is to invite exploratory/dev and algorithms in biomedical computing, informatics, and data science addressing priority and diagnosis, cancer prevention, cancer control and epidemiology, and/or cancer health (ITCR) Initiative, this FOA encourages applications focused on the development of novel c improve acquisition, management, analysis, and dissemination of relevant data and/or kn across the development lifecycle to address priority needs in cancer research. In order to on why it is novel and how it will benefit the cancer research field. Potential applicants wh adaptation, should consult the other companion FOAs listed above.

Background

Over the last decade, major advances in biology coupled with innovations in information te the genomic revolution and many of its manifestations to developments in high-throughput research data that are so rich and comprehensive, and yet so massive and complex. This confronts researchers, especially bench biologists and clinicians, with significant challenge and clinical practice. For example, advances in genomics create new opportunities to expl

Specific Research Objectives

This FOA encourages applications that involve development of highly innovative methods and mathematical or computational algorithms of significant value at any point in the cancer research continuum, from bench to bedside. The emphasis will be on novelty and potential for impact. Potential applicants are advised to consult with the Scientific/Research contact listed in Section VII for appropriateness of submission to this FOA.

Some general examples of needs that may be appropriate for this FOA include:

- Innovative methods and algorithms for:
 - experiment design and execution
 - data collection
 - data processing and analysis
 - data quality assessment
 - data integration
 - data presentation and visualization
 - text mining and natural language processing
 - data compression, storage, organization, transmission
- New approaches to addressing:
 - semantic interoperability
 - patient-centric laboratory, behavioral, and clinical data coalescence
 - interpretation of experimental results
 - modeling and simulation

Wet-lab based technology development is supported by the NCI IMAT Program <http://imat.cancer.gov/>. Potential applicants who are interested in the development of molecular technologies are advised to consult with scientific staff of the IMAT Program for suitability of submission.

- Check:

Section II. Award Information

Funding Instrument

Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

Application Types Allowed

New
Resubmission

The [OER Glossary](#) and the SF424 (R&R) Application Guide provide details on these application types.

Funds Available and Anticipated Number of Awards

The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

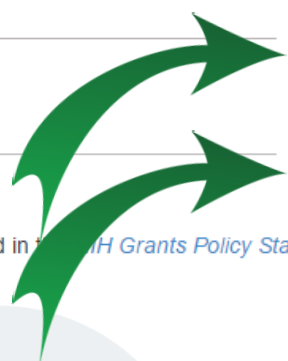
Award Budget

Direct costs are limited to \$275,000 over a two year period. No more than \$200,000 may be requested in any single year.

Award Project Period

The maximum project period is two years.

NIH grants policies as described in the [NIH Grants Policy Statement](#) will apply to the applications submitted and awards made in response to this FOA.



- Check:

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NI

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal gov)
- Faith-based or Community-based Organizations
- Regional Organizations
- Non-domestic (non-U.S.) Entities (Foreign Institutions)

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are** eligible to apply.

Foreign components, as defined in the [NIH Grants Policy Statement](#), **are** allowed.

- Check:

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

The NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see [NOT-OD-11-101](#)).

Letter of Intent

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

By the date listed in [Part 1. Overview Information](#), prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity

The letter of intent should be sent to:

Juli Klemm, Ph.D.
National Cancer Institute (NCI).
Telephone: 301-480-5778
Email: juli.klemm@nih.gov

- Check:

Page Limitations

All page limitations described in the SF424 Application Guide and the [Table of Page Limits](#) must be followed

Instructions for Application Submission

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

SF424(R&R) Cover

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Other Project Information

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Senior/Key Person Profile

All instructions in the SF424 (R&R) Application Guide must be followed.

R&R or Modular Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

Travel: Applicants are required to include travel support for an investigator from their research team to attend the annual meeting. Travel to one annual meeting per year should be accounted for in the budget.

R&R Subaward Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Cover Page Supplement

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Research Plan

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Research Strategy: As the goal of this FOA is to support novel computational, mathematical, and statistical algorithms and methods in support of hypothesis-driven cancer research and cancer care, investigators should clearly describe:

- The potential to support a transformative capacity for a cancer-relevant area of research.
- The level of interaction with collaborators in the cancer research field and the potential for wide adoption by the relevant research community.
- The level of innovation of the proposed computational, mathematical, or statistical algorithm and the advantages it offers relative to those currently available.

Investigators should describe their plan for participating in the ITCR program activities, including the annual meetings and working groups. NCI has established a National Cancer Informatics Hub (NCIP Hub, <https://nciphub.org>) to provide an online forum for scientific exchange among grantees and the user community. Investigators should describe how they plan to use the NCIP Hub to support project and program goals.

- Page limits:

Section of Application	Activity Codes	Page Limits * (if different from FOA, FOA supersedes)
Introduction to Resubmission and Revision Applications	For all Activity Codes (including each applicable component of a multi-component application)	1
Specific Aims	For all Activity Codes that use an application form with the Specific Aims section (including each component of a multi-component application)	1
Research Strategy	For Activity Code DP1	5
	For Activity Codes R03 , R13 , U13 , R13 , U13 , R21 , R35 , R36 , R41 , R43 , SC2 , SC3 , X01 ¹ , X02 ¹ , R50	6
	For Activity Code DP2	10
	For Activity Codes DP3 , DP5 , G08 , G11 , G13 , RC2 , RC4 , RF1 , R01 , R15 , R18 , R21 , R33 , R24 , R28 , R33 , R34 , R42 , R44 , R61 , R33 , SB1 , SC1 , SI2 , UB1 , UC2 , UH2 , UH3 , UG1 , UC4 , UF1 , UG3 , UH3 , UH2 , UH3 , U01 , U18 , U24 , U2C , U34 , U42 , U44 , X01 ¹ , X02 ¹	12
	For all other Activity Codes	Follow FOA instructions
Commercialization Plan	For Activity Codes R42 , R44 , SB1 , UT1 , U44 , UB1 (Attachment 7 on SBIR/STTR Information form)	12
Biographical Sketch	For all Activity Codes (including DP1 and DP2 which previously had special page limits)	5

* FOA instructions always supersede these instructions.

