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Select Agent Distribution Activity

National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)

Centers for Disease Control and Prevention (CDC)

REQUEST FOR SELECT AGENT

The National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) established the Select Agent Distribution Activity (SADA) to facilitate the distribution of select agents to qualified users. SADA uses an application process that serves to screen requests for access to NCEZID select agents. The application process must be followed by all scientists interested in acquiring select agents from NCEZID and requires the completion of the SADA Application. This procedure is necessary in order to be granted status as a SADA “Qualified Applicant.” To be a Qualified Applicant, you must be a Principal Investigator, Laboratory Director, or equivalent (public or academic institution), or a Director of Research or equivalent (private or for-profit institution) registered with the Select Agent Program (<http://www.selectagents.gov/RegistrationForm.html>) The application can be obtained via download from the SADA website <http://wwwdev.cdc.gov/ncpdcid/dsr/sada/index.html> Instructions accompany the application and should be followed carefully. The application process requires a description of the investigator's area of research focus and proposed use of the requested select agent. Also required is a biosketch or curriculum vitae of the applicant. **In addition, we will need a Certificate of Registration and the Transfer Authorization by the Select Agent Program.**

Applicant submissions will be evaluated based on the following criteria:

1. Expertise in field, based on recent publication record and biosketch/curriculum vitae;
2. Determination of the appropriate nature of the proposed research;
3. Evidence of a strong existing infrastructure for research support.

The NCEZID SADA Executive Committee will review, on a monthly basis, all requests and make recommendations to the NCEZID Director. All applicants will be notified promptly after the review process.

Public reporting burden of this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS E-11, Atlanta, Georgia 30333; ATTN: PRA (0920-0591).

APPLICATION INSTRUCTIONS

All scientists interested in acquiring select agents from NCEZID must submit the attached application form to SADA each time a different select agent is requested. Please read these instructions carefully.

Eligibility

To apply to the SADA, you must be a Principal Investigator, Laboratory Director, or equivalent (public or academic institution), or a Director of Research or equivalent (private or for-profit institution). The requestor must be previously registered with the Select Agent Program <http://www.selectagents.gov/RegistrationForm.html> for use of the select agent at the site and facility where the research will take place. The CDC has been designated as the Department of Human Services (HHS) agency responsible for providing guidance on biological agents and toxins deemed a threat to public health. The Animal and Plant Health Inspection Service (APHIS) has been designated as the United States Department of Agriculture (USDA) agency responsible for providing guidance on select agents deemed a threat to animal or plant health. Agents that appear on both the HHS and the USDA list of agents and toxins have been designated HHS/USDA overlap agents. Requests for USDA or overlap agents may require the intended recipient to obtain a USDA transport permit (VS 16-3) prior to importation or interstate movement of the agent. The USDA permit application is available on the web at http://www.aphis.usda.gov/animal_health/permits/ A list of HHS/USDA overlap agents can be found at http://www.aphis.usda.gov/programs/ag_selectagent/ag_bioterr_toxinlist.shtml

User fee

All requestors (except for public health laboratories) are required to pay a user fee (in advance of shipment and after application approval) that includes costs for materials, handling and shipping. User fees vary by agent; they are posted on the SADA website at <http://wwwdev.cdc.gov/ncpdcid/dsr/sada/index.html>

Procedure

1. Obtain the SADA application form from the website at <http://wwwdev.cdc.gov/ncpdcid/dsr/sada/index.html>
2. Download the SADA application to your computer and print it.
3. Applicants must submit the following documents. **Application documents must contain original, ink signatures.** The SADA Program *cannot* accept application forms electronically or by FAX.
 - Section 1. Provide the required information
 - Section 2. Initial where indicated. If you are not a United States Government employee, you must complete either the Standard Indemnification Agreement or the State Institution Compliance Agreement provided with the application packet, as appropriate for your institution. **Please Note: If your institution cannot agree to the terms of either indemnification agreement, you are not eligible to receive Select Agents from the NCEZID.** The form must be signed by the applicant and countersigned by an official capable of legally binding the institution (e.g., president, vice-president, dean, provost, corporate officer).
 - Section 3. Complete the enclosed Biographical Sketch and publications form or attach brief curriculum vitae. A Biographical Sketch from a recent NIH grant proposal is also acceptable.
 - Section 4. Research Focus. Limit to a maximum of one page in length. Complete or attach abstract from grant proposal.

