

1SUPPORTING STATEMENT

1110-0039

FEDERAL BUREAU OF INVESTIGATION BIOTERRORISM PREPAREDNESS ACT: ENTITY/INDIVIDUAL INFORMATION

A. Justification.

1. Necessity of Information Collection

In June 13, 2002, the President of the United States signed the Public Health and Bioterrorism Preparedness and Response Act of 2002, (Bioterrorism Act), Public Law 107-188 into effect. Under this Act, the Secretaries of the United States Department of Agriculture (USDA) and Health and Human Services (HHS), in consultation with the U.S. Attorney General, are responsible for establishing the appropriate safeguards and security requirements for persons possessing, using, or transferring select biological agents and toxins. Responsibility for implementing these requirements has been designated to the Animal and Plant Health Inspection Service and by the Secretary, USDA, and to the Centers for Disease Control and Prevention by the Secretary, HHS. Under the Bioterrorism Act, the Department of Justice/FBI is responsible for conducting a Security Risk Assessment (SRA) of individuals who have been identified by the USDA and HHS as requiring access to select biological agents and toxins.

On January 30, 2003, the U.S. Attorney General directed the FBI to conduct the Bioterrorism SRAs under sections 201, 212 and 221 of the Public Health Security and Bioterrorism Act, Pub. L. 107-188, 166 Stat. 594 (2002). On March 25, 2003, FBI Director Mueller directed the Criminal Justice Information Services (CJIS) Division to conduct the Bioterrorism SRAs. Under this delegation, the FBI receives names and other identifying information submitted by individuals requesting access to specified agents and toxins; utilizes electronic databases and other sources of information to conduct SRAs of such individuals; and consult with appropriate officials of the HHS and the USDA to determine whether certain individuals should be denied access to or granted limited access to specified agents.

The HHS and USDA provide the CJIS Division with completed FD-961 Information Forms which contain identifying information on the individual seeking access to the listed agents and toxins. The CJIS Division uses identification information submitted by each individual to complete SRAs on the following databases: Interstate Identification Index (III), the National Crime Information Center (NCIC) "hot files", the FBI Indices, the Foreign Terrorist Tracking Task Force (FTTTF) Database, the Bureau of Immigration and Customs Enforcement (ICE) Databases, and the FBI's Department of Veterans Affairs (DVA) Database. A "routine use" is being established to allow the CJIS Division access to the Department of Defense's (DOD) dishonorable discharge data for Bioterrorism SRAs.

A revision of this currently approved collection is requested in addition to a 3-year extension.

1The revisions on the existing form are:

Under INSTRUCTIONS add the following in bold type:

Accessing the FD-961 Form and Instructions

The first paragraph will be revised as follows:

The FD-961 Form and these instructions can be accessed at the FBI, Criminal Justice Information Services (CJIS) Division web page at www.fbi.gov/about-us/cjis/bioterrorism-security-risk-assessment-form.

Requesting Fingerprint Cards

Fingerprint card packages can be obtained by faxing a request to the CJIS Division at 304-625-3984. The request should include the following: entity name, point of contact, mailing address, contact's telephone number and quantity of requested bioterrorism fingerprint card packages.

Requirements for New or Inactive Applicants

For applicants that do not have an active Security Risk Assessment (SRA) on file with the Bioterrorism Risk Assessment Group (BRAG), the FD-961 Form and two legible fingerprint cards must be completed and mailed as one package to:

Bioterrorism Risk Assessment Group, Module E-3
Criminal Justice Information Services Division
Federal Bureau of Investigation
1000 Custer Hollow Road
Clarksburg, WV 26306

Requirements for Active Applicants

If the applicant has an active SRA on file with BRAG, the FD-961 Form can be completed and faxed to BRAG at 304-625-2198. Fingerprint cards are not required; however, BRAG reserves the right to request additional fingerprint cards if necessary.

Federal Select Agent Program (FSAP) Information

Please refer to the APHIS/CDC National Select Agent website at www.selectagents.gov or contact your APHIS or CDC Representative for questions regarding the FSAP. General guidance can be found at the website including who requires an SRA, obtaining a Unique Identifying Number (UIN), expediting an SRA, and other frequently asked questions.