- Agency contacts
- They usually answer emails (and phone) quickly & efficiently

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to assist you.

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons registration, submitting due date, post submission issues)

Finding Help Online: <https://grants.nih.gov/support/> (preferred method of contact)

Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

[Grants.gov Customer Support](#) (Questions regarding Grants.gov registration and submission)
Contact Center Telephone: 800-518-4726

Email: support@grants.gov

GrantsInfo (Questions regarding application instructions and process, finding NIH grant)

Email: GrantsInfo@nih.gov (preferred method of contact)

Telephone: 301-945-7573

Scientific/Research Contact(s)

Juli Klemm

Center for Biomedical Informatics and Information Technology (NCI)

Telephone: 301-480-5778

Email: juli.klemm@nih.gov

Peer Review Contact(s)

Referral Officer

National Cancer Institute (NCI)

Telephone: 240-276-6390

Email: ncirefof@dea.nci.nih.gov

Financial/Grants Management Contact(s)

Jackie Boudjeda

Office of Grants Administration (NCI)

Telephone: 240-276-6312

Email: Boudjedaj@mail.nih.gov

- Eligible?
 - No (end of story)
 - Yes (continue to submission)

And here's when things started to be much more complex...

- Options:

Required Application Instructions

It is critical that applicants follow the instructions in the [SF424 \(R&R\) Application Guide](#), except where instructed to do otherwise (in this FOA or in a Notice from the [NIH Guide for Grants and Contracts](#)). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in [Section IV](#). When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners.


1. Use the NIH ASSIST system to prepare, submit and track your application online.

Apply Online Using ASSIST



2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons to track your application. Check with your institutional officials regarding availability.
3. [Go to Grants.gov](#) to download an application package to complete the application forms offline or create a Workspace to complete the forms online; submit your application to Grants.gov; and track your application in eRA Commons.

Learn more about the various [submission options](#).



- Assist (Online):


Important Note for All Applicants:



Applicants MUST Follow ALL Application Guidance

Conformance to all instructions documented in the following is required and strictly enforced:

- Funding Opportunity Announcement
 - Pay special attention to FOA-specific notices in the Related Notices section and to FOA-specific requirements in section IV
- Policy notices in the [NIH Guide for Grants and Contracts](#)
- [Application guides and supplemental instructions](#)



Registrations in Multiple Federal Systems are Required to Submit

See [Registrations](#) for details.

All registrations must be completed and active to apply. [System for Award Management](#) (SAM) registration must be renewed annually. We urge you to complete all registrations and renewals as soon as possible.

Proceed to Assist

Not so fast...

- Two processes in parallel:
 - Scientific authoring (aims, research strategy, bios)
 - Grant admin (registration, budget, submission)



A whole new world
Problem solving inclusive

- From the FOA:

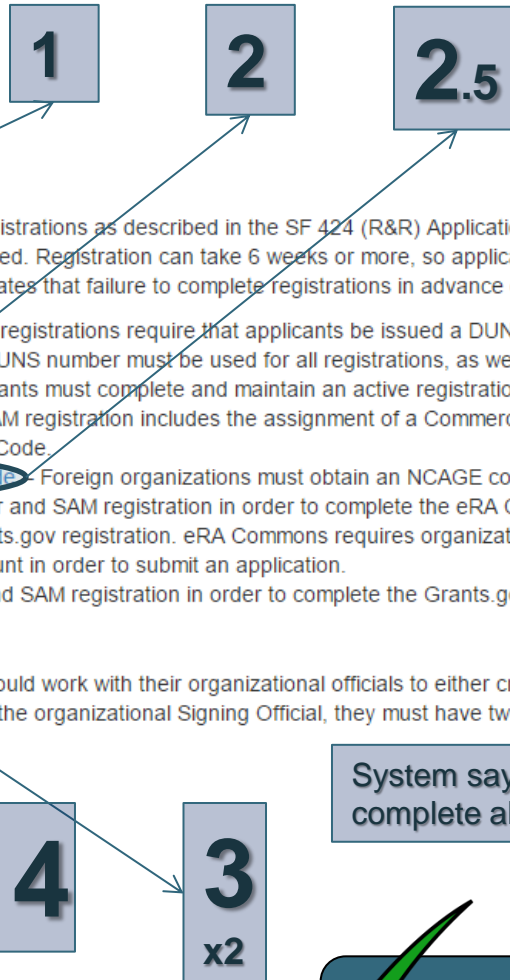
Required Registrations Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The [NIH Policy on Late Submission of Grant Applications](#) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- [Dun and Bradstreet Universal Numbering System \(DUNS\)](#) – All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- [System for Award Management \(SAM\)](#) (formerly COR) – Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
- [NATO Commercial and Government Entity \(NCAGE\) Code](#) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- [eRA Commons](#) – Applicants must have an active DUNS number and SAM registration in order to complete the eRA Commons registration. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- [Grants.gov](#) – Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