Mail your completed application with original signatures and other required documents to:

SADA Administrator
 Select Agent Distribution Activity (SADA); MS C-17
 National Center for Emerging and Zoonotic Infectious Diseases
 Centers for Disease Control & Prevention
 1600 Clifton Road NE
 Atlanta, GA 30333

The SADA Executive Committee (an advisory board established to review applications and provide program oversight and guidance) will review each application. Once approved, applicants will be notified.

Request for Select Agent

Do Not Write In This Block. For CDC Use Only.		
Request Number: _____	Certification verification by: _____	Date: _____
	Identity verification by: _____	Date: _____
Committee recommendation:		
Approve <input type="checkbox"/>	Date _____	
Deny <input type="checkbox"/>	Date _____	Explanation: _____

Approval Signature(s): _____	(SME)	Date: _____
	(SADA)	Date: _____
	(NCEZID OD)	Date: _____

Section 1.

Institution: _____
 Name: _____
 Title: _____
 Department: _____
 Street Address: _____
 City, State, zip: _____
 Telephone Number: _____
 Fax Number: _____
 Email Address: _____

Full Shipping Address:

Please write the address exactly as it should appear on a mailing label. Select Agents will NOT be shipped to a post office box.

Select Agent requested: _____ **Quantity:** _____
Strain(s): _____ **User fee*:** _____

*User fees vary by agent; they are posted on the SADA website at <http://wwwdev.cdc.gov/ncpdcid/dsr/sada/index.html>

Research Support (please list all grant/award numbers supporting this protocol):

Organization / Agency Name	Grant / Award Number	Type*						
*Type	A	B	C	D	E	F	G	H
	NIH Intramural Research	NIH Extramural Research	Other Federal Funding	State Funding	Funding Outside of US	Private Foundation	Industry	Other; specify

Section 2.**Liability**

Initials of Applicant: _____

Requester's Institution acting through its investigator ("Applicant") agrees that any Select Agent delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. The United States Government, and their Suppliers and contributors of Select Agents ("Providers") MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE SELECT AGENTS WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Unless prohibited by federal and/or state law, Applicant assumes all liability for claims for damages against it by third parties which may arise from the use, storage, or disposal of the Select Agents except that, to the extent permitted by federal and/or state law, the Providers shall be liable to the Applicant when the damage is caused by the gross negligence or willful misconduct of the Providers. The legal process for filing and adjudicating such claims against the Applicant or Providers will be subject to all applicable state and/or federal laws.

Certification of Compliance with Safety Standards

Initials of Applicant: _____

I am aware that all Select Agents distributed by the SADA are biohazardous and are specifically designated by a biohazard symbol. I understand that the Select Agents might pose health risks to the environment, the community, and people handling or in the vicinity of the Select Agents. I certify that I am cognizant of and will employ the appropriate biosafety standards, including special practices, equipment, and facilities. I shall comply with all applicable institution and Government health and safety regulations and the guidelines detailed in *Biosafety in Microbiological and Biomedical Laboratories*, 5th Edition, HHS Publication No. (CDC) 21-1112, Revised December 2009, or the most recent revision of these guidelines. I will directly supervise all users of the Select Agents and I will assume responsibility for assuring that those users are cognizant of and comply with safety standards and good laboratory practices.

Certification of Use

Initials of Applicant: _____

I certify that all Select Agents (or derivatives containing entire or partial sequences derived or contained with the material) provided by the SADA Program will be used for research purposes only, in my laboratory only, at this institution only. Also, the Select Agents or derivatives will not be allowed to come into the possession of any people other than those engaged in research under my direct supervision in this laboratory without advance written approval of Provider. These materials and derivatives will not be transferred to another laboratory or facility or Principal Investigator. The Select Agents obtained under this agreement will not be used for commercial purposes such as screening, production or sale, for which a commercialization license may be required, unless a separate Commercial License agreement is obtained. The contributors of the Select Agents and SADA reserve the right to distribute the Select Agents to others and to use the Select Agents for its own purposes. When the Research Focus is completed or three (3) years have elapsed, whichever occurs first, the Select Agents will be disposed of as directed by the contributors of the Select Agents and SADA.