Remove **GENERAL GUIDANCE ON COMPLETING THE FD-961 FORM:** and replace with the following in bold type: **Completion of FD-961 Form**

Add the following statement in italics:

Please note that incomplete, expired (Rev. 10-31-09 and earlier) or outdated forms (signature date exceeds 90 days) will not be processed.

Section I block 1 should be changed to read Provide the legal name of the entity and the entity registration number supplied by APHIS or CDC (AGRXXXXXX or CDCXXXXXX).

Section I block 2 – Provide the physical address for the entity including street, city, state and zip code.

Remove Section I block 3.

Section II should be revised as follows:

3. Provide the UIN supplied by APHIS or CDC, formerly known as the DOJ Number. APHIS or CDC provides the UIN for each individual listed on the APHIS/CDC Form 1 to the RO.

4. Applicant's full name (last, first, middle, and suffix, e.g. Jr. or III). The name provided in block 4 should be identical to that listed on the APHIS/CDC Form 1. Include any Aliases/Maiden names.

7. Applicant's physical residential address including street, city, state and zip code. Forms received with a foreign address will not be processed. Additionally, list all states that the applicant resided in as an adult (18 yrs of age and older).

Please note that forms submitted prior to a foreign national's entry into the U.S. will return an immigration check result of "no record of legal entry into the U.S." The SRA will be completed and the individual will be identified as a restricted person (unlawful or illegal alien). If a foreign national will be in the U.S. briefly and completion of the SRA is urgent, an expedited SRA request can be submitted to APHIS or CDC once the individual enters the country.

10. Applicant's city and state, or country of birth. If the applicant is a national of more than one country, list each country of citizenship. Additionally, list any citizenship(s) that the applicant has renounced.

11. If born to a US citizen serving a military or diplomatic post in a foreign country please include a copy of the US Citizen Born Abroad Certificate or a copy of the applicant's U.S. Passport with the FD-961 Form.

Alien registration or admission numbers are issued by the Bureau of Immigration and Customs Enforcement for individuals who are granted lawful permanent resident or naturalized citizen statuses in the U.S. Other situations that individuals would have an alien registration or admission number include the following: Employment Authorization Cards, Temporary Resident Cards, Border Crossing Cards, I-94 or Visa Numbers.

The most common immigration statuses include: naturalized citizen, lawful permanent resident, student (F1), exchange visitor (J1), or temporary specialty worker (H1, H1B). The status expiration date is also referred to as the "admitted until" date. Temporary statuses may list "duration of status" as an expiration date. Please include this in the status expiration field on the form.

Add Section III:

Section III:

18 U.S.C. § 1001 states that knowingly and willfully falsifying or concealing a material fact is a felony that may result in fines or imprisonment for not more than 5 years or both.

12a - 12i: Answer all questions with a "yes", "no" or "unsure" in the boxes provided. FD-961 Forms with questions left blank will not be processed.

If the applicant is not sure how to answer any question, they should check "not sure". For any questions answered "not sure", the applicant must provide additional information or supporting documentation to assist BRAG in processing the SRA. This information can include court documents, arresting agency information, arrest date, charges, etc. For medical documentation the applicant should contact the medical facility, sign a release and have the medical facility mail the documentation directly to BRAG.

12a. Indictment - Includes an indictment or information in any court, under which a crime punishable by imprisonment for a term exceeding 1 year may be prosecuted, or in military cases to any offense punishable by imprisonment for a term exceeding 1 year which has been referred to a general court-martial. An information is a formal accusation of a crime, differing from an indictment in that it is made by a prosecuting attorney and not a grand jury.

12a. &b. Crime punishable by imprisonment for a term exceeding 1 year - Any Federal, State or foreign offense for which the maximum penalty, whether or not imposed, is capital punishment or imprisonment in excess of 1 year. What constitutes a conviction of such a crime shall be determined in accordance with the law of the jurisdiction in which the proceedings were held. Any conviction which has been expunged or set aside or for which a person has been pardoned shall not be considered a conviction.

12c. Fugitive from justice - Any person who has an active warrant, regardless of reason (to avoid prosecution for a felony or misdemeanor, or to avoid giving testimony in any criminal proceeding, etc).