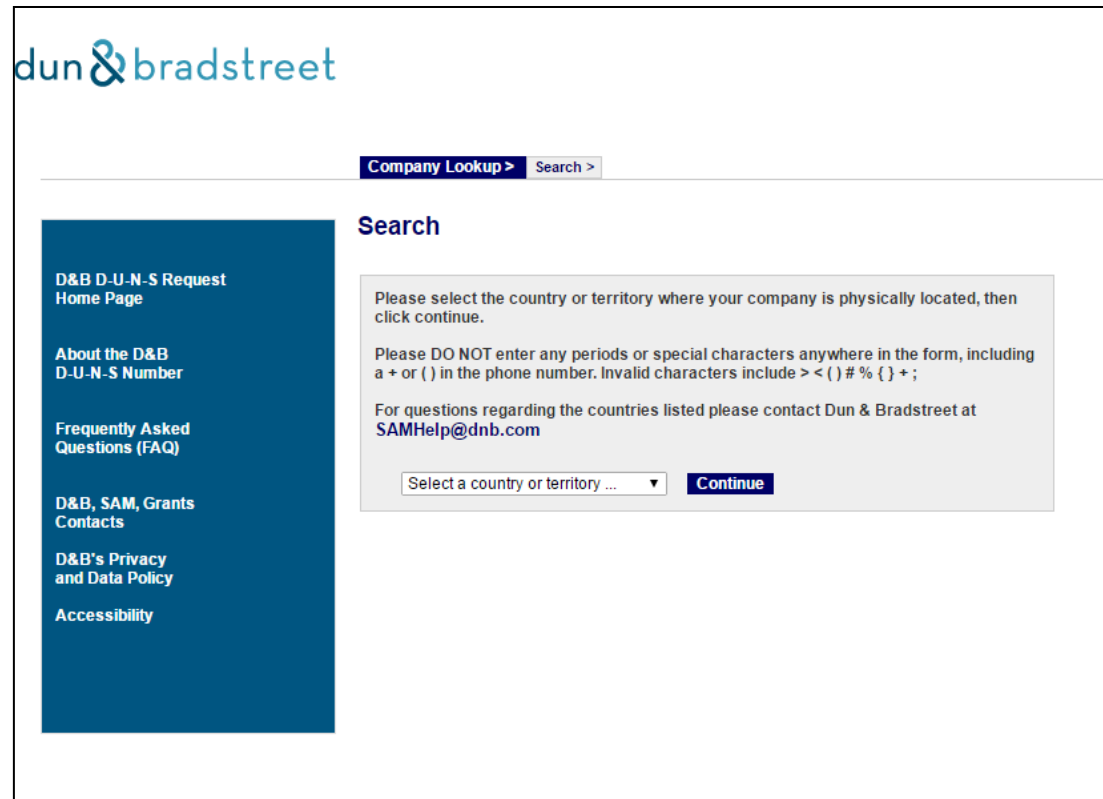


System says to plan for 4-6 weeks ahead to complete all necessary registrations



We have 2.5 months

- 1 – DUNS
 - Response Time: 24-48hrs
 - Done. Got DUNS number.



The screenshot shows the Dun & Bradstreet website's registration interface. At the top, the logo "dun & bradstreet" is displayed. Below it, there is a navigation bar with "Company Lookup >" and "Search >". The main content area is divided into two sections. On the left, a dark blue sidebar contains links: "D&B D-U-N-S Request Home Page", "About the D&B D-U-N-S Number", "Frequently Asked Questions (FAQ)", "D&B, SAM, Grants Contacts", "D&B's Privacy and Data Policy", and "Accessibility". The right section, titled "Search", contains instructions: "Please select the country or territory where your company is physically located, then click continue." and "Please DO NOT enter any periods or special characters anywhere in the form, including a + or () in the phone number. Invalid characters include > < () # % { } + ;". It also provides contact information: "For questions regarding the countries listed please contact Dun & Bradstreet at SAMHelp@dnb.com". At the bottom of the search section, there is a dropdown menu labeled "Select a country or territory ..." and a "Continue" button.

- 2 – SAM
 - RT: 3-7 business days response time
 - Problem: info does not match DUNS record info
 - Source: DUNS changed info
 - Solution: Comply
 - Price: 2 days
 - Hold: need NCAGE to complete SAM reg

The screenshot shows the SAM website homepage. At the top, there is a header with the SAM logo (a stylized 'S' with an American flag motif) and the text 'SYSTEM FOR AWARD MANAGEMENT'. To the right of the logo are login fields for 'Username' and 'Password', with links for 'Forgot Username?', 'Forgot Password?', 'Log In', and 'Create an Account'. Below the header is a navigation bar with links: 'HOME', 'SEARCH RECORDS', 'DATA ACCESS', 'CHECK STATUS', 'ABOUT', and 'HELP'. The main content area starts with a paragraph: 'The System for Award Management (SAM) is an official website of the U.S. government. There is no cost to use SAM. You can use this site for FREE to:' followed by a bulleted list: 'Register to do business with the U.S. government', 'Update or renew your entity registration', 'Check status of an entity registration', and 'Search for entity registration and exclusion records'. Below this is a section titled 'Getting Started' with three columns. The first column is 'Create A User Account' with a person icon and the text 'Start by creating a SAM user account.' The second column is 'Register Entity' with a folder icon and the text 'After creating your SAM user account, log in to register to do business with the U.S. government.' The third column is 'Search Records' with a magnifying glass icon and the text 'Do a public search for existing entity registration records or exclusion records. Federal users can log in to see additional information.'

- 2.5 – NCAGE (Nato CAGE)
 - RT: 7-10 business days
 - Request filled. After few days got inquiry from...
IL MOD repr.
 - Inquiry completed. After few days got NCAGE code.
 - Back in SAM to complete reg
 - Problem: info in NCAGE record does not match SAM record info
 - Source: Nato
("St"/"Street")
 - Solution: Fix Nato
 - Price: 14 days (!)
(Major holiday ++)
 - Finally able to complete SAM reg

The screenshot shows the 'NATO Codification Tools' website. The header includes the NATO logo, the text 'NATO Codification Tools', and the NSPA logo (NATO Support and Procurement Agency). Below the header is a navigation bar with links: 'NMCRL-WEB', 'NMCRL Offline', 'CAGE/NCAGE Code Request' (highlighted), and 'ACodP2/3'. A breadcrumb trail shows 'Home > CAGE/NCAGE Code Request'. The main content area contains a paragraph explaining the purpose of the link, followed by a 'Search Criteria' section. This section includes a note that the 'Request New' button will become available after the search. The form fields are organized into two columns: the left column contains 'CAGE/NCAGE Code', 'Organization Name', 'Country' (a dropdown menu), and 'City'; the right column contains 'Postal Code', 'Phone Number', and 'Identification Number (IDN)'. All input fields are represented by light blue rectangular boxes.

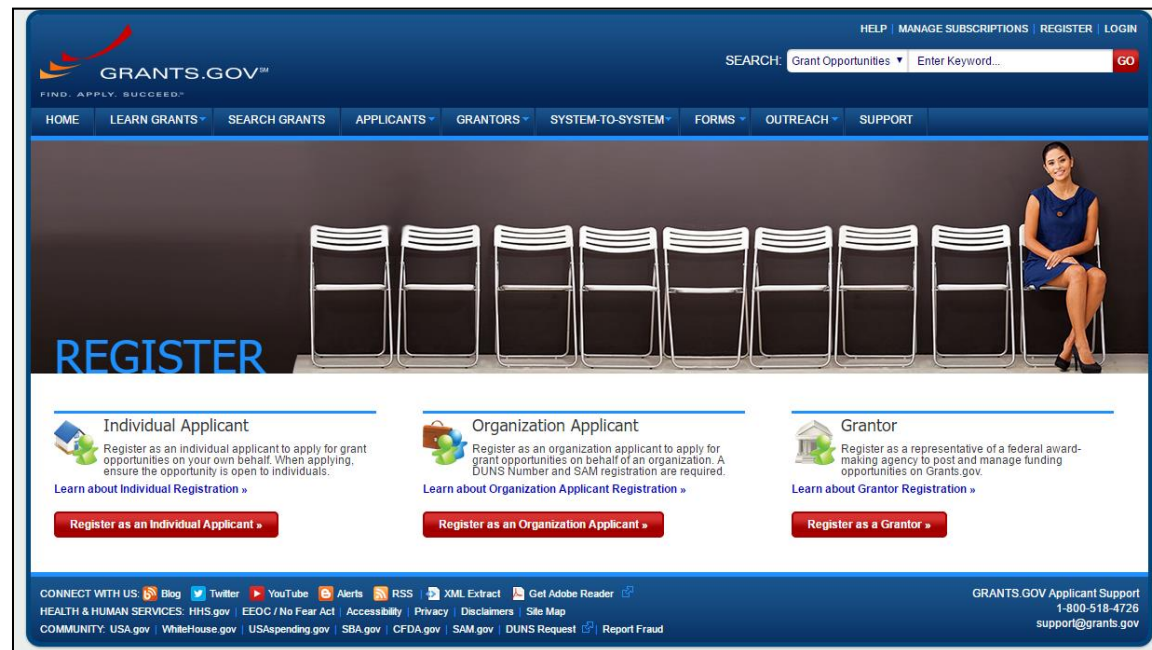
- 3 (x2) – eRA Commons
 - RT: 2 weeks
 - Organisation registered
 - PI registered (yet another usr/pwd)
 - Time: 1 week

The screenshot displays the eRA Commons website interface. The header includes the eRA Commons logo and navigation links. The main content area is divided into several sections:

- Commons Login:** A section for users to log in, featuring fields for username and password, and buttons for 'Login' and 'Reset'. It also includes links for external users to forget their password or unlock their account.
- Federated Institutions/Organizations:** A section with a dropdown menu to select an institution and a 'Sign in' button.
- Federal User Login:** A link to the federal user login page.
- eRA Service Desk:** A section providing contact information for the service desk, including hours, website, toll-free number, and phone number.
- Welcome to the Commons:** A central section with a system notification message stating 'All systems are currently available'. It also includes links to the eRA Scheduled Maintenance Calendar, support-related resources, and commons-related resources.
- Privacy Act Statement:** A section containing a detailed statement about the website's privacy and security policies.
- Register Grantee Organization:** A link to the registration page for organizations.
- About the Commons:** A section with links to frequently asked questions and latest release notes.
- Additional Links:** A section with links to various resources, including RePORT, Grants.gov, eCommons, National Institutes of Health, Public Access Policy Page, Loan Repayment Program, and Commons Quick Queries.

The footer contains contact information for the National Institutes of Health (NIH) and the Department of Health and Human Services, along with copyright information and a version number.

- 4 – Grants.gov
 - RT: web service
 - Organisation Applicant registered (yet another usr/pwd)
 - Not so simple...
check instructions



- 4 (&4.5) – Grants.gov
 - Steps...
 - Ebiz POC
 - Authorise AOR
 - PB1: DUNS unrec.
 - Sol1: add 0000
 - PB2: no record
 - Sol2: use the other username...
 - Price: 2-3 days

APPLICANT ACTIONS

Purpose of EBiz POC Authorization

Your organization's EBiz POC can authorize the AOR role, which allows your organization to only approve specific people to submit grants on behalf of the organization. This authorization protects an organization from individuals who may submit applications without permission.

The EBiz POC is likely to be your organization's chief financial officer or authorizing official, and there can only be one EBiz POC per DUNS number when [registering with SAM](#).

How to Authorize Grants.gov Roles (*steps for the EBiz POC*)

1. [Log in to Grants.gov](#) under the EBiz POC tab, using your username and password. Legacy users may need to use their organization's DUNS number for the username and the MPIN password obtained in [Step 2: Register with SAM](#).
2. Click the Manage Applicants for Organization link, search for the new user, and assign the appropriate roles in Grants.gov. For more detailed instructions, review the [Authorize User Role help article](#).
3. After approval, Grants.gov automatically sends the organization applicant a confirmation email.

How long does it take to authorize roles?

This can be completed on the same day, but it depends on how long it takes the EBiz POC to log in and complete the steps listed above.

» Encountering Error Messages

Complete the steps listed above.

- Finally, ASSIST
 - 5th system already...
 - 2 weeks from the deadline
 - 2 external codes (DUNS/NCAGE) and 5 different usr/pwd pairs

U.S. Department of Health & Human Services

Application Submission System & Interface for Submission Tracking (ASSIST)
Sponsored by the National Institutes of Health

Login

User Name

Password

[Forgot Password/Unlock Account?](#)

[Login](#) [Cancel](#)

Federated Institutions/ Organizations

Select Login Here

[Login](#) [Cancel](#)

Submit grant applications electronically to NIH and other Public Health Service Agencies...