Commercial license information requests should be directed to Technology Development Coordinator, OD, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), MS E-51, 1600 Clifton Road, N.E., Atlanta, Georgia 30333. Phone (404) 498-3262, Facsimile (404) 498-3255; or Email: ncidtecdev@cdc.gov.

Human Use

Initials of Applicant: _____

I agree to comply with Protection of Human Subjects, Title 45, Code of Federal Regulations, Part 46. I certify that none of the Select Agents and any derivatives provided will be used in humans or for any clinical diagnosis without receiving prior written approval from the Director, NCEZID, CDC.

Animal Use

Initials of Applicant: _____

I agree that Select Agents provided by the SADA Program and any materials derived from said Select Agents will be used in animals only as described in *Public Health Service Policy on Humane Care and Use of Laboratory Animals*, October, 2000, or the latest version thereof. (Copies can be obtained from the NIH Division of Animal Welfare [301-594-2506] or the United States Government Printing Office, Publication No. 249-260). I understand that Institutional Animal Care and Use Committee (IACUC) approval is required prior to use of any SADA Select Agents in research involving animal subjects. Might the Select Agents be used in animals?

Yes ___ No ___. If yes, please provide the following: Most Current Institutional Animal Welfare Assurance of Compliance Number: _____ Approval Date: _____

Assumption of User Fee

Initials of Applicant: _____

I agree to assume the costs of a user fee for Select Agents requested. No shipments will be made until the SADA Program has received the user fee from the Approved Applicant.

Acknowledgment of Source

Initials of Applicant: _____

I agree that in all oral presentations or written publications concerning the Select Agents, I will acknowledge the contributors of the Select Agents and SADA unless requested otherwise. To the extent permitted by law, I agree to treat in confidence, for a period of three (3) years from the date of its disclosure, any of SADA's written information about the Select Agents that is stamped "CONFIDENTIAL," except for information that was previously known to applicant investigator or that is or becomes publicly available or which is disclosed to applicant investigator without a confidentiality obligation. Any oral disclosures from the contributors of the Select Agents and SADA to applicant investigator shall be identified as being CONFIDENTIAL by notice delivered to applicant investigator within ten (10) days after the date of the oral disclosure. Applicant investigator may publish or otherwise publicly disclose the results of the research focus, but if the contributors of the Select Agents and SADA have given CONFIDENTIAL information to applicant investigator such public disclosure may be made only after the contributors of the Select Agents and SADA have had thirty (30) days to review the proposed disclosure to determine if it includes any CONFIDENTIAL information, except when a shortened time period under court order or the Freedom of Information Act pertains.

The suggested form for acknowledgment is: "The following Select Agents were obtained through the Select Agent Distribution Activity (SADA) of NCEZID, CDC: (Select Agents name) from (Select Agents contributor name)."

Reporting Agreement

Initials of Applicant: _____

I agree to provide the SADA Program with a description of the proposed use of the requested Select Agents with each isolate request, to be separately submitted for each isolate request I place. (This description of proposed use is for internal tracking purposes only). If my employment and/or association

with the institution identified on the first page of this form is terminated, I further agree to provide written notification to the SADA Program at least thirty (30) days prior to my departure from said institution.

