Personnel Suitability Program for Tier 1 Biological Select Agents and Toxins—BSAT

Pursuant to compliance with CDC/NIH Biosafety in Microbiological and Biomedical Laboratories, NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acids, and 42 CFR 73.
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Introduction

The Arizona State University Personnel Suitability Committee has developed this document to ensure compliance with federal regulations involving Tier 1 Biological Select Agents and Toxins—BSAT, including 42 C.F.R. Part 73, 7 C.F.R. Part 331, and 9 C.F.R. Part 121. Pursuant to 42 C.F.R. § 73.11, ASU’s security plan for Tier 1 select agents or toxins must include a pre-access suitability assessment of individuals who will have access or could gain access to a Tier 1 BSAT. The regulation further requires ASU to have procedures for the ongoing assessment of the suitability of personnel with access to Tier 1 BSAT. These procedures must include self- and peer-reporting of incidents or conditions that could affect an individual’s ability to have access to Tier 1 BSAT, training of these individuals, and ongoing suitability monitoring of these individuals.

This document describes procedures for conducting pre-access and ongoing suitability assessments of persons with access to a Tier 1 BSAT. The ongoing suitability assessment includes provisions for self- and peer-reporting of incidents or conditions that could affect an individual’s ability to safely have access to or work with Tier 1 BSAT. These measures are intended to safeguard these agents from theft, loss, or release. As stated in the Guidance for Suitability Assessments, published by the Centers for Disease Control and the Animal and Plant Health Inspection Services, it is critical to consider insider threats:

With respect to select agents or toxins, the “insider threat” generally refers to an individual who has access to select agents or toxins as part of his or her job and has the potential to misuse these materials. Some examples of the “insider threat” include an individual with malevolent intent who infiltrates a research facility under the guise of a legitimate researcher in order to steal, release or divert select agents or toxins; an individual with access to select agents or toxins who is coerced or manipulated into providing access or expertise to unauthorized individuals with malevolent intent; or an individual whose job duties require legitimate access to select agents or toxins but who may misuse, release or divert select agents or toxins as a result of a significant life changing event.

In order to help ensure compliance with federal, state, and local requirements, this document describes necessary training and the policies and procedures on how to report, evaluate, and take corrective action regarding personnel suitability. This plan is also intended to establish the methodology and procedures for determining personnel suitability of individuals with access to Tier 1 BSAT. The purpose of a suitability assessment is to ensure that an individual who requests to have access, or continues to have access, to Tier 1 BSAT actually merits access. Accordingly, this Personnel Suitability Plan is an integral part of daily operations for research with Tier 1 BSAT at ASU.

In accordance with 42 C.F.R. § 73.12, all individuals with access to Tier 1 BSATs must be enrolled in the biosafety occupational health program. The plan provides the requirements and details for participation in the biosafety occupational health program.
This plan was last reviewed on April 2, 2019 and will be reviewed, and revised as necessary, at least annually.

Leon C. Igras, Chief Safety Officer
Executive Director, Environmental Health and Safety

David Gillum, Responsible Official
Chief of Staff, Environmental Health and Safety
I. **Definitions**

**Access to Tier 1 BSAT:** An individual will be deemed to have access to a Tier 1 BSAT at any point in time if the individual has possession of a Tier 1 BSAT (e.g., ability to carry, use, or manipulate) or the ability to gain possession of a Tier 1 BSAT.

**Alternate Responsible Official—ARO:** Serves as the Responsible Official or designee when requested to do so by the Responsible Official or in his/her absence.

**Biosafety Officer—BSO:** The BSO is responsible for administering ASU biological health and safety programs. The BSO serves as an ARO.

**Biosecurity:** Protection of high-consequence biological agents and toxins, or critical relevant information, against theft or diversion by those who intend to pursue intentional misuse.

**Bioterrorism Security Risk Assessment Form —FD-961 Form:** The Federal Bureau of Investigation’s (FBI) application for security risk assessment that assists the FBI, Criminal Justice Information Services Division (CJIS), to perform an electronic records check to determine if an individual who has been identified by a registered entity as having a legitimate need to access select agents or toxins exhibits one of the statutory restrictors which would either prohibit or restrict access.

**BSAT:** Biological Select Agent or Toxin (see definition for Select Agents and Toxins).

**Certifying Official—CO:** The Director of Recruiting and Selection will serve as the CO for the Tier 1 BSAT pre-access program and certifies that personnel meet the established requirements for pre-access.

**Entity:** According to 42 C.F.R. § 73.1, the term “entity” refers to any government agency (federal, state, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity that is registered with the Federal Select Agent Program. For the purposes of this document, the term “entity” refers to Arizona State University.

**Entity Leadership:** Entity leadership includes all entity officials who have responsibilities for science, safety, and security at an institution. These officials may include the ASU President, Vice Presidents of Research, Deans, Chief Executive Officers (CEOs), Institutional Officials, Department Chairs, Ranking Officials, etc.

**Federal Select Agent Program:** The joint management of Centers for Disease Control and Prevention’s (CDC) Division of Select Agents and Toxins and the Animal and Plant Health Inspection Service’s (APHIS) Agricultural Select Agent Program of the select agent regulations.

**Human Resources—HR:** The division of ASU that is focused on activities relating to employees. These activities normally include recruiting and hiring of new employees, orientation and training of current employees, employee benefits, and retention.
On-going Suitability Assessment: A standardized procedure to assess whether an individual displays behaviors which have been determined by the CDC to increase the risk of a theft, loss, or release of a select agent or toxin.

Opt-Out: Process of allowing individuals working with Tier 1 BSATs to voluntarily remove themselves from Tier 1 access for a temporary, limited period of time.

Personnel Suitability: Personnel with access to select agents or toxins should not display behaviors determined by the CDC to increase the risk of a theft, loss, or release of a select agent or toxin.

Personnel Suitability Committee—PSC: Advises the RO and ARO on matters covered by the Personnel Suitability Program for Tier 1 BSATs

Pre-Access Suitability Assessment: The evaluation of an individual using a standardized procedure to determine if the individual displays behaviors determined by the CDC to increase the risk of a theft, loss, or release of a select agent or toxin.

Principal Investigator—PI: The individual who is designated by ASU to direct a project or program and who is responsible for the scientific and technical direction of that project or program.

Responsible Official—RO: The individual designated by the ASU President to have the authority and control to ensure compliance with the select agent regulations (42 C.F.R. §§ 73.1, 73.9).

Security Risk Assessment—SRA: Electronic records check performed by the Criminal Justice Information Services (CJIS) Division to determine if an individual who has been identified by a registered entity as having a legitimate need to access select agents or toxins exhibits one of the statutory restrictors which would either prohibit or restrict access.


Select Agents and Toxins: Biological select agents or toxins listed in the Select Agent Regulations. 42 C.F.R. §§ 73.3 - 73.4.

Suitability Assessment Program: A combination of pre-access and on-going suitability practices, in conjunction with comprehensive and consistent review mechanisms, used to determine the reliability of personnel for access to Tier 1 BSAT, and to allow individuals to report potential risks and threats to safety and security concerning Tier 1 BSAT to the Responsible Official (RO) and University leadership.

Tier 1 BSAT: A subset of select agents or toxins designated in the select agent regulations as “Tier 1” because these agents and toxins present the greatest risk of deliberate misuse with the most significant potential for mass casualties or deleterious effects on the economy, critical infrastructure, or public confidence.
“Whole Person” Assessment: A balanced assessment of an individual, establishing a behavioral baseline, along with mitigating circumstances, and discerning overall qualities of credibility and suitability for access to Tier 1 BSAT.
II. **Roles and Responsibilities**

A. **ASU Leadership**

The ASU President has the authority to designate the Responsible Official (RO) and Alternate Responsible Officials (AROs) on behalf of the institution. The ARO serves as the RO in his/her absence and serves as the RO designee when requested to do so by the RO. ASU leadership provides support to the RO in the development and implementation of a suitability assessment program for individuals with access to Tier 1 BSAT.

Engaging ASU Leadership promotes a shared sense of responsibility for the safe and secure use of Tier 1 BSAT by all stakeholders and will serve to strengthen the culture of reliability, safety and security at ASU. Furthermore, ASU Leadership encourages a culture of responsibility, safety and security, and does not tolerate retaliation or retribution for the legitimate reporting of information that may affect the safety and security of Tier 1 BSAT. ASU Leadership makes a concerted effort to ensure the authorized need and anonymity of personal information when obtained as part of the Personnel Suitability Program, and will keep such information confidential to the extent allowed by law. All ASU officials who have responsibilities for science, safety, and security represent potential resources and support for ASU’s select agent program.

ASU Leadership responsibilities and duties include the following:

- Appointing the RO for the institution.
- Collaborating with the RO to develop and implement a suitability assessment program for personnel with access to Tier 1 BSAT.
- Providing resources for the RO to establish a suitability assessment program. This may include direct financial support or promoting connections between the RO and existing institutional resources (e.g., ASU Leadership, Health Services, Human Resources, security personnel, legal counsel, and occupational health program).
- Supporting the RO in the establishment of policies and administrative procedures to execute an effective suitability assessment program.

Essential program components include:

- Pre-access suitability assessment protocols (42 C.F.R. § 73.11).
- Implementation of an occupational health program for individuals with access to Tier 1 BSAT and assurance that individuals with access to Tier 1 BSAT are enrolled in the occupational health program (42 C.F.R. § 73.12).
- Ongoing assessment of the suitability of personnel with access to Tier 1 BSAT which must include: (1) self-reporting and peer-reporting, (2) training on how to report, evaluate, and take corrective action regarding personnel suitability, and (3) the ongoing suitability monitoring of individuals with access to Tier 1 BSAT. (42 C.F.R. § 73.11).
- Protocols that allow an individual to voluntarily “opt-out” of Tier 1 BSAT work (e.g., coordination with human resources, supervisors).
- Procedures for the temporary or permanent denial of access to Tier 1 BSAT.
- Procedures to manage appeals of administrative actions that may result from suitability assessments.

- Supporting efforts to protect individuals reporting adverse personnel suitability information from retribution. Also, supporting the efforts to appropriately investigate and discipline any individual who knowingly initiates a false report.
- Ensuring that grant proposals meet the requirements of the Personnel Suitability Program (e.g., researchers consider costs for background checks and exclusionary criteria when hiring personnel with access to Tier 1 BSAT).
- Establishing communication channels for the sharing of suitability program information, as appropriate, among relevant stakeholders and the RO. At a minimum, this will involve the timely communication to ASU personnel (e.g., administrators, supervisors, laboratory personnel, security) of the development, implementation, expected support, and personnel responsibilities associated with the ASU’s Personnel Suitability Program.
- Promoting a culture of reliability, safety, and security in all matters dealing with access to select agents or toxins, including Tier 1 BSAT.

B. Personnel Suitability Committee

The Personnel Suitability Committee is responsible for working with the RO to ensure that personnel with access to Tier 1 BSAT undergo an appropriate suitability assessment. The Personnel Suitability Committee has representatives from ASU Biosafety and Biosecurity, the Employee Assistance Program, Health Services (Occupational Health), Environmental Health and Safety, Office of Human Resources, the Institutional Biosafety Committee, Knowledge Enterprise and Development, Legal, Police, and other groups when appropriate. The RO or his/her designee chairs the Committee.

The responsibilities and duties of the Personnel Suitability Committee or, if so determined by the RO, a Subcommittee established by the RO, include:

- Monitoring the suitability assessment program and reviewing employee actions that impact suitability.
- At the request of the RO, evaluating the personal information required to administer a suitability assessment program. In so doing, protects the confidentiality of the information to the extent allowed by law.
- Working with the RO to administer both the pre-access and on-going suitability assessments. Collects information and may vote on components of the pre-access and ongoing suitability program.
For the Personal Suitability Committee to take action, a measure must be affirmed by a majority vote of the full Committee membership and, thereafter, must be reviewed and approved by the RO.

C. Responsible Official—RO

The Director of Environmental Health and Safety serves as the RO for ASU. The RO must be approved by the U.S. Health and Human Services (HHS) Secretary or Administrator following a security risk assessment by the Attorney General and be familiar with 42 CFR 73 et seq. The RO has authority and responsibility to act on behalf of Arizona State University and is responsible for ensuring compliance with the select agent regulations. The RO has a physical presence, and not merely an audio/visual presence, at the University in order to be able to respond in a timely manner to onsite incidents involving select agents and toxins.

The RO is the person with the authority to immediately restrict or deny access to Tier 1 BSAT based on behavioral, medical, or administrative grounds, and is ultimately responsible for notifying the Federal Select Agent Program of terminations to personnel access to select agents and toxins through the submission of amendments to ASU’s select agent and toxin registration (i.e., APHIS/CDC Form 1). With available resources, the RO establishes and implements procedures for conducting suitability assessments for individuals requesting access to Tier 1 BSAT.

RO responsibilities and duties include the following:

- Ensuring the APHIS/CDC Form 1 lists all individuals who will have access to select agents and toxins, including Tier 1 BSAT.
- Ensuring the development of the Tier 1 BSAT suitability assessment program and leads its implementation and administration.
- Appointing the Biological Safety Officer (BSO) for ASU.
- Designating one or more Alternate Responsible Officials (AROs) who have authority and control to ensure compliance with the select agent regulations.
- Designating the membership of the Personnel Suitability Committee and appointing a Certifying Officer (CO).
- Serving as chair of the Personnel Suitability Committee or appoints a designee.
- Coordinating with other ASU resources (e.g., safety and security personnel, legal counsel, human resources) in the development, implementation, and administration of the Tier 1 BSAT suitability assessment program.
- Granting or removing Tier 1 BSAT access.
- Collecting, evaluating, and taking measures to protect the personal information obtained during the suitability assessment process, or may designate these tasks to the BSO/ARO.
- Ensuring that access to Tier 1 BSAT is limited to individuals who have undergone a pre-access suitability assessment, are part of ASU’s on-
going suitability monitoring and occupational health program, and have current Federal Select Agent Program approval (e.g., FD-961 Security Risk Assessment clearance) to access select agents or toxins.

- Ensuring that appropriate annual training is completed and documented prior to the approval or continuance of access to Tier 1 BSAT.
- Ensuring that annual inspections are performed for each registered space where select agents or toxins are stored or used. The results of each inspection must be documented and deficiencies must be corrected.
- Promoting a culture of reliability, safety, and security in all matters dealing with access to select agents and toxins.
- Coordinating with the individual’s supervisor, ASU Health Services, Employee Assistance Office (EAO) counselors, security personnel, legal, Biosafety Officer (BSO) or other leadership or qualified persons in the assessment or adjudication of suitability.

The RO and ARO must have sufficient familiarity with all individuals having access to Tier 1 BSAT, and their supervisory chain, to permit a continual evaluation of their suitability, and have the authority to engage supervisors when warranted.

The RO must immediately notify the CDC or APHIS when an individual’s access to select agents or toxins is terminated and must give the reasons for the termination (42 C.F.R. § 73.10).

D. Certifying Official—CO

The ASU Director of Recruiting and Selection is a representative from the Office of Human Resources and will serve as the CO for the Tier 1 BSAT program. The CO works with departments to ensure that job descriptions and job postings include appropriate requirements and/or contingencies for working with select agents or toxins. The CO certifies that personnel meet the established requirements for pre-access.

The CO certifies that all individuals meet post-offer contingencies. The CO will perform the reference checks or appoint a designee. The CO will oversee the preparation and sending of the offer letter and any other onboarding documents. The CO serves as a voting member of the Personnel Suitability Committee. The CO certifies that personnel meet established background check requirements as described in the section on Pre-Access Suitability Requirements of this document.

For each employee with Tier 1 BSAT access, the CO will perform the following every three years:

- County criminal felony and misdemeanor check; and
- National sex offender registry check.
The CO promptly provides all results to the RO. The CO will collect, evaluate, and protect personal information and records. The CO will be familiar with the pre-access recommendations included in the most current version of the CDC/APHIS Guidance for Suitability Assessment (7CFR Part 331, 9 CFR Part 121, 42 CFR 73).

E. Biosafety Officer—BSO

The BSO or designee oversees Biosafety and Biosecurity programs at ASU which include the administrative policies, work practices, facility design, and safety equipment necessary to prevent unauthorized or inappropriate transmission of biological agents to workers, other persons, and the environment. The Biosafety and Biosecurity programs at ASU are specifically designed to minimize the risks of lab-acquired illness, to ensure proper containment for activities utilizing biohazardous materials, and to maintain compliance with regulations pertaining to select agents and toxins, recombinant and synthetic nucleic acids, bloodborne pathogens, and other biohazardous materials.

The goals of the Biosafety and Biosecurity programs are to assure a safe and healthy environment for individuals working with biohazardous materials and to assure the protection of the community and environment by preventing exposure to those materials. The Biosafety and Biosecurity programs encompass the knowledge, techniques, equipment, and facilities necessary to prevent or minimize an exposure to, or release of, a biological agent.

BSO responsibilities and duties include assisting the RO with the following:

- Administering the biological safety and biosecurity programs for ASU.
- Collecting, evaluating, and protecting personal information required as part of the annual peer review process for the personnel suitability assessment program.
- Assisting in the oversight of the ASU Tier 1 BSAT program to ensure compliance with the federal select agent regulations.
- Coordinating correspondence for the Federal Select Agent Program.
- Coordinating with an individual’s supervisor, ASU Health Services, Employee Assistance Office (EAO) counselors, security personnel, legal, or other leadership or qualified persons in the assessment or adjudication of suitability.
- Serving as a voting member of the Personnel Suitability Committee.
- Serving as the Alternate Responsible Official (ARO) in the RO’s absence or as the RO designee when requested to do so by the RO.
- Serving on the Institutional Biosafety Committee (IBC), Institutional Animal Care and Use Committee (IACUC), and Pandemic Committee to ensure select agent compliance in research projects taking place at ASU.
- Assisting in the development, enrollment of individuals, and implementation of an occupational health program for select agents and toxins, including Tier 1 BSAT (42 C.F.R. § 73.12).
F. Supervisors of Tier 1 BSAT Personnel

Supervisor responsibilities and duties include supporting the Tier 1 BSAT program through the following:

- Encouraging personnel to report behaviors and conditions that may impact an individual’s Tier 1 BSAT access.
- Reporting behaviors, conditions, and other security concerns that may impact an individual’s Tier 1 BSAT access.
- Promoting a culture of reliability, safety, and security in all matters dealing with Tier 1 BSAT.
- Ensuring personnel receive the appropriate training to work safely with Tier 1 BSAT and ensuring compliance with the Federal Select Agent Program regulations (42 C.F.R. § 73).
- Ensuring employees receive and complete the Annual Ongoing Suitability Assessment Form (see Appendix B) and return the completed form within the timeframe allotted by the RO.

G. Personnel Enrolled in the Suitability Program

Individuals with access to Tier 1 BSAT have a responsibility to monitor their own suitability, as well as the suitability of their colleagues who perform duties that require access to Tier 1 BSAT. Individuals are required to report to their supervisor or the RO any issues that could have an adverse impact on their own performance, suitability, or safety while performing Tier 1 BSAT duties. Individuals must also advise their supervisor, ARO, RO, or RO’s supervisor when another individual with access to Tier 1 BSAT manifests behaviors, or otherwise appears to be involved in situations that may adversely affect the safety or security of Tier 1 BSAT.

Individual responsibilities (not intended to be comprehensive):

- Following institutional policies and procedures for the safe and secure use of Tier 1 BSAT and complying with the select agent regulations.
- Participating in and understanding training associated with the suitability assessment program.
- Reporting any situations that may affect safety and/or security of Tier 1 BSAT.
- Voluntarily “opts out” of the Tier 1 BSAT program when necessary (e.g., during life-changing events, certain medical conditions).
- Respecting the privacy and confidentiality of colleagues by only reporting suitability concerns in the manner established by this policy, and supporting an environment where direct or indirect retaliation for policy compliance is not tolerated.
- Participating in the Occupational Health Program for those individuals with access to Tier 1 BSAT.
III. Pre-Access Suitability Requirements

ASU is required to develop and implement procedures to evaluate an individual's suitability for access to Tier 1 BSAT. These requirements are described in this section of the Personnel Suitability Plan. This plan recognizes the importance of fostering a culture of suitability, responsibility, safety and security for individuals with access to Tier 1 BSAT.

A. ASU Pre-Access Suitability Assessment

Candidates that will have access to Tier 1 BSAT must successfully complete a pre-access suitability assessment. All employment applications meeting the requirements for a job opening are referred to the University's hiring officials. Hiring officials are responsible for conducting initial reference checks provided by the candidate during the selection process. Once a final candidate is recommended for hire, the candidate will be required to complete a Consent Form to authorize ASU to perform various background checks.

The CO will make certain the candidate signs a Consent Form authorizing ASU to conduct a background check. An employment offer is contingent upon a successful background and reference check, which includes:

- County criminal felony and misdemeanor check with social security trace and a national FBI fingerprint check.
- National sex offender registry check and other applicable public records.
- Home address history for the past 99 years, or from the age of 18, whichever represents a shorter period of time, and should, at a minimum, include the states or countries where an individual has resided during that time.
- Employment verification for the past seven years of work history or from the age of 18, whichever represents a shorter period of time, including an explanation of any gaps in employment.
- Education verification from all post-secondary institutions the individual claims to have attended; or other supporting education documentation if an individual has not attended post-secondary institutions.
- Resume or curriculum vitae (including scientific publications and affiliations) to assess the person’s recent paid and unpaid work experiences, scientific publications, and affiliations for research with select agents or toxins.
- Professional license and certification history and verification (including contacting state boards of licensure in each location where the individual has lived to identify any negative information associated with each license).
- Visa status (if applicable).
- Reference checks; CO will ensure the hiring official verifies or conducts the following:
- Professional references selected from previous work experiences in the past 7 years or from the age of 18, whichever represents a shorter period of time.
- Technical references, if applicable.
- Peer references to speak to the person’s reliability, trustworthiness, honesty, judgment, emotional or mental stability, potential conflicting allegiances and potential or propensity for coercion.
- Personal interviews with sources such as supervisors and associates.

If the candidate recommended for hire does not sign or complete a Consent Form, or if the results of the assessment are unsatisfactory, the contingent offer will be rescinded. If the results are satisfactory, the CO will notify the hiring official. The CO will make certain that third party reference information is obtained, kept confidential, and not available to candidates.

When assessing criminal history, all events will be put into the context of the “whole person.” Consideration will be given to:

- The nature of the event and whether the demonstrated behavior increases the risk in the laboratory or animal facility;
- An individual’s circumstances at the time of an event;
- The time that has passed since the event of concern; and
- The total number of events causing concern.

The FBI Security Risk Assessment will only be affected by indictments or convictions punishable by imprisonment for a term exceeding one year. Individuals may have been arrested for or convicted of lesser crimes. For example, these may show a pattern or practice of engaging in wrongful or inappropriate conduct or exhibiting poor judgment. These actions must be considered as part of the “whole person” assessment. Criminal records should be obtained to verify information. The CO will determine if an Adverse Action letter is necessary.

ASU may also choose to assess the person’s honesty and truthfulness in answering questions during the interview process. The willingness to provide facts will be seen as “positive,” while an attempt to cover up an event would be assessed as a “negative.” As possible mitigating factors, positive information about the person should also be considered, including work performance or education since the occurrence of any derogatory event(s), the interpretation of the event(s) by supervisors at the time (and supervisors since), and how the individual interprets the event(s) during his or her interview.

ASU may refuse to hire the candidate, may rescind an offer of employment to a candidate, or may terminate the employment of a current employee who does not successfully pass the background-check process. Please refer to the ASU Policy on Reference Checks and Background Verification, ACD-126. The ACD-126
policy is used in conjunction with other recruitment and employment policies to help ASU identify the best-qualified candidates for employment at ASU.

Arizona State University does not discriminate on the basis of race, color, national origin, sex, sexual orientation, gender identity, disability, religion, age or veteran status in the university’s services, educational programs and activities, including, but not limited to, admission to and employment by the university. The Office of Equity and Inclusion has been designated to handle inquiries regarding the university’s non-discrimination policies.

B. Information Collection, Evaluation, and Disposition

1) Information Collection

A signed authorization from the candidate is required before criminal record information or background information may be requested. This information will be collected in coordination with the Office of Human Resources. If a candidate refuses to provide such authorization, the individual will be ineligible for consideration for such position.

2) Pre-Adverse Action Notice

In some cases, an outside vendor may uncover information that may disqualify a candidate from further employment consideration. In such a case, ASU will notify the candidate of the information and provide a minimum of five business days for the candidate to refute, explain, or correct the information.

3) Information Release

Only the Office of Human Resources and RO may initiate a criminal background check and receive the results. Results of all background checks will be kept confidential and will not be disclosed except to the extent necessary to administer and enforce this policy, as provided by law or pursuant to appropriate legal process. The university may release the results of a reference or background check to another university under the jurisdiction of the Arizona Board of Regents for employment purposes.

C. Federal Select Agent Program – Security Risk Assessment—SRA

An additional level of background investigation is required for individuals with access to Tier 1 BSAT. This involves an individual completing the FD-961 Bioterrorism Security Risk Assessment Form and requires a fingerprint check for determining whether an individual will be approved for access to select agents. The BSO or designee manages the submission of the FD-961 Form and the fingerprint process.
The FBI conducts the Security Risk Assessment (SRA), which involves a check of electronic databases to identify any of nine “prohibitions” and three potential “restrictions.” SRA is not a comprehensive “background investigation” and not regarded as a substitute for ASU’s personnel suitability assessment. The list of prohibitions and restrictions under 18 USC § 175b include:

- Individual is under indictment for a crime punishable by imprisonment for a term exceeding 1 year.
- Individual has been convicted in any court of a crime punishable by imprisonment for a term exceeding 1 year.
- The individual is a fugitive from justice.
- The individual is an unlawful user of any controlled substance (as defined in Section 102 of the Controlled Substance Act).
- The individual is an alien illegally or unlawfully in the United States.
- The individual has been adjudicated as a mental defective or has been committed to any mental institution.
- Individual is 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 lawful determination (that remains in effect) that such country has repeatedly provided support for acts of international terrorism.
- The individual has been discharged from the Armed Services of the United States under dishonorable conditions.
- The individual is a member of, acts for or on behalf of, or operates subject to the direction or control of, a terrorist organization as defined by Section 212 of the Immigration and Nationality Act.

The Federal Select Agent Program may limit or deny access to individuals reasonably suspected by any federal law enforcement or intelligence agency of:

- Committing a crime considered an act of terrorism transcending national boundaries [specified in 18 USC 2332b(g)(5)].
- Knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 USC 2331) or with any other organization that engages in intentional crimes of violence.
- Being an agent of a foreign power (as defined in 50 USC 1801).

Passing the FBI Bioterrorism Security Risk Assessment (FD-961) is a condition of employment for individuals who will have access to, or the ability to access, Tier 1 BSAT. Any new hire that does not pass the assessment will be dismissed from ASU.
D. Pre-Access Health Assessment

All offers of employment are contingent upon successful completion of an occupational health assessment by ASU and a Certificate of Occupational Health Clearance (refer to Appendix C) to participate in ASU’s select agent program. ASU will cover the cost for the pre-access occupational health assessment. This assessment may include the following at the discretion of the ASU Occupational Health Physician.

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<th>Table 1. ASU Health Services Pre-Access Occupational Health Assessment</th>
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<td>Medical Questionnaire</td>
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<td>Baseline Physical Exam / Medical Screening</td>
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<td>ACAM 2000 Vaccination</td>
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<td>Audiometry Evaluation</td>
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<td>Baseline Kidney Function Test</td>
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<td>Baseline Liver Function Test</td>
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<td>Complete Blood Count (CBC)</td>
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<td>Hemochromatosis Screening</td>
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<td>Measles, Mumps, Rubella Titer or Vaccination</td>
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<td>Respirator Fit Testing</td>
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<tr>
<td>Serum Banking</td>
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<td>Spirometry Evaluation</td>
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<tr>
<td>T-spot lab test (if not available for 2 day follow-up)</td>
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<tr>
<td>Tetanus Titer or Vaccine</td>
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<tr>
<td>Tuberculosis skin test, 2 appointments, 2 days apart</td>
</tr>
<tr>
<td>Vision Exam</td>
</tr>
<tr>
<td>Other Vaccinations Based Upon Research Requirements</td>
</tr>
</tbody>
</table>

Additional costs for other health assessments must be approved by the RO or RO’s designee and must be necessary for the select agent program.

E. Pre-Access Suitability for Visitors

In the rare instance where visiting scientists are sponsored by an ASU faculty member to conduct experiments requiring independent, unescorted access to select agents or toxins, the individual will be required to meet all current ASU requirements for Tier 1 BSAT access, including a pre-access suitability assessment performed by ASU as described in this plan and the latest version of the CDC/APHIS Guidance for Suitability Assessments. Arrangement for such assessments will be coordinated with the ASU Office of Human Resources and will be verified by the RO prior to granting access.
IV. Ongoing Suitability Assessments

All individuals with access to, or the ability to gain access to, Tier 1 BSAT are subject to ASU’s ongoing suitability assessment program and have a shared responsibility for the safe and secure use of these agents. Individuals exhibiting behaviors that demonstrate they are incapable of controlling their actions or adhering to safety or security practices may be denied access to Tier 1 BSAT on a temporary or permanent basis.

Requirements addressed in this section include:

- Mechanisms for self- and peer-reporting of behaviors of concern. Specifically, incidents or conditions that could affect an individual’s ability to have access to, or work safely with, Tier 1 BSAT or to safeguard Tier 1 BSAT from theft, loss, or release.
- Ongoing monitoring of suitability for individuals with access to Tier 1 BSAT.
- Training on ASU policies and procedures for reporting, evaluations, and corrective actions concerning the assessment of personnel suitability for employees with access to, or the ability to gain access to, Tier 1 BSAT.

A multi-resource committee (i.e., Personnel Suitability Committee) approach to an ongoing suitability assessment program aids the RO in making sound access decisions to ensure the safety and security of Tier 1 BSAT.

A. Behaviors and Conditions of Concerns

Anyone involved with Tier 1 BSAT, must notify appropriate university leadership (e.g., supervisor, RO, BSO, CO, HR, EAO) if they become aware of any circumstances, conditions, or observations such as those identified below:

1. Circumstances that may affect the Security Risk Assessment status of an individual:

   The current mechanism used by the Federal Select Agent Program for determining whether an individual will be approved for access to select agents is the Security Risk Assessment conducted by the FBI’s Criminal Justice Information Services (CJIS) Division. The Security Risk Assessment process is a check of electronic databases to identify any of nine “prohibitions” and three potential “restrictions.” The Security Risk Assessment is not a comprehensive “background investigation” and not regarded as a substitute for the “whole person” suitability assessment. Circumstances that may affect Security Risk Assessment status of an individual are considered Reportable Conditions.

   The categories under 18 USC § 175b include the following situations:

   - The individual is under indictment for, or convicted of, a crime punishable by imprisonment for a term exceeding 1 year.
   - The individual is a fugitive from justice.
• The individual is an unlawful user of any controlled substance (as defined by the Controlled Substance Act).
• The individual is an alien illegally or unlawfully in the United States.
• The individual has been adjudicated as a mental defective or has been committed to any mental institution.
• Individual is 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 lawful determination (that remains in effect) that such country has repeatedly provided support for acts of international terrorism.
• The individual has been discharged from the Armed Services of the United States under dishonorable conditions.
• The individual is a member of, acts for or on behalf of, or operates subject to the direction of, a terrorist organization as defined by the Immigration and Nationality Act.

The Federal Select Agent Program may limit or deny access to individuals reasonably suspected by any federal law enforcement or intelligence agency of:

• Committing a crime considered an act of terrorism transcending national boundaries [specified in 18 USC 2332b(g)(5)].
• Knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 USC 2331) or with any other organization that engages in intentional crimes of violence.
• Being an agent of a foreign power (as defined in 50 USC 1801).

2. Circumstances that may affect the ability of an individual to perform his or her job in a safe and secure manner (e.g., performance of duties declines markedly, significant increase in distraction or mistakes, increase in risk-taking behaviors).

3. Significant changes in behavior, attitudes, demeanor, or actions (e.g., increasingly withdrawn; significant and prolonged deterioration in appearance; unjustified anger or aggression; unexplained absences; signs of alcohol/drug abuse; criminal activity; and unexplained absences).

4. Stated or implied threats to colleagues, institutions, the security of Tier 1 BSAT, the wellbeing of laboratory animals, or the general public, whether verbal or written.

5. Willful non-compliance with the select agent regulations.

6. Any information that causes an individual to have concerns about his or her own ability to perform a job safely and securely.

7. Any circumstances that appear suspicious such as laboratory work that does not correspond to official project goals or work, requests for security or laboratory information without justification, acts of vandalism or
property damage, attempts to gain unauthorized access for friends or colleagues.
8. Unlawfully carrying weapons (or carrying weapons in violation of ASU policies).
9. Providing false information on applications or other formal institutional documents.
10. Unauthorized work performed by an individual(s) in a facility during off-hours.

B. Ongoing Monitoring

The purpose of the ongoing monitoring of suitability is to provide an opportunity to gauge the performance of the individual with access or the ability to gain access to Tier 1 BSAT with respect to the adherence to biosafety and security procedures and training, and address any potential problems that may affect work performance in the future. Ongoing suitability monitoring at ASU is accomplished through the following methods:

- The RO, in conjunction with supervisors, will periodically review Tier 1 BSAT access requirements, based on employee duties and responsibilities.
- For each person with access or the ability to gain access to Tier 1 BSAT, the CO will conduct a criminal background check (including misdemeanors) and a sex offender register check every three years.
- ASU Health Services will conduct an annual occupational health assessment for each person with access to, or the ability to gain access to, Tier 1 BSAT.
- The FBI CJIS conducts a Security Risk Assessment every three years for each individual enrolled in the ASU Select Agent Program. Passing the FBI Bioterrorism Security Risk Assessment (FD-961) is required to have access for any individual who will have access to, or the ability to access, Tier 1 BSAT. Any employee that does not pass the assessment will be immediately denied access to Tier 1 BSAT. Pursuant to 42 CFR §73.20, an individual may appeal a denial, limitation, or revocation of access approval of the FD-961 Bioterrorism Security Risk Assessment. Even if an appeal is granted and the Secretary of the U.S. Department of Health and Human Services approves access, the final decision regarding access, or the ability to gain access, to Tier 1 BSAT, is at the discretion of the RO who will consider the totality of the facts and circumstances.

For the periodic review of Tier 1 BSAT access requirements, personnel will be divided into three categories:

1. Personnel who currently do not need access to the Tier 1 BSAT;
2. Personnel who only need access during regular working hours (e.g., Monday-Friday, 6AM - 7PM); and
3. Personnel who need access to Tier 1 BSAT 24 hours, 7 days a week (24/7).
Evaluation of personnel access privileges serves two goals:

1. Optimizes the number of users with access to Tier 1 BSAT based on each individual’s work objectives; and
2. Limits the duration of time Tier 1 BSAT can be accessed.

C. Annual Ongoing Suitability Assessment

The Center for Disease Control and Prevention has determined that essential elements of Annual Ongoing Suitability Assessment Form are self and peer assessments. Thus, each employee who has access to, or could gain access to, a Tier 1 BSAT will be assessed by his or her peers at least once a year. For purposes of this Program, a “Peer” is defined, in a broad sense, as someone who observes, interacts, and/or works with the Tier 1 Employee on a regular or frequent basis. A Peer will assess a Tier 1 Employee by completing a Personnel Suitability Assessment Form (see Appendix B).

Individuals who are asked to complete an Annual Ongoing Suitability Assessment Form are instructed to keep the information confidential to the extent permitted by law. To protect the integrity of the program and to honor and respect the privacy of others, individuals completing the form are instructed not to discuss assessment answers or any actions arising from the Ongoing Personnel Suitability Assessment process (see Appendix A).

Supervisors will also be required to complete an Annual Ongoing Suitability Assessment Form (see Appendices A and B) for each individual under her/his supervision with access to Tier 1 BSAT. The purpose of the form is to prompt supervisors to consider relevant safety and security considerations for individuals under their supervision, and render an assessment to the RO. Instances where suitability is questionable or unsatisfactory will be referred to RO for further consideration and a determination as to the appropriate course of action.

The CDC also recommends that the following information should be collected for people in a supervisory role:

- Review of performance evaluations;
- History of grievance/complaint records;
- Information gathered upon exit interviews with staff;
- History of retention of subordinate staff;
- Record of previous or current collaborations;
- History of compliance with the federal select agent regulations; and
- Life changing events (personal and professional).

The RO must also undergo a peer assessment annually. The peer group must include at least one Principal Investigator involved in the Tier 1 BSAT program. The results of the RO's assessment will be forwarded to the Personnel Suitability Committee for review. The committee will forward any concerns reflected in the
assessment to Legal who will provide it to the Associate Vice President for Business and Finance for appropriate action.

Examples of circumstances, conditions or observations that must be shared by the individual(s) observing them to the appropriate University leadership (e.g., supervisor, RO, BSO, CO, HR, EAO) are provided below:

1. Has the employee been involved in circumstances that may affect their SRA status?
2. Has the employee been involved in circumstances that may affect the ability of an individual to perform his or her job in a safe and secure manner (e.g., performance of duties declines markedly, significant increase in distraction or mistakes, increase in risk-taking behaviors)?
3. Has the employee had significant changes in behavior, attitudes, demeanor, or actions (e.g., increasingly withdrawn; significant and prolonged deterioration in appearance; unjustified anger or aggression; unexplained absences; signs of alcohol/drug abuse; criminal activity; and unexplained absences)?
4. Has the employee stated or implied threats to colleagues, institutions, the security of Tier 1 BSAT, the wellbeing of laboratory animals, or the general public, whether verbal or written?
5. Has the employee been willfully non-compliant with the select agent regulations?
6. Is there any information that causes an individual to have concerns about the employee’s ability to perform a job safely and securely?
7. Are there any circumstances regarding the employee that appear suspicious such as laboratory work that does not correspond to official project goals or work, requests for security or laboratory information without justification, acts of vandalism or property damage, attempts to gain unauthorized access for friends or colleagues?
8. Has the employee unlawfully carried weapons (or carried weapons in violation of ASU policies)?
9. Has the employee provided false information on applications or other formal institutional documents?
10. Has the employee performed unauthorized off-hours work in the facility?
D. ASU Self- and Peer-Reporting Process

An individual who has Tier 1 BSAT access or the ability to gain access is exhibiting concerning behavior or if there is concern about such individual’s well-being.

Notify RO, ARO, and/or supervisor to express concern.

RO, ARO, and/or supervisor evaluates concern.

RO, ARO, and/or supervisor contacts Employee Assistance Program at (480) 965-2271 to share concerns regarding behavior and determine if referral is appropriate.

Referral is appropriate

RO, ARO, and/or supervisor meets with employee to discuss concerns; provides the Employee Assistance Office (EAO) and/or ASU Health Services as a resource and offers 1 hour of release time for employee to participate. (Voluntary Service)

If/when the employee makes use of EAO, the supervisor will receive a courtesy call confirming attendance from EAO.

Additional information will only be provided if the employee chooses to do so.

RO, ARO, and/or supervisor continues to monitor behavior and performance.

Referral is not appropriate

EAO consults with supervisor and helps to identify more appropriate campus resources to assist in managing the situation.

RO, ARO, and/or supervisor contacts Human Resources at (480) 965-5221 for support with performance/policy.

Guidance provided by Human Resources to assist with administrative options within policy.

Ongoing consultation as needed to investigate allegations and/or manage performance.

RO, ARO, and/or supervisor contacts

Employee Assistance Program at (480) 965-2271 to share concerns regarding behavior and determine if referral is appropriate.

ASU maintains a hotline to anonymously report observations or issues. The number for the ASU Hotline is (877) 786-3385.

RO, ARO, and/or supervisor calls 911 for imminent threats to life and safety or criminal activity (if supervisor reports, supervisor must notify the ASU Responsible Official at (480) 965-1823).

Officer dispatched

Note: At any step in the process, the RO/ARO may make a determination to limit or deny access to Tier 1 BSAT.
Self- and Peer-Reporting Process (continued)

Self Report

Peer Report

“Opt Out?”

Verify Information

Monitor

Opt Out Process/ Monitor

Annual Suitability evaluation

Previous Suitability Issues

Threat of Violence?

Yes

Gather any other factual information

No

Threat of workplace violence

Investigation

Individual provides

Peer Provides

Whole Person/Individualized Assessment

Organizational Perspectives

Mitigating Factors

Safety Concerns
Security Concerns
PSC or BRT Input
HR Input
Legal Input
Supervisor Input

Situation Circumstances
Severity History

RO Assessment Regarding Access to Tier 1 BSAT

Permanent removal

Temporary removal

Limit Access

Monitor and Refer to EAO

No Limitations

Allow the person to respond

No additional Information

Notify the person of results

Environmental Health and Safety
E. Reporting of Individuals Working with Select Agents

Individuals at ASU are required to report incidents or conditions that could affect an individual’s ability to have access to or work safely with select agents, or safeguard select agents from theft, loss, or release.

Inquiries or reports of concerning behaviors or activities in the ABSL-3 or BSL-3 at ASU facilities may be submitted by self, peers, students, researchers, subordinate staff, animal care personnel, visitors or anyone that witnesses a concerning behavior or activity regarding select agents at ASU. Concerning behaviors should be reported to the supervisor, RO, or other university personnel (e.g., BSO). The privacy and confidentiality of the individual making the report as well as the content of the report will be protected to the extent permitted by law. In addition, ASU maintains a hotline to enable individuals to anonymously report observations or issues related to Tier 1 BSAT. The number for the ASU Hotline is 877.786.3385. Anonymous reports may also be mailed to:

Attn: Tier 1 BSAT RO
University Services Building
PO Box 876412
Tempe, AZ 85287-6412  EHS Mail Code: 6412

Training will be provided annually to all personnel working with select agents on reporting concerning behaviors or suspicious activities in the ABSL-3 and BSL-3 facilities at ASU. The training will be provided during the mandatory CDC annual training that all DOJ-cleared personnel attend. The RO and BSO will highlight the importance of peer-review and self-reporting of any suspicious or concerning behaviors. The annual training will also cover individual responsibilities as well as expectations from everyone in the select agent program.

F. Occupational Health Assessment and Surveillance

The annual health assessment includes the following at the discretion of the ASU Occupational Health Physician.

<table>
<thead>
<tr>
<th>Table 2. ASU Health Services Ongoing Occupational Health Assessment</th>
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<tbody>
<tr>
<td>Medical Questionnaire</td>
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<tr>
<td>Baseline Physical Exam / Medical Screening</td>
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<td>ACAM 2000 Vaccination</td>
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<tr>
<td>Audiometry Evaluation</td>
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<tr>
<td>Baseline Kidney Function Test</td>
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<td>Baseline Liver Function Test</td>
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<td>Complete Blood Count (CBC)</td>
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<td>Hemochromatosis Screening</td>
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<td>Measles, Mumps, Rubella Titer or Vaccination</td>
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<td>Respirator Fit Testing</td>
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<td>Other Vaccinations Based Upon Research Requirements</td>
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</tbody>
</table>

Continued access to Tier 1 BSAT is contingent upon successful completion of an annual occupational health assessment and a Certificate of Occupational Health Clearance (refer to Appendix C). The need for any intermittent assessments will be determined by the Occupational Health Provider. ASU will cover the cost for the annual occupational health assessment. Additional costs for other health assessments must be approved by the RO or his/her designee and must be necessary for the select agent program.

Although employees with access, or the ability to gain access, to Tier 1 BSAT, are required to have an occupational health assessment, this does not preclude individuals from reporting conditions or behaviors which they believe may impact their own, or another individual's, ability to work safely with or around Tier 1 BSAT.

G. **Select Agent Opt-Out Process**

ASU allows personnel enrolled in the select agent program to voluntarily opt-out of work with select agents or toxins. Opting-out is a voluntary decision to interrupt or stop working with select agents or toxins for a short period of time. A voluntary opt-out must not exceed two weeks for a single incident, and no more than 15 total working days in a calendar year. An employee-initiated opt-out must be communicated to the supervisor and RO of the institution, but is not required to be reported to the CDC. This decision must be made and implemented by the individual working in conjunction with their supervisor and the RO. The voluntary opt-out period is intended for those times when an employee is at work but voluntarily determines that they should not have access, or the ability to have access, to Tier 1 BSAT. Upon initiation of the voluntary opt-out period, the RO will remove the individual's access to Tier 1 BSAT for the duration of the opt-out period (refer to Appendix D for Temporary Voluntary Opt-Out Form).

Voluntary opt-out may be an option during a temporary condition or situation. If allowed to opt-out for this short period, it is anticipated that the individual will be able to perform select agent work safely and responsibly in the near future. The supervisor may, but is not required, to request documentation during the voluntary opt-out period. Reasons for a voluntary opt-out include but are not limited to the following:
• Temporary emotional or personal crisis (e.g., relationship drama);
• Periods of high stress for an individual or any condition that the individual feels would prevent him/her from performing select agent work safely and securely (e.g., news of a close friend’s death, dissertation defense).

ASU’s Employee Assistance Office (EAO) is available to assist employees who voluntarily opt-out. This service offers free, voluntary, and confidential behavioral health and organizational consultation for personal and work-related issues. The EAO is located in University Towers, Suite 101 and may be reached at 480.727.7775.

ASU Human Resources is also available to assist employees who are considering or have initiated a voluntary opt-out. Human Resources is located at University Center (UCNTRA) at 1100 E. University Drive in Tempe or by calling 480.965.5221.

H. Procedures for Temporary Voluntary Opt-Out

1. An individual informs their supervisor of their decision to temporarily opt-out of working with BSATs (refer to Appendix D for Temporary Voluntary Opt-Out Form).
2. The supervisor notifies the RO of the voluntary opt-out. The RO may contact Human Resources, EAO, or other applicable ASU resources as necessary to help facilitate the voluntary opt-out.
3. The reasons for the opt-out will be kept confidential to the extent permitted by institutional policies and the law.
4. The RO will grant the voluntary opt-out and establish a plan or procedures, in conjunction with Human Resources if necessary, for the employee to resume duties.
5. The RO will communicate to the individual the conditions and procedures for voluntarily opting-out.
6. The RO will authorize Biodesign IT to temporarily remove access for the individual opting-out to all areas where Tier 1 select agents are used or stored.
7. The supervisor will assign other job duties and responsibilities to the individual for the voluntary opt-out period or will work with Human Resources to identify other work that the employee can perform during the opt-out period.

I. Procedures for Resuming Normal Work Duties After Opt-Out

1. If the employee is ready to resume normal work duties before the opt-out period expires, or if the period of voluntary opt-out has expired, the RO and the supervisor will discuss the resuming of normal work duties with the individual.
2. However, if the employee will not be returning to work at the end of the voluntary opt-out period because, for example, the employee is continuing on medical leave, pregnancy leave, or if the employee cannot
return to work in an area containing Tier 1 BSAT due to an employee’s medical condition, Human Resources will so notify the RO. The RO will work with Human Resources on all matters that involve the Family Medical Leave Act, ADAAA, or other applicable state or federal laws to make certain that appropriate and lawful steps are taken to address issues related to the employee leave and return to work.

3. Once the employee is able to return to work, the supervisor and RO will meet with the individual to assess if the employee is ready to resume work in an area that contains Tier 1 BSAT. The RO will include Human Resources as appropriate.

4. If the temporary opt-out and/or any other leave was for medical reasons, the RO and Human Resources will determine if a “fit-for-duty” clearance is warranted before the individual is given access to Tier 1 BSAT. Only the RO can authorize Biodesign IT to grant access to the individual to areas containing Tier 1 BSAT.

5. Re-training of the individual may be necessary depending on the length of the absence.

J. Procedures for Permanently Opting-Out

An individual may also permanently opt-out of working with select agents or toxins. If this decision is made and if working with select agents or toxins is an essential function of the individual’s position, the RO and supervisor will work with Human Resources to identify an alternative, comparable assignment within the department. Human Resources may also help the employee determine if there are other open positions within ASU for which the employee is qualified and is capable of performing the essential functions of the position. ASU will provide reasonable assistance to the employee but cannot guarantee or promise an alternative assignment within the department or another position within ASU.

K. Preventing Stigmatization of Voluntary Opt-Out Process

To ensure that opting-out is not stigmatizing to the employee, this topic will be addressed during the annual CDC training and emphasized by supervisors during periodic lab meetings. The range of possible reasons for opting-out will be addressed during the annual training to highlight that opting-out may be for a multitude of reasons.

L. Risk and Threat Reporting Mechanism

Individuals are expected to self-report and advise University leadership (e.g., supervisors, RO, ARO, BSO, HR, EAO, Health Services) of any issues that could have an adverse impact on his/her performance, suitability, or safety while performing Tier 1 BSAT duties or accessing areas containing Tier 1 BSATs. In the instance where HR or EAO are consulted, it is both essential and expected that individuals ensure that consultants are made aware of their access to Tier 1 BSAT. Similarly, individuals are expected to advise their supervisor, BSO, and/or RO when another individual with Tier 1 BSAT access manifests behavior, or
otherwise appears to be involved in a situation that may adversely affect the safety or security of any Tier 1 BSAT. If there is an imminent danger, an individual should call 911 for immediate assistance. Finally, ASU maintains a hotline to enable individuals to anonymously report observations or issues related to Tier 1 BSAT. The number for the ASU Hotline is 877.786.3385. Anonymous reports may also be mailed to:

Attn: Tier 1 BSAT RO
University Services Building
PO Box 876412
Tempe, AZ 85287-6412
EHS Mail Code: 6412

M. Responses to Self- and Peer-Reporting

Ultimately, the RO, based on the feedback from the Personnel Suitability Committee, University leadership, and other will take actions as necessary to ensure the safety, security, and integrity of Tier 1 BSAT. Potential actions include:

- Grant continued access to Tier 1 BSAT without limitation.
- Grant continued access with ongoing monitoring from resources (e.g., HR, EAO).
- Approve voluntary removal or “opt-out” of Tier 1 BSAT access, with designated time for return or re-evaluation.
- Deny or suspend Tier 1 BSAT access, with designated time for re-evaluation.
- Terminate Tier 1 BSAT access.

Note: In accordance with the Federal Select Agent Regulations, the RO must immediately notify CDC when an individual’s access to select agents is terminated by the entity and the reasons therefore.

N. Preventing Retaliation for Reporting

To prevent retaliation against individuals reporting behaviors of concern or suspicious activities, all information received in the report, including the reporter’s identifying information, will be kept confidential to the extent allowed by institutional policies and the law. Any allegation of retaliation will be taken seriously and will be promptly and thoroughly investigated.

O. Investigations and Appeal Process

During the CDC annual training, all DOJ-approved employees with Tier 1 BSAT access will receive training on what constitutes behaviors of concern or suspicious activities that should be reported. The training will also cover who should receive these reports regarding behaviors of concern or suspicious
activities. Individuals that would like to make a report regarding anyone who is engaging in suspicious activity or displaying behaviors of concern, may do so directly to the RO. The RO will make certain that all reports are thoroughly investigated. The Personnel Suitability Committee may be requested to review the investigative findings and recommend a course of action to the RO.

During the investigation period, access to Tier 1 BSAT may be limited or revoked for the reported individual depending on the suspicious activity or concerning behavior. If access is to be revoked or suspended, the RO will authorize Biodesign IT to remove access to the select agent facilities for that individual.

- If the allegation is confirmed based on a preponderance of the evidence, the RO will make a decision whether to remove or suspend the individual access to Tier 1 BSAT. The RO will coordinate with the individual’s supervisor, ASU Health Services, Employee Assistance Office (EAO) counselors, security personnel, legal, Biosafety Officer (BSO) or other leadership or qualified persons in the assessment or adjudication of suitability as appropriate under the circumstances.
- The RO has sufficient familiarity with all individuals having access to Tier 1 BSAT, and their supervisory chain, to permit a continual evaluation of suitability, and has the authority to engage supervisors when warranted.

At the end of the investigation and after the RO has made a determination as to the appropriate course of action, the investigative findings and the course of action of the investigation will be communicated to the individual in writing. The individual has 14 calendar days to request, in writing to the RO, that the decision be reconsidered. The request must include justification for reconsideration. The RO has the discretion to ask the Personnel Suitability Committee or other professional resources, as appropriate, to review the request for reconsideration and recommend a course of action. The RO’s decision to uphold, modify, or overturn the decision regarding Tier 1 BSAT access is final.

Investigative reports will be kept confidential to the extent permitted by institutional polices and the law.

P. Training

All individuals with access to Tier 1 BSAT must complete the annual CDC Select Agent and Toxin Security. This training includes:

- Insider threat awareness;
- Pre-access suitability assessment requirements;
- Self- and peer-reporting procedures (including examples of behaviors of concern);
- Corrective actions, procedures, and policies;
- Procedures for voluntary and involuntary removal of Tier 1 BSAT access;
• Reducing the stigma for individuals who “opt-out” from the Tier 1 BSAT; and
• Information security.

All training must be documented and the training records kept for three years.

Mandatory initial and annual in-person training with the RO and BSO are also interactive forums from which to detect any hostile attitudes towards safety, security, regulatory requirements, or leadership that might compromise the intended safety and security of program participants. Individuals exhibiting behaviors that demonstrate that they are incapable of controlling their actions or adhering to safety or security practices should be denied access to Tier 1 BSAT and referred to HR and the EAO for further assessment. The Office of Human Resources is responsible for evaluating the circumstances per appropriate University policy (e.g., Fitness for Duty) and forwarding information to the RO so that a determination can be made regarding access to Tier 1 BSAT.
Appendix A: Annual Ongoing Suitability Assessment Letter

[Date]

Dear Peer:

According to federal regulations, Arizona State University is required to have an Ongoing Personnel Suitability Assessment Program covering all personnel with access, or the ability to gain access, to Tier 1 Biological Select Agents and Toxins (BSAT). The completion of the enclosed Personnel Suitability Assessment Form is an important component of this Program.

The Center for Disease Control and Prevention has determined that essential elements of an Ongoing Personnel Suitability Assessment Program are self and peer assessments. Thus, each employee who has or could gain access to a Tier 1 BSAT (“Tier 1 Employee”) will be assessed by his or her peers at least once a year. For purposes of this Program, a “Peer” is defined, in a broad sense, as someone who observes, interacts, and/or works with the Tier 1 Employee on a regular or frequent basis. A Peer will assess a Tier 1 Employee by completing a Personnel Suitability Assessment Form.

You have been identified as a Peer for the Tier 1 Employee identified on the enclosed Personnel Suitability Assessment Form. As a Peer, the information which you provide in the Personnel Suitability Assessment Form will be taken seriously and addressed in a security/safety context. Therefore, you must be honest, forthright, and truthful in your assessment of the Tier 1 Employee. As a Peer, you must sign the Personnel Suitability Assessment Form upon completion. By signing the form, you are affirming that your answer to each question is truthful and accurate to the best of your knowledge and belief.

You are asked to keep the completed Personnel Suitability Assessment Form as confidential as permitted by law. Confidentiality is necessary because the information disclosed may be security and/or safety sensitive. Therefore, once you have completed the enclosed Personnel Suitability Assessment Form, please seal the form in the envelope provided and return it to the named individual on the envelope label who will provide the sealed envelope to me. To protect the integrity of the program and to honor and respect the privacy of others, please do not discuss assessment answers or any actions arising from the Ongoing Personnel Suitability Assessment process.

Please remember that the purpose of this assessment process is to strengthen laboratory security and to enhance public safety. Your full cooperation is necessary and appreciated. If you have any questions or comments regarding the Ongoing Personnel Suitability Assessment Program, please do not hesitate to contact me at 480.965.6927.

Sincerely,

Leon Igras, CDC Responsible Official
Environmental Health and Safety

Enclosure
## Appendix B: Annual Ongoing Suitability Assessment Form

<table>
<thead>
<tr>
<th>Suitability Assessment Item</th>
<th>Yes</th>
<th>No</th>
<th>If yes, explain in detail, include relevant dates/times: (use back of this form for additional space)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. To the best of your knowledge and belief, has the employee been involved in circumstances that may affect the ability of an individual to perform his or her job in a safe and secure manner (e.g., performance of duties declines markedly, significant increase in distraction or mistakes, increase in risk-taking behaviors)?</td>
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<td>2. To the best of your knowledge and belief, has the employee had significant changes in behavior, attitudes, