**Select Agent Distribution Activity (SADA): Request for Select Agent**
**(OMB Control No. 0920-0591**
**Request for Reinstatement without change**

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This is a request for a reinstatement without change to a currently approved information collection request (ICR). This ICR expired on February 28, 2011. This ICR does not contain any revisions to the currently approved data collection instrument.

## A. Justification

### 1. Circumstances Making the Collection of Information Necessary

### Background

On June 12, 2002, Former President G.W. Bush signed Public Law 107-188 "Public Health Security and Bioterrorism Preparedness and Response Act of 2002" to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies. Section 319D ("Revitalizing the Centers for Disease Control and Prevention", Attachment B) of Public Law 107-188 states that the CDC "has an essential role in defending against and combating public health threats". Distribution of select agents without first reviewing the scientific merit of the proposed research for which the select agents are being requested does not support Public Law 107-188 nor does it stress the importance of accountability and responsibility that the CDC expects from the requestor.

The term select agents is used to described a limited group of viruses, bacteria, rickettsia, and toxins that have the potential for use as agents of bioterrorism, inflicting significant morbidity and mortality on susceptible populations. The Centers for Disease Control and Prevention (CDC) is requesting OMB approval to extend OMB Control No. 0920-0591: Select Agent Distribution Activity (SADA. The purpose of this project is to provide a systematic and consistent mechanism to review requests that come to CDC for Select Agents. In light of Public Health and Bio-Defense needs, research with Select Agents is being encouraged and funded at significant levels ($1.7 billion in NIH grants). The National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) receives request for Select Agents because most researchers do not have these Select Agents in hand and will have to obtain them. In order to respond in a consistent fashion and provide appropriate review, CDC established a process which includes the creation of the Select Agent Distribution Activity.

Section 361 of the Public Health Service (PHS) Act (42 USC 264, Attachment A) authorizes the Secretary of Health and Human Services to make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States, or from one state or possession into any other state or possession.

Privacy Impact Assessment
Overview of Data Collection System

This data collection activity is for facilitating the evaluation of requests and the distribution of select agents from NCEZID to qualified users. The SADA application includes an updated version of the Material Transfer Agreement (MTA) that is specific to the transfer of select agents.

Items of Information to be Collected

The items will include the requestors name and contact information, the Select Agent they are interested in obtaining, including the quantity, grants/awards they have received to support the protocol, a Biographical Sketch or curriculum vita and a description of the research project/focus of which the materials are being requested.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age
Under no circumstances will CDC sponsored data collection, website or internet content be directed at children under the age of 13.

**2. Purpose and Use of the Information**

NCEZID established 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 (Attachment D). This procedure is necessary in order to be granted status as a SADA "Qualified Applicant." The Qualified Applicant 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. 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 bio-sketch or curriculum vita of the applicant and a Certificate of Registration and the Transfer Authorization by the Select Agent Program

The NCEZID SADA Executive Committee (an advisory board composed of NCEZID subject matter experts and established to review applications and provide program oversight and guidance) 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.

Privacy Impact Assessment Information

Although sensitive information is collected, in terms of which Select Agents are being collected and by whom, this is more of an internal security matter rather than in regards to respondent's privacy. Personal information of a sensitive nature is not collected from requestors. Regardless,

stringent safeguards (locked files located in a very limited access area) are in place.

**3. Use of Information Technology and Burden Reduction**

The requestor will be able to retrieve the SADA application (Adobe Acrobat format, .PDF) via download from the SADA website (www.cdc.gov/sada) to their computer and print it. Because all application documents must contain original ink signatures for identification and indemnification, SADA *will not accept* application forms electronically or by FAX. The completed application with original signatures must be mailed directly to the SADA Administrator for processing.

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

Meetings with key staff from the CDC Select Agent Program (SAP), CDC Responsible Facility Official, CDC General Counsel, CDC Forms Management, and NCEZID Administrative and Scientific Management were held to identify potential areas of duplication. In addition, an activity diagram was developed to address the logic behind the flow of information between the various parties, components and offices involved in requesting and approving a select agent transfer. Some data about the principal investigators and facilities exist within the SAP; however SADA is precluded from accessing that information for security reasons. The SADA form standardizes the Material Transfer Agreement (MTA), which is normally negotiated and created uniquely for each situation, thus eliminating a burden for both the requestors and NCEZID staff. The SADA form eliminates the need for duplication of information on several forms by consolidating the MTA and indemnification statements with the request. The SADA form allows for copies of CVs and grant proposal abstracts to be attached in lieu of filling out the bio-sketch and project description portions of the application.

**5. Impact on Small Businesses or Other Small Entities**

No small businesses will be involved in this data collection.

**6. Consequences of Collecting the Information Less Frequently**

This is essential to the missions of the CDC, NIH and DHHS in that research with Select Agents is vitally urgent to Public Health interests. If the form and process are not used, research will be significantly delayed and, potentially, the public health will be affected. Further delay will preclude the use of or the ability to apply for the NIH grant funds as designated in legislation within the established deadlines. If a system that justifies why select agents are being distributed is not in place, it will not reflect favorably on the CDC or the Federal government.

By requiring scientists to submit an application each time a different select agent is being requested, and having a standard means of carefully reviewing those applications, prior to distribution of such agents, the risk that the agents will be used for bioterrorism is minimized. If the information is not collected, NCEZID will not have sufficient means to determine the validity of the request.

Regarding technical and legal obstacles to reducing the burden of information collection: Online collection of information and requests was considered. It would require registration of individuals, verification of identity, and digital identity management; the sum total of which was determined to be more onerous to the requestor and far more expensive to the government than the completion of a paper form. The legal requirements of the MTA contract and Select Agent transfer necessitate original, physical signatures.

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

This is essentially a one-time activity. If a scientist is interested in acquiring a different select agent than the one requested on the initial application, s/he will have to complete a new SADA "Request for Select Agent" application for that select agent.

Multiple select agent requests may not be submitted on the same form for both record keeping sake and processing ease. By entering each request individually, we can know exactly how many individual requests for select agents have been received and watch out for suspicious request patterns. In addition, the SADA Executive Committee is composed of a group of Subject Matter Experts (SMEs) that are assigned to specific select agents. If a requestor were to request two or more select agents per application, this would increase the review process time as it would have to be reviewed by each SME assigned to the requests made on the application.

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

**A.** A 60-day Federal Register Notice was published in the Federal Register on March 4, 2011, vol. 76, No.43, pp. 12118-12119 (see Attachment C). There was one public comment. A copy of that comment and CDC's response is found in Attachment D.

**B.** In 2003 several researchers outside the agency who were known to have a desire to obtain select agents were contacted. The contacts included: Dr. James Rogers, Research Microbiologist, US Army (410-436-8990); Dr. Jean Citron, Medical Researcher, Kansas City VA Medical Center (816-861-4700 ext. 7118); Dr. Bob Perry, Professor of Microbiology, University of Kentucky (859- 323-6341); Dr. Fred Heffron, Professor of Microbiology, Oregon Health Sciences University (503- 494-7768) and Dr. James D. Marks, Professor of Anesthesia and Pharmaceutical Chemistry, University of California at San Francisco. A telephone number is not available for Dr. Marks as he was contacted by email. (MarksJ@anesthesia.ucsf.edu).

Evaluation of the form on clarity, content and time required was requested. The final draft of the form was sent to those who volunteered and minor formatting revisions were made based on their comments.

**9. Explanation of Any Payment or Gift to Respondents**

No payment or gift will be provided to respondents.

**10. Assurance of Confidentiality Provided to Respondents**

The CDC Privacy Act Officer has reviewed the OMB request and has determined that the Privacy Act is not applicable. The primary focus of this activity is on the institution that will be housing the select agent. While there will be limited information on that institution's staff (the applicant investigators and their qualifications), the key element is the institution (which already maintains information on these individuals). While limited information on publications of applicants is requested on the form, the individuals will be speaking in their roles as applicant investigators requesting a select agent. Further, the application instructions point out that the requestor must already be registered with the Select Agent Program. The determination on the "Possession, Use and Transfer of Select Agents and Toxins, 42 CFR Part 73" was that the Privacy Act did not apply because respondents were speaking in their roles as the Responsible Officials possessing the select agent or toxin. Furthermore, the information has been deemed to not be FOIAable. Pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, we would withhold the data in response to a FOIA request under exemption 3 (other statutes).

The information is being treated at the highest level of sensitivity because it contains the potential location of select agents and who will have access to them. The applications received will be stored under triple lock security: they will be locked in a secure file cabinet located inside a locked file room, which is located within a secured (via cardkey reader) office. Keys and access have been and will be severely restricted; initially to only the SADA Administrator and Director of the Scientific Resources Program. The office is located inside a limited access corridor. In addition, data entry will be conducted inside the secured file room into a "free-standing" (non-networked) computer. The SADA Administrator will not divulge any identifying information about SADA applicants to anyone other than personnel on a “need to know” basis to conduct official business. In general conversation outside the workplace, neither the identifying information, the nature of the data collected, nor the means by which they are collected will be discussed in any detail. No data (or copies of the data) are to be retained by any contractor after completion of the period of performance of the contract.

<u>IRB Approval</u>
IRB approval is not required for this study.

<u>Privacy Impact Assessment Information</u>

A. This submission has been reviewed by ICRO, who determined that the Privacy Act does not apply. The applicable System of Records Notice is 09-20-0168.

B. The applications received are locked in a secure file cabinet located inside a locked office. Keys and access are severely restricted; available only the SADA Administrator and Director of the Scientific Resources Program.

C. Consent is not obtained because the primary focus of this activity is on the institution that will be housing the select agent. Respondents are told that the intended use of the information collected on the SADA application is to facilitate the evaluation of requests and the distribution of select agents from NCEZID to qualified users.

D. Requestors are informed that they are required to complete the SADA application; a specialized Material Transfer Agreement (MTA) if they would like to receive the material.

**11. Justification for Sensitive Questions**

Questions of a sensitive nature, such as race, ethnicity, sexual behaviors and attitudes, religious beliefs, and other matters that are commonly considered private will not be asked on the SADA application. It is not necessary to obtain such information for the purpose of this activity.

**12. Estimates of Annualized Burden Hours and Costs**

A. The form was tested to determine hour burden based on previous experience with forms from the last OMB clearance. Although the rate of requests received has dramatically decreased, we would like to continue providing this service. However, the number of respondents in a given year is unknown. The estimates below are based on if we were to receive requests from 900 respondents:

A.

| Respondents | No. of Respondents | No. of Responses per Respondent | Average Burden per Response (in hours) | Total Burden (in hours) |
|---|---|---|---|---|
| Researcher | 900 | 1 | 30/60 | 450 |

B. Based on the rates of pay for employees in senior-level and scientific or professional positions gathered from the Office of Personnel Management (OPM) website, we estimate that the hourly rate ranges from $30-$75/hour with an average of $53/hour. At this rate, the annual cost burden for 450 hours of work would be $23,850.

| Employees | Hourly Rate Range | Average Rate | Total Burden (in hours) | Annual Cost Burden |
|---|---|---|---|---|
| senior-level scientific/professional positions | $30-$75/ hour | $53/hour | 450 | $23,850 |

**13. Estimates of other total annual cost burden to respondents or record keepers**

An estimate of the total annual user fee cost for the select agents is between $21,600 and $246,600 with an average of $134,100 (the lowest and highest user fees were multiplied by 450 respondents to get these figures).

A user fee (inclusive of the cost for the select agent, handling, and shipping) will be collected from all respondents except those from public health laboratories. However, the cost to the respondent will vary based on which select agent is requested.

**14. Annualized Cost to the Federal Government**

| **Annualized Expenses Incurred for SADA** | **$Amount** |
|---|---|
| Estimate of annualized cost to the Federal government per year: | $ 40,236.15 |
| Total cost for purchase of startup materials | $ 31,835.30 |
| Total startup cost for personnel: | $ 21,518.63 |
| Total Start Up Cost (materials + personnel): | $53,353.93 |

**15. Explanation for Program Changes or adjustments**

CDC is updating the name of the National Center at CDC responsible for this activity. The National Center for Emerging and Zoonotic Infectious Diseases was officially recognized in July, 2010. In addition, based on transfer authorization requirements of the Select Agent Program, new verbiage was added to the SADA application coversheet.

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

CDC is requesting a 3-year application approval from OMB. The information collected will not be published unless it is decided that a report on the various research projects being conducted using the various select agents is found to be in the best interest of the public/scientific community.

**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.

**18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to this certification.