Additional Requirements

Initials of Applicant: _____

- a. Recipient's Biosafety Committee/Office shall accept full responsibility for the safety of the Research Project.
- b. No later than one (1) month before a publication concerning the results obtained with the Select Agent is going to be submitted, Recipient agrees to send a copy or draft of the paper to the SADA Program Administrator. If there is no publication, the Recipient agrees to communicate the results of the studies concerning the Select Agent to the SADA Program Administrator. All results and papers received by SADA will be forwarded to the Select Agent Contributor in NCEZID. All results and papers received by SADA and Select Agent Contributors will be treated as CONFIDENTIAL until published. Recipient will notify SADA of dates of publication of any reports of results with Select Agent and furnish published copies of the report.
- c. Recipient shall comply with Select Agent rules applicable to the Select Agent received.
- d. The Select Agent (or derivatives) will not be used in research projects involving collaboration with a for-profit organization; sponsored or funded by a for-profit organization; in which the requestor's institution or the applicant is obligated to assign inventions containing the research material or offer an exclusive license to inventions containing the research material to an organization other than the recipient or a contractor of the recipient that manages the recipient's inventions on behalf of the recipient; or in which the recipient or the recipient scientist is obligated to receive permission from an organization other than the recipient before publicly disclosing results of research involving the research material.
- e. The recipient will obtain the appropriate USDA permit (when applicable) prior to the importation or interstate movement of the requested select agent when such agent is an overlap or USDA only select agent.

Indemnification

If applicant is not an U.S. Federal government employee, please complete the Standard Indemnification OR the U.S. State Compliance Agreement as appropriate.

Standard Indemnification Agreement

Researchers at private (for profit) universities, foundations, companies, foreign entities, or state institutions must accept the wording of the Standard Indemnification Agreement and must complete this form by signing below in order to obtain Select Agents from SADA, NCEZID.

United States Government employees are not required to submit an indemnification agreement. For researchers at state institutions in the United States that cannot accept the terms of this agreement, a State Institution Compliance Agreement is provided on the next page.

As a Receiving Party of Select Agents (the “Substances”) from SADA, NCEZID, the Applicant’s Institution, _____, agrees to indemnify and hold harmless the United States Government and its divisions, affiliates, parents, subsidiaries, all their directors, officers, employees and agents, and their suppliers and contributors of Select Agents, from any claims, judgments, costs, damages, or expenses (including reasonable attorney fees) resulting from any injury to property and persons (including death), that may arise from the possession and use of the Substances or any derivative thereof by the Receiving Party. The officer who is executing this agreement on behalf of the Applicant’s Institution warrants that the officer has full authority to do so, and to thereby legally bind the Applicant’s Institution.

Applicant (Signature)

Officer of Institution (Signature)

Printed Name

Printed Name

Title

Title

U.S. State Institution Compliance Agreement

Note: This agreement is for researchers at state institutions in the United States only; researchers at private (for profit) institutions may not submit this form.

Researchers at public institutions in the United States that cannot sign the Standard Indemnification Agreement on the previous page must complete this State Institution Compliance Agreement to obtain Select Agents, which are all biohazardous and are designated by a biohazard symbol.

As a receiving party of Select Agents (the “Substances”) from the SADA, NCEZID the Applicant’s Institution, _____, agrees to be responsible for any claims, judgments, costs, damages, or expenses resulting from any injury to property and persons (including death), damage, or loss that may arise from the possession and use of the Substances or any derivative thereof by the Receiving Party ***to the extent permitted under the laws of the State identified below.***

The officer who is executing this agreement on behalf of the Applicant’s Institution warrants that the officer has full authority to do so, and to thereby legally bind the Applicant’s Institution.

Applicant (Signature)

Officer of Institution (Signature)

Printed Name

Printed Name

Title

Title

I Concur with All Statements Made Above

*The officer who cosigns below must be someone who can legally bind your institution, such as a president, vice-president, dean, provost, or corporate officer. A department chairman cannot serve as a cosigner for this form.

Applicant (Signature)

Printed Name

*Officer of Institution (Signature)

Printed Name

Title

Institution

Street Address

City, State Zip

Date



Section 3.**Biographical Sketch**

Complete this section or, alternately, attach a Biographical Sketch from a recent NIH Grant Proposal or a brief curriculum vita.

Education

List the degrees you have received in chronological order, ending with the most recent.
Begin with Baccalaureate or other initial professional education and include postdoctoral training.

Institution	Location	Degree	Year Conferred	Field of Study

Research and Professional Experience

Concluding with your present position, please list, in chronological order, your three most recent professional positions.

Employer	Title	Dates of Employment

Publications

List articles you have published recently (maximum of one page in length).

Section 4.

Research Focus

The Select Agents will be used by Applicant investigator solely in connection with the research project described below or in attached abstract from grant proposal (one page or less.)