The Application Submission System & Interface for Submission Tracking (ASSIST) system is used to prepare and submit grant applications electronically to NIH and other Public Health Service agencies. Prior to using ASSIST, applicants should identify a Funding Opportunity Announcement (FOA) to which they'd like to apply. FOAs are posted in the NIH Guide for Grants & Contracts and/or in Grants.gov each of which has robust search capabilities. The FOA text will indicate whether ASSIST can be used to apply to that opportunity. You will need the FOA number (e.g., PA-15-987) to initiate an application.

Active Grants.gov and eRA Commons credentials are required to prepare and submit applications using ASSIST.

WARNING NOTICE: This warning banner provides privacy and security notices consistent with applicable federal laws, directives, and other federal guidance for accessing this Government system, which includes all devices/storage media attached to this system. This system is provided for Government-authorized use only. Unauthorized or improper use of this system is prohibited and may result in disciplinary action and/or civil and criminal penalties. At any time, and for any lawful Government purpose, the government may monitor, record,

Need Help?

Resources

- [APPLICATION GUIDE](#)
- [ASSIST USER GUIDE](#)

- Meanwhile, in a parallel universe...
- The scientific part is built
 - 3 partner organisations
(Mayo Clinic, Cleveland Clinic, University of Utah)
 - Research strategy written, roles defined, information collected including bios and budget (Mayo)
 - Main contractor budget prepared (detailed, per year)
 - Partner's budget is negotiated and prepared
- Time to input everything into ASSIST

- Initiate application

U.S. Department of Health & Human Services eRA Commons Home

Application Submission System & Interface for Submission Tracking (ASSIST)

Sponsored by the National Institutes of Health

Welcome [redacted]

Welcome to the Application Submission System Interface for Submission Tracking (ASSIST)

INITIATE APPLICATION
Funding Opportunity Announcement #
(Example: PA-XX-XXX or LITC-ABCD-XX-000) **GO**

The National Institutes of Health posts Funding Opportunity Announcements (FOAs) in the [NIH Guide for Grants & Contracts](#) and in [Grants.gov's Search Grants](#). Each resource has robust search functionality to identify opportunities of interest. ASSIST can only be used to prepare and submit applications when explicitly stated in the FOA.

SEARCH FOR APPLICATION **Search Applications**

- Here we go...
- 6-9 tabs to fill in
- In our case: 8

Application Information ?

Tip:

- Some actions (e.g., Preview Application) are only available from this screen. The Return to Application action can be used to return to this screen.

1

2

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4

5

6

7

8

Summary

R&R Cover

Cover Page Supplement

Other Project Information

Sites

Sr/Key Person Profile

R&R Budget

R&R Subaward Budget

Research Plan

»

Application Information

Application Identifier:	154628
Application Project Title:	Embedding HSD3B1 genotypes in a mathematical tool to personalize prostate cancer therapy
PD/PI Name:	Agur, Zvia
Organization:	INSTITUTE FOR MEDICAL BIOMATHEMATICS
Project Period:	04/01/2018 - 03/31/2020
Status:	Work in Progress Submit Application
Status Date:	2017-04-15 04:29:59.000 PM EDT

»

FOA Information

FOA Number:	PAR-15-334
Opportunity Title:	Development of Innovative Informatics Methods and Algorithms for Cancer Research and Management (R21)
Agency:	National Institutes of Health
CFDA Number:	
Competition ID:	FORMS-D
Opportunity Open Date:	05/14/2016
Opportunity Close Date:	06/14/2018
Agency Contact:	eRA Service Desk Monday to Friday 7 am to 8 pm ET http://grants.nih.gov/support/

SAM Registration Expiration Date: 11/04/2017

An active SAM Registration is required to submit your application to the agency

Click for SAM Registration Details

- Edit...
- Long version of DUNS
- Unexplained codes
- Budget?
- Mandatory Q

1

Summary	R&R Cover	Cover Page Supplement	Other Project Information	Sites	Sr/Key Person Profile	R&R Budget	R&R Subaward Budget	Research Plan
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Application for Federal Assistance
SF 424 (R&R) v2.0 ?

OMB Number: 4040-0001
 Expiration Date: 10/31/2019

[Edit](#) ☒ Expand All * Required field(s)

1. * TYPE OF SUBMISSION

* Type of Submission ☐ Pre-Application ☒ Application ☐ Changed/Corrected Application

15. * ESTIMATED PROJECT FUNDING

* a. Total Federal Funds Requested	██████████
* b. Total Non-Federal Funds	██████████
* c. Total Federal & Non-Federal Funds	██████████
* d. Estimated Program Income	0.00

16. * IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

a. * Yes ☐ This pre-application/application was made available to the State Executive Order 12372 process for review on: Date

b. * No ☒ Program is not covered by E.O. 12372; or ☐ Program has not been selected by State for review

17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the information provided is true and accurate to the best of my knowledge. I also provide the required assurance of funding. I am aware that any false, fictitious, or fraudulent information provided may result in the application being disapproved and the applicant being ineligible for future funding.

Street 2

* City

County/Parish

State

- High level ethics
- No issues here...



Summary

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Cover Page Supplement

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R&R Budget

R&R Subaward Budget

Research Plan

PHS 398 Cover Page Supplement

PHS398 CoverPageSupplement v3.0

OMB Number: 0925-0001
Expiration Date: 10/31/2018

Edit

View Burden Statement

* Required field(s)

1. Human Subjects Section

Clinical Trial? ☐ Yes ☒ No

Agency-Defined Phase III Clinical Trial? ☐ Yes ☐ No

2. Vertebrate Animals Section

Are vertebrate animals euthanized? ☐ Yes ☒ No

If "Yes" to euthanasia

Is method consistent with American Veterinary Medical Association (AVMA) guidelines? ☐ Yes ☐ No

If "No" to AVMA guidelines, describe method and provide scientific justification

3. * Program Income Section

* Is program income anticipated during the periods for which the grant support is requested? ☐ Yes ☒ No

If you checked " Yes " above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

Budget Period	Anticipated Amount (\$)	Source(s)
1		

4. Human Embryonic Stem Cells Section

* Does the proposed project involve human embryonic stem cells? ☐ Yes ☒ No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: <http://stemcells.nih.gov/research/registry/> . Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

☐ Specific stem cell line cannot be referenced at this time. one from the registry will be used.

Cell Line(s): (Example: 0004)

5. Inventions and Patents Section (RENEWAL)

* Inventions and Patents ☐ Yes ☒ No

If " Yes, " then answer the following:

- Low level ethics
- And some science, distributed/split sections

3

Summary	R&R Cover	Cover Page Supplement	Other Project Information	Sites	Sr/Key Person Profile	R&R Budget	R&R Subaward Budget	Research Plan															
<p>Research & Related Other Project Information</p> <p>R&R OtherProjectInfo v1.3 ?</p> <p>OMB Number: 4040-000 Expiration Date: 10/31/201</p> <p>Edit</p> <p><i>* Required field(s)</i></p> <p>1. * Are Human Subjects Involved <input type="radio"/> Yes <input checked="" type="radio"/> No</p> <p>1.a If YES to Human Subjects</p> <p>Is the project exempt from Federal regulations? <input type="radio"/> Yes <input type="radio"/> No</p> <p>If yes, check the appropriate exemption number. <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6</p> <p>If no, is the IRB review Pending? <input type="radio"/> Yes <input type="radio"/> No</p> <p>Explanation:</p> <table border="0"> <tr> <td>* 7. Project Summary / Abstract</td> <td>abstract.pdf</td> <td>View Attachment</td> </tr> <tr> <td>* 8. Project Narrative</td> <td>narrativeP.pdf</td> <td>View Attachment</td> </tr> <tr> <td>9. Bibliography & References Cited</td> <td>bibliography.pdf</td> <td>View Attachment</td> </tr> <tr> <td>10. Facilities & Other Resources</td> <td>facilities_resources.pdf</td> <td>View Attachment</td> </tr> <tr> <td>11. Equipment</td> <td></td> <td>View Attachment</td> </tr> </table> <p>Other</p> <p>(EIS) been performed?</p> <p>4.d. If yes, please explain:</p> <p>5. * Is the research performance site designated, or eligible to be designated, as a historic place? <input type="radio"/> Yes <input checked="" type="radio"/> No</p> <p>5.b. If yes, please explain:</p> <p>6. * Does this project involve activities <input checked="" type="radio"/> Yes <input type="radio"/> No</p>									* 7. Project Summary / Abstract	abstract.pdf	View Attachment	* 8. Project Narrative	narrativeP.pdf	View Attachment	9. Bibliography & References Cited	bibliography.pdf	View Attachment	10. Facilities & Other Resources	facilities_resources.pdf	View Attachment	11. Equipment		View Attachment
* 7. Project Summary / Abstract	abstract.pdf	View Attachment																					
* 8. Project Narrative	narrativeP.pdf	View Attachment																					
9. Bibliography & References Cited	bibliography.pdf	View Attachment																					
10. Facilities & Other Resources	facilities_resources.pdf	View Attachment																					
11. Equipment		View Attachment																					

- Partners information
- Price: 2-3 days - time diff

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Summary	R&R Cover	Cover Page Supplement	Other Project Information	Sites	Sr/Key Person Profile	R&R Budget	R&R Subaward Budget	Research Plan
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Project/Performance Site Locations Summary

Primary Performance Site ?

Organization Name	DUNS	Address	Action
Institute for Medical Biomathematics	[REDACTED]	10 Hateena Bnei Atarot 006099100 ISRAEL	Edit View

Project/Performance Site Location(s) [Add Site](#)

1 - 3 of 3 records, Page 1 of 1

Entry #	Organization Name	DUNS	Address	Action
1	Mayo Clinic	[REDACTED]	200 First Street SW Rochester, MN 55905-0001 UNITED STATES	Edit Remove View
2	University of Utah	[REDACTED]	2000 Circle of Hope Salt Lake City, UT 84112-9008 UNITED STATES	Edit Remove View
3	Cleveland Clinic	[REDACTED]	9500 Euclid Avenue Cleveland, OH 44195-0001 UNITED STATES	Edit Remove View

- PIs information
- Bio sketches

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Summary

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Sr/Key Person Summary

PROFILE - Project Director/Principal Investigator ?

PD/PI Name	Project Role	Action
Prof. [REDACTED]	PD/PI	Edit View

PROFILE - Senior/Key Person(s) [Add Sr/Key](#)

1 - 3 of 3 records, Page 1 of 1

Entry #	Sr/Key Person	Project Role	Action
1	Dr. [REDACTED] M.D.	Co-Investigator	Edit Remove View
2	Dr. [REDACTED] M.D.	Co-Investigator	Edit Remove View
3	Dr. [REDACTED] M.D.	Co-Investigator	Edit Remove View

- Main partner budget
- Per period, detailed
- Cumulative view
- Consortium budget
- Budget ceiling? TBC
- Price: 2-3 days

Summary

R&R Cover

Period 1

Period 2

Research and Re

R&R Budget v1.

Edit

The Organizational D

Organization Informa

Cover; you will not be

* Organizational DUNS

(e.g. 123456789 or

1234567891234)

* Enter Name of Organ

* Budget Type

Budget Period: 1

A. * Senior/Key Person

A. Senior/Key Person

Section A, Senior/Key Person	\$	35,000.00
Section B, Other Personnel	\$	115,200.00
Total Number Other Personnel		2
Total Salary, Wages and Fringe Benefits (A+B)	\$	150,200.00
Section C, Equipment Description	\$	0.00
Section D, Travel	\$	31,200.00
1. Domestic Travel Costs	\$	0.00
2. Foreign Travel Costs	\$	31,200.00
Section E, Participant/Trainee Support Costs	\$	0.00
1. Tuition/Fees/Health Insurance	\$	0.00
2. Stipends	\$	0.00
3. Travel	\$	0.00
4. Subsistence	\$	0.00
5. Other	\$	0.00
Number of Participants/Trainees		0
Section F, Other Direct Costs	\$	140,912.00
1. Materials and Supplies	\$	4,000.00
2. Publication Costs	\$	0.00
3. Consultant Services	\$	0.00
4. ADP/Computer Services	\$	1,883.00
5. Subawards/Consortium/Contractual Costs	\$	135,029.00
6. Equipment or Facility Rental/User Fees	\$	0.00
7. Alterations and Renovations	\$	0.00
8. Other 1	\$	0.00
9. Other 2	\$	0.00
10. Other 3	\$	0.00
Section G, Direct Costs (A thru F)	\$	322,312.00
Section H, Indirect Costs	\$	25,785.00
Section I, Total Direct and Indirect Costs (G + H)	\$	348,097.00
Section J, Fee	\$	0.00

- Partners (subawards) budget
- Same detail level
- PB1: OH 8% vs. 52% ?
- Sol: ask the agency contact (2 days time diff)
- PB2: unable to import (wrong SF-424 version)
- Sol: manual input

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SummaryR&R CoverCover Page SupplementOther Project InformationSitesSr/Key Person ProfileR&R BudgetR&R Subaward BudgetResearch Plan

Research and Related Subaward Budget ?

OMB Number: 4040-0001

Prepare the subawardee budget(s) online within ASSIST or download, complete and attach the subaward budget form(s).

Add New Subaward

Remove All Subawards

Download Subaward Form

Attach Subaward Form

Subaward	Organization	Action
Subaward1	Mayo Clinic	<div>EditRemoveView</div>

- Last one but not least
- Research strategy
- Letters of Support
- PB: Specific Aims = mandatory

Summary R&R Cover Cover Page Supplement Other Project Information Sites Sr/Key Person Profile R&R Budget R&R Subaward Budget **Research Plan**

PHS 398 Research Plan
PHS398 Research Plan v3.0 ?

OMB Number: 0925-0001
Expiration Date: 10/31/2018

[Edit](#) [View Burden Statement](#) * Required field(s)

Introduction

1. Introduction to Application (for RESUBMISSION and REVISION) [View Attachment](#)

Research Plan Section

2. Specific Aims [specific_aimsP.pdf](#) [View Attachment](#)

* 3. Research Strategy [reasearch_strategy.pdf](#) [View Attachment](#)

4. Progress Report Publication List [View Attachment](#)

Human Subjects Section

5. Protection of Human Subjects [View Attachment](#)

6. Data Safety Monitoring Plan [View Attachment](#)

5. Inclusion of Women and Minorities [View Attachment](#)

8. Inclusion of Children [View Attachment](#)

Other Research Plan Section

9. Vertebrate Animals [View Attachment](#)

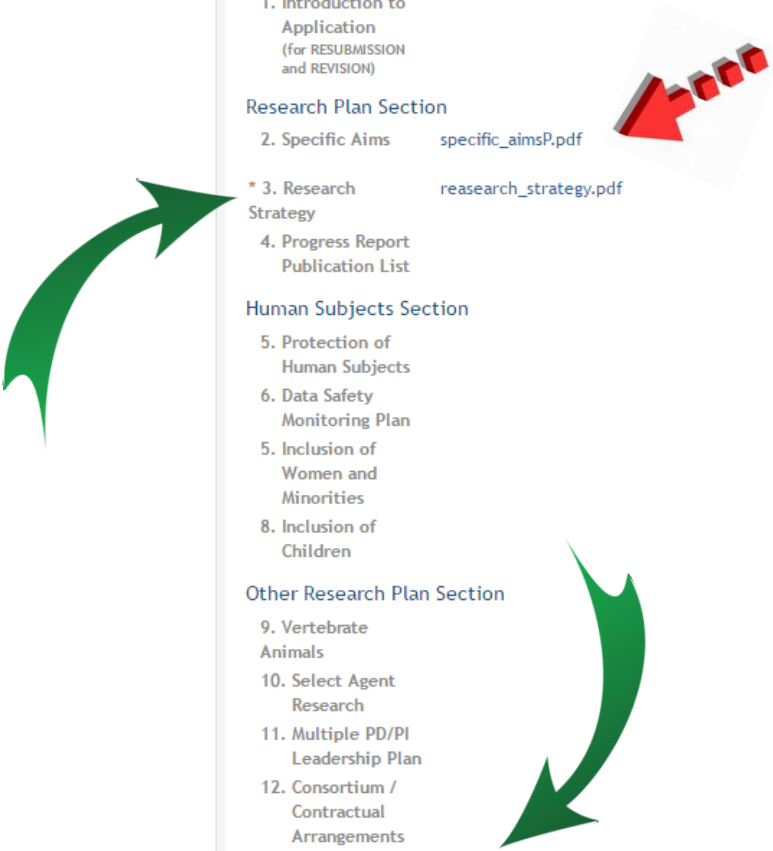
10. Select Agent Research [View Attachment](#)

11. Multiple PD/PI Leadership Plan [View Attachment](#)

12. Consortium / Contractual Arrangements [View Attachment](#)

13. Letters of Support [LoS-pack.pdf](#) [View Attachment](#)

14. Resource Sharing Plan(s) [View Attachment](#)



- We are done
- 2 days for the deadline
- All validations passed
- We need to submit!

Application Errors and Warnings Results

 Application Information	
Application Identifier:	154628
FOA Number:	PAR-15-334
Application Project Title:	Embedding HSD381 genotypes in a mathematical tool to personalize prostate cancer therapy
PD/PI Name:	Agur, Zvia
Organization:	INSTITUTE FOR MEDICAL BIOMATHEMATICS

All Validations Passed

- Preview application
PDF 66 page length
- Page 52 reveals total budget ceiling <275K

Page 51

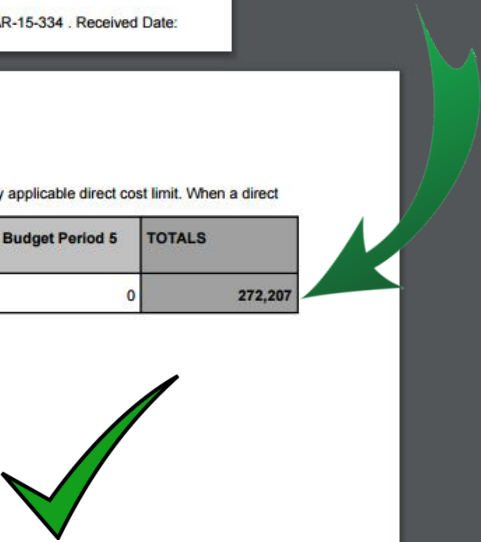
Tracking Number: Funding Opportunity Number: PAR-15-334 : Received Date:

Contact PD/PI: Agur, Zvia

Total Direct Costs less Consortium F&A

NIH policy (NOT-OD-05-004) allows applicants to exclude consortium/contractual F&A costs when determining if an application falls at or beneath any applicable direct cost limit. When a direct cost limit is specified in an FOA, the following table can be used to determine if your application falls within that limit.

Category	Budget Period 1	Budget Period 2	Budget Period 3	Budget Period 4	Budget Period 5	TOTALS
Total Direct Costs less Consortium F&A	139,721	132,486	0	0	0	272,207



- Last checks, 12 hours before deadline
- We need to submit!
- How to get a “submit button”?
- Trying to submit...
- PB: PDF errors (checksum)
- Sol: re-PDF all “erroneous” PDFs

• Submitted!

- Ack received
- Everyone's



Actions ?

RETURN TO APPLICATION

MANAGE ACCESS

ADD OPTIONAL FORM

PREVIEW APPLICATION

VALIDATE APPLICATION

VIEW STATUS HISTORY

UPDATE SUBMISSION STATUS

COPY APPLICATION

DELETE APPLICATION

Update Submission Status

Select the new status

Enter a comment on the status of this submission [without adding a comment.](#)

Add comment

Cancel

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Screen Rendered: 04/23/2017 07:19:11 EDT | Screen Id: ASSIST0034@3863

Version:
2.23.00

- That's it!
- What happened next?
- After a few days(!) a short letter arrived
- Problem with submission
- Rejected on the spot
- Reason: Proposal submitted to a closed PA

• Seriously? How can that be?



- Let's check:

1st Application (old)

Application Information ?

Tip:

- Some actions (e.g., Preview Application) are only available from this screen. The Return to Application action can be used to return to this screen.

Summary	R&R Cover	Cover Page Supplement	Other Project Information	Sites	Sr/Key Person Profile	R&R Budget	R&R Subaward Budget	Research Plan
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Application Information

Search for Application Results

1 - 2 of 2 records, Page 1 of 1

Application Identifier	Application Project Title	Agency	PD/PI Name	Lead Applicant Organization	Submission Status	Submission Date	Project Start Date	Project End Date	Action
119292	Embedding HSD3B1 genotypes in a mathematical tool to personalize prostate cancer therapy	NIH	Agur, Zvia	INSTITUTE FOR BIOMEDICAL MATHEMATICS	Submitted	11/21/2016	07/01/2017	06/30/2019	Select
154628	Embedding HSD3B1 genotypes in a mathematical tool to personalize prostate cancer therapy	NIH	Agur, Zvia	INSTITUTE FOR BIOMEDICAL MATHEMATICS	Work in Progress		04/01/2018	03/31/2020	Select



FOA Information

FOA Number: PAR-15-344

Opportunity Title: NIDCR Small Research Grants: Oral Health Data Analysis and Statistical Methodology Development (R03)

Agency: National Institutes of Health

CFDA Number:

Competition ID: FORMS-D

Opportunity Open Date: 05/16/2016

Opportunity Close Date: 09/07/2018

Agency Contact: eRA Service Desk Monday to Friday 7 am to 8 pm ET
http://grants.nih.gov/support/

SAM Registration Expiration Date: 11/04/2017

An active SAM Registration is required to submit your application to the agency.

[Click for SAM Registration Details](#)

2nd Application (new)

Application Information ?

Tip:

- Some actions (e.g., Preview Application) are only available from this screen. The Return to Application action can be used to return to this screen.

Summary	R&R Cover	Cover Page Supplement	Other Project Information	Sites	Sr/Key Person Profile	R&R Budget	R&R Subaward Budget	Research Plan
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Application Information



FOA Information

FOA Number: PAR-15-344

Opportunity Title: Development of Innovative Informatics Methods and Algorithms for Cancer Research and Management (R21)

Agency: National Institutes of Health

CFDA Number:

Competition ID: FORMS-D

Opportunity Open Date: 05/14/2016


Opportunity Close Date: 06/14/2018

Agency Contact: eRA Service Desk Monday to Friday 7 am to 8 pm ET
http://grants.nih.gov/support/

SAM Registration Expiration Date: 11/04/2017

An active SAM Registration is required to submit your application to the agency.

[Click for SAM Registration Details](#)

- The system enables to initiate proposals to closed PAs
 - The system does not warn about that
 - Not during initiation, nor during submission
 - The feedback comes only after a few days!
 - Deadline already pass by this time
 - Case closed
-
- Wish us luck for the next round (deadline 14 June 2017)
 - We have more than 1.5 months.... 
 - Here we go again...

- Find a suitable PA
- Check rules (e.g. deadlines, ceiling, pre-application, heads up)
- Check eligibility for Non-US
- If not registered already – **start registration earliest!**
- Get partners info (legal name, address, DUNS, LoS) **well ahead**
- Proposal admin is a key (75% of the time for first timers)
- The proposal is the ASSIST distributed/split section submission
- Don't hesitate to ask for assistance and guidance from the agency contacts
- Expect last minute problems
- Check, check, check.... And then – QA
- Prepare to moderately sophisticated yet cumbersome systems.

Thank you!



Yoram Lev-Yehudi

yly@beacontech.eu

For more information please visit beacontech.eu