12d. Unlawful user of or addicted to any controlled substance - A person who uses a controlled substance and has lost the power of self-control with reference to the use of controlled substance; and any person who is a current user of a controlled substance in a manner other than prescribed by a licensed physician. Such use is not limited to the use of drugs on a particular day, or within a matter of days or weeks before, but rather that the unlawful use has occurred recently enough to indicate that the individual is actively engaged in such conduct. A person may be an unlawful current user of a controlled substance even though the substance is not being used at the precise time the person seeks access to biological select agents and toxins. An inference of current use may be drawn from evidence of a recent use or possession of a controlled substance or a pattern of use or possession that reasonably covers the present time, e.g., a conviction for use or possession of a controlled substance within the past year; multiple arrests for such offenses within the past 5 years if the most recent arrest occurred within the past year; or persons found through a drug test to use a controlled substance unlawfully, provided that the test was administered within the past year. For a current or former member of the Armed Forces, an

inference of current use may be drawn from recent disciplinary or other administrative action based on confirmed drug use, e.g., court-martial conviction, nonjudicial punishment, or an administrative discharge based on drug use or drug rehabilitation failure.

Controlled Substance – A drug or other substance, or immediate precursor, as defined in section 102 of the Controlled Substances Act, 21 U.S.C. 802. The term includes, but is not limited to, marijuana, depressants, stimulants, and narcotic drugs. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in Subtitle E of the Internal Revenue Code of 1954, as amended.

12e. Adjudicated as a mental defective – (a) A determination by a court, board, commission, or other lawful authority that a person, as a result of marked subnormal intelligence, or mental illness, incompetency, condition or disease: (1) is a danger to himself or to others; or (2) lacks the mental capacity to contract or manage his own affairs. (b) The term shall include (1) a finding of insanity by a court in a criminal case; and (2) those persons found incompetent to stand trial or found not guilty by reason of lack of mental responsibility pursuant to articles 50a and 72b of the Uniform Code of Military Justice, 10 U.S.C. 850a, 876b.

Committed to a mental institution – A formal commitment of a person to a mental institution by a court, board, commission, or other lawful authority. The term includes a commitment to a mental institution involuntarily. The term includes commitment for mental defectiveness or mental illness. It also includes commitments for other reasons, such as for drug use. The term does not include a person in a mental institution for observation or a voluntary admission to a mental institution.

Mental institution – Includes mental health facilities, mental hospitals, sanitariums, psychiatric facilities, and other facilities that provide diagnoses by licensed professionals of mental retardation or mental illness, including a psychiatric ward in a general hospital.

12f. Alien – Any person not a citizen or national of the United States.

Alien illegally or unlawfully in the United States - Aliens who are unlawfully in the United States are not in valid immigrant, nonimmigrant or parole status. The term includes any alien (a) who unlawfully entered the United States without inspection and authorization by an immigration officer and who has not been paroled into the United States under section 212(d)(5) of the Immigration and Nationality Act (INA); (b) who is a nonimmigrant and whose authorized period of stay has expired or who has violated the terms of the nonimmigrant category in which he or she was admitted; (c) paroled under INA section 212(d)(5) whose authorized period of parole has expired or whose parole status has been terminated; or (d) under an order of deportation, exclusion, or removal, or under an order to depart the United States voluntarily, whether or not he or she has left the United States.

12g. – (i) An alien (other than an alien lawfully admitted for permanent residence) who is a national of a country as to which the Secretary of State has made a determination that such country has repeatedly provided support for acts of international terrorism or, (ii) any individual (regardless of nationality) that acts for or on behalf of, or operates subject to the direction or control of, a government or official of the countries listed below.

State Sponsor of Terrorism	Designated Date
Syria	12-29-1979
Cuba	03-01-1982
Iran	01-19-1984
Sudan	08-12-1993

12h. Discharged under dishonorable conditions - Separation from the U.S. Armed Forces resulting from a dishonorable discharge or dismissal adjudged by a general court-martial. The term does not include any separation from the Armed Forces resulting from any other discharge, e.g. a bad conduct discharge.

12i. Terrorist organization - An organization (i) designated by the Secretary of State as a foreign terrorist organization (ii) otherwise designated by the Secretary of State in consultation with or upon the request of the Attorney General or the Secretary of Homeland Security as a terrorist organization; or (iii) that is a group of two or more individuals, whether organized or not, which engages in, or has a subgroup which engages in terrorist activity [as defined in 8 U.S.C. 1182 (a) (3)(B)]

Add Section IV:

Section IV:

By signing, the applicant certifies that the questions in Section III are true, correct and complete. Also, the applicant's signature gives consent to the U.S. Department of Justice to complete the SRA. The printed name must be legible. The signature date must be current (occurring within the last 90 days).

Add Section V:

Section V:

By signing, the RO or ARO certifies that the completed FD-961 Form was reviewed for completeness, legibility, and that the certification questions have been reviewed and handled accordingly. Please include an email address for requests for additional or incomplete information.

Questions concerning completion of the FD-961 Form can be directed to BRAG at 304-625-4900.

Completion of Fingerprint Cards

Modify the existing paragraphs with the following paragraph:

The fingerprint card packet consists of two fingerprint cards, general instructions, fingerprint instructions, and a pre-addressed return envelope. The following fields should be completed on the fingerprint cards: residence, employer and address, name, aliases, citizenship, social security number, sex, race, height, weight, eye color, hair color, date of birth and place of birth. The

applicant must have the two fingerprint cards printed by a local law enforcement agency. The individual or entity must arrange for this service. In most instances, law enforcement offices will charge a fee for this service. The two fingerprint cards and completed FD-961 Form must be submitted to the FBI as one package for the security risk assessment to be completed. The FBI may request a second set of prints to process in the event that the initial two fingerprint cards are rejected from the Integrated Automated Fingerprint Identification System for image quality.

The **PRIVACY ACT STATEMENT** will remain unchanged

1The FD-961 Form Revisions:

On the top header, change FD-961 Revision date of 10-31-09 and replace with 03/14/2012. Replace the expiration date of 10-31-2012 with 10/13/2015.

Section I, block 1 replace Application Number with Registration Number. Replace (Supplied by APHIS or CDC) with (AGRXXXXXX or CDCXXXXXX)

Section I, block 2 remove County.

Section I block 3 remove Type of Applicant

Section II add block 3 Unique Identifying Number (UIN Supplied by Sponsor):.

Section II block 7 remove Number. Add 7a. Additional State(s) of Residence:.

Section II block 9 remove Place of Birth and add Race: White, Black of African, Hispanic or Latino, Asian/Native Pacific Islander, American Indian or other Alaska Native with check mark boxes.

Section II block 10 remove race and add Place of Birth (City and State or Foreign Country);, Country or Countries of Citizenship; Renounced Country or Countries of Citizenship:.

Section II block 11 remove DOJ Number and add Foreign Place of Birth Information (If born in the U.S., proceed to Section III. If a U.S. Citizen Born Abroad, attach a copy of the born abroad certificate or U.S. passport and proceed to Section III), Alien Registration Number or Admission Number (9-11 digits);, Current Immigration Status and Expiration; Mother's Full Maiden Name; Father's Full Name; Date and Place of Entry; Immigration Status at Entry:.

Section III - Start Section III Certification Questions after block 11 and before 12a.

Section III block 12a remove "a felony or" and add check box Unsure.

Section III block 12b remove "including" and replace with "or" before probation and add check box Unsure.

Section III block 12c add check box Unsure.

Section III block 12d add check box Unsure.

Section III block 12e remove If yes, a complete copy of medical records regarding the commitment will be required and add check box for Unsure.

Section III block 12f add check box Unsure.

Section III block 12g replace with the following: (I) Are you an alien (other than an alien lawfully admitted for permanent residence) who is a national of a State Sponsor or Terrorism; or (II) acts for or on behalf of, or operates subject to the direction or control of, a government or official of a State Sponsor of Terrorism? and add check box Unsure.

Remove IF NOT BORN IN THE US PLEASE COMPLETE QUESTIONS BELOW TITLED FOREIGN BORN INFORMATION.

Section III block 12h add check box Unsure.

Section III block 12i add the following: Are you a member of, act for or on behalf of, or operate subject to the direction or control of a terrorist organization (as defined in Section 212 of the Immigration and Nationality Act [8 USC 1182])? with check boxes for Yes, No, Unsure.

Remove the following statement: I certify that the above answers are true, correct and complete. I understand that the making of a false, oral or written statement is a crime. Remove Signature and Date lines.

Remove Foreign Born Information including block 13 through 21.

Section III Consent - change to Section IV: Certification and Consent of Applicant (bold type).

Add in bold type: By signing this form, I certify that the above certification answers are true, correct and complete. I understand that making of a false oral or written statement is a crime.

Paragraph 1 - remove By signing this form.

Paragraph 3 - change paragraph to read: I further authorize the U.S. Department of Justice to disclose the results and records or information supporting such results relating to, or obtained in connection with, my security risk assessment to: the U.S. Department of Agriculture; the Department of Health and Human Services; or any agency contractors assisting in the determination of risk.

Paragraph 4 Add after security, in accordance with the U.S. Department of Agriculture and Department of Health and Human Services regulatory authority.

Paragraph 6 - delete.

Bold I understand that this is a legally binding document and false statements provided by me are violations of federal law and may lead to criminal prosecutions or other legal actions.

Add after the signature:

Section V: Certification of Responsible or Alternate Responsible Official (in bold print)

As the Responsible or Alternate Responsible Official, I certify that I have reviewed this form in its entirety for completeness and legibility. Furthermore, I have reviewed the certification questions (Section III) and discussed any issues with the applicant and determined, based up my review, that all certification questions have been answered no prior to transmitting this information to the FBI for the Security Risk Assessment.

Add Print Name: (line for printed name)

Date: (line for date) Email: (line for email)

Signature: (line for signature)

2. Needs and Uses

The Bioterrorism Preparedness Act: Entity/Individual Information FD-961 forms are mandatory in order to receive a Bioterrorism Security Risk Assessment conducted by the CJIS Division. The CJIS Division is provided with completed FD-961 Information Forms which contain identifying information on the individual seeking access to the listed agents and toxins. The CJIS Division uses identification information submitted by each individual to complete SRAs on the following databases: III, the NCIC “hot files”, the FBI Indices, the FTTTF Database, the ICE Databases, and the FBI’s DVA Database. A “routine use” is being established to allow the CJIS Division access to the DOD's dishonorable discharge data for Bioterrorism SRAs. The routine use is established per 42 CFR 73.10(e), 7 CFR 331.10(e), and 9 CFR 121.10(e).

The SRAs are completed and weekly letters are mailed to HHS and USDA as to whether certain individuals should be denied access to or granted limited access to specific agents.

3. Use of Information Technology

Currently, the FD-961 form is not submitted electronically to the CJIS Division. The FD-961 form is available online in a PDF format. The FD-961 form can be completed electronically online but must be printed and mailed to the CJIS Division for processing. The electronic possibility is under consideration with the three agencies (CJIS Division, HHS and USDA) involved in the SRA process. The enhancement to allow for electronic submissions is being looked at but will not be possible until after the Next Generation IAFIS is fully operational. The BRAG will keep looking at this issue and will revisit it once Next Generation IAFIS is complete.

The fingerprint cards cannot be submitted electronically at this time. The current process for submission of electronic fingerprints does not allow for the response to be returned to the BRAG, it will be returned to the submitting agency. Also, civil fingerprints cards are normally submitted with a retention code of do not retain, however, these fingerprints must be retained in our system

in order to be flagged for notification of any new criminal history information. If the submitting agency were to transmit the fingerprints with the wrong retention or other information and the fingerprints were not retained properly in our system, the applicant would be required to return to the submitting agency and be fingerprinted again.

The applicant is required to submit both the FD-961 and the fingerprint cards in order to initiate the SRA. The FD-961 cannot be submitted electronically with the fingerprint cards because IAFIS will not accept this type of submission. Also the signature is required on the FD-961 because the individual is certifying that the information is correct and that false statements are a violation of federal law and may lead to criminal prosecution or other legal action. If there were ever any legal action we would need the signature to verify that the individual was the person who submitted the form. If the FD-961 and fingerprints were submitted separately this would require the BRAG to match up the fingerprints with the correct FD-961 which would require some sort of tracking number to ensure that the fingerprints were not matched up with the wrong FD-961 (especially for individuals with common names).

4. Efforts to Identify Duplication

This information collection was authorized in direct response to enactment of Public Health and Bioterrorism Preparedness and Response Act of 2002, (Bioterrorism Act), Public Law 107-188. The CJIS Division is the only agency collecting extensive data for SRAs. The information being collected is used for the sole purpose of conducting SRAs.

5. Minimizing Burden on Small Businesses

This information will have minimal effect on small entities.

6. Consequences of Not Conducting or Less Frequent Collection

If the FD-961 is not submitted the agencies and or individuals will not be in compliance with the Public Health and Bioterrorism Preparedness and Response Act of 2002, (Bioterrorism Act), Public Law 107-188 which has been congressionally mandated.

7. Special Circumstances

Currently all Bioterrorism SRA information is collected on dates not less than every five years. However, effective June 1, 2011, individuals renewing SRAs will receive access approval to select agents and toxins for a period of three years unless terminated earlier by the entity, APHIS, or CDC. This means that an individual approved for an SRA prior to June 1, 2011 will still be good for a period of five years. The first three year renewal will be seen on June 1, 2014.

On January 9, 2009, President George W. Bush signed Executive Order (EO) 13486 entitled "Strengthening Laboratory Biosecurity in the United States." This EO established a Working Group (WG) co-chaired by the Secretary of Defense and the Secretary of Health and Human Services. The scope of the WG activities pertained to the policy of the United States that facilities that possess biological select agents and toxins have appropriate security and personnel

assurance practices to protect against theft, misuse, or diversion to unlawful activity of such agents and toxins. The WG provided final recommendations through careful consideration of proposals from subgroups, and comments received from select agent entities and the public. The report is available at: <http://orise.orau.gov/emi/scapa/files/biosecurity-report.pdf>.

One of the recommendations to enhance security was to perform an SRA required by the Select Agent Regulations (7 CFR § 331.10, 9 CFR § 121.10, 42 CFR § 73.10) every three years for all individuals with access to select agents and toxins instead of the current policy of performing the SRA every five years. The Federal Select Agent Program concurs with this recommendation.

8. Public Comments and Consultations

This information collection has been overseen by a multi-agency forms steering committee. The final rule regarding possessing use transfer of specific toxins and agents was completed in March 2005. The 30 and 60 day notices were published and the FBI received no comments.

9. Provision of Payments or Gifts to Respondents

The Bioterrorism SRA program does not provide any payments or gifts to respondents.

10. Assurance of Confidentiality

All information will be held confidential in accordance with Title 42, U.S.C. Section 3789 (g). Information will be utilized by the BRAG for the sole purpose of conducting Bioterrorism SRAs in accordance with the Bioterrorism Act and the regulations promulgated thereunder.

11. Justification for Sensitive Questions

The FD-961 Form does ask sensitive questions which are covered under the congressionally mandated Public Health and Bioterrorism Preparedness and Response Act of 2002, (Bioterrorism Act), Public Law 107-188.

The social security number (SSN) is optional for the individual. The SSN is requested on the form in order to conduct a thorough search of the databases. The SSN eliminates candidates who match the individual by name and descriptors which could delay the approval or possibly deny them access to select agents and toxins.

12. Estimate of Respondent's Burden

We estimate the respondent's burden for this data collection as follows:

Number of respondents 4,005 (Fiscal Year 2011)

Frequency of respondents varies depending upon individual applicants but not less than every 5 years

Total annual responses	4,005 (Fiscal Year 2011)
Minutes per response	45 minutes
Annual hour burden	3,004 hours

13. Estimate of Cost Burden

Respondents will incur the cost of \$.88 for postage fees to submit the FD-961 form and two completed fingerprint cards. The total annual cost incurred by the FY2011 respondents is \$3524.40. The fingerprint cards are furnished by the FBI at no cost to the individual.

14. Cost of Federal Government

The estimated average cost per security risk assessment is approximately \$181. The annual cost to the FBI (based solely on FY2011 respondents) is \$724,905.

15. Reason for Change in Burden

Decrease in hour burden and cost burden due to a decrease of security risk assessment renewals received.

16. Anticipated Publication Plan and Schedule

This data collection does not publish any results.

17. Display of Expiration Date

All information collected under this clearance will display the OMB Clearance Number. Any forms disseminated from the FBI's Bioterrorism Risk Assessment Program will include the OMB clearance number.

18. Exception to the Certification Statement

The FBI's CJIS Division does not request an exception to the certification of this information collection.

B. Collection of Information Employing Statistical Methods

The CJIS Division does not employ statistical methods when collecting this information.