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:

Revisions for the Instructions:

Under Completion of FD-961 Form – change the revision date to Rev. 12-05-2012

Section II:

Question 4 should be revised to remove "Include any Aliases/Maiden names."

Add the following:

- 4a. List all Aliases/Maiden Names.
- 5. Provide date of birth.
- 6. Social Security Number

Question 7 should be revised to remove "Additionally, list all states that the applicant resided in as an adult (18 yrs of age and older)."

Add the following:

7a. Indicate if applicant has any additional states of residence.

7b. List all states that the applicant resided in as an adult (18 years of age and older).

Question 11 remove "or a copy of the applicant's U.S. Passport"

Section III:

Change 12i to 12j

Modify the following paragraphs:

If the applicant is not sure how to answer any question, they should check "not sure". For any questions answered "yes" or "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.

Change 12h to the following: *12h. Service in the Armed Forces* – Indicate if the applicant has served in the Armed Forces

Renumber 12h to 12i

Renumber 12i to 12j

Section IV:

Add the following to the end of the paragraph: Electronic signatures are not acceptable.

Section V:

Add the following: Electronic signatures are not acceptable.

The **PRIVACY ACT STATEMENT** will remain unchanged

1The FD-961 Form Revisions:

On the top header, change FD-961 Revision date of 12-05-2012 and replace with 04/01/2014. Replace the expiration date of 5-31-2014 with 5/31/2017.

Add the following in bold print before Section I:

Please answer all questions or put "none' or "not applicable" in the space provided.

Section II block 7. Question 7a "Do you have any additional states of residence?" and add a check box. Question 7b "If yes, list all additional states of residence."

Section II block 11: After Foreign Place of birth Information modify the following sentence to read "(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 and proceed to Section III

Section III block 12h: Change to the following question: "Have you served in the Armed Forces?"

Renumber question 12h as question 12i and replace Armed Services with Armed Forces.

Renumber question 12i as question 12j.

Section IV: Change the last sentence of the first paragraph to read: "This information may include, but is not limited to, biographical, financial, law enforcement and intelligence information, as well as medical records including mental health history."

Section V: Certification of Responsible or Alternate Responsible Official – modify the statement to read as follows:

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, based upon my review, have determined that all certification questions have been answered prior to transmitting this

information to the FBI for the Security Risk Assessment. For any questions answered "yes" or "not sure" the applicant must provide additional information or supporting documentation.

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 submitted both electronically and in hard copy to the CJIS Division. The FD-961 form is available online in a PDF format. The FD-961 form can be completed electronically online and can be faxed, emailed or mailed to the CJIS Division for processing. Applicants who are renewing their access can submit their FD-961 by fax, email or by mail. New applicants must mail their FD-961 along with their fingerprint cards to CJIS. In fiscal year 2013 approximately 51% of all applicants were renewals.

The electronic possibility of submitting fingerprints to CJIS is still 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 fully operational.

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). Currently BRAG does not have the required staffing levels to support this effort.

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. <u>Special Circumstances</u>

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 was 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 3,796 (Fiscal Year 2013)

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

Total annual responses 3,796 (Fiscal Year 2013)

Minutes per response 45 minutes

Annual hour burden 2,847 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 FY2013 respondents is \$3,340.48. 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 FY2013 respondents) is \$687,076.

15. Reason for Change in Burden

Decrease in hour burden and cost burden is due to a decrease of security risk assessments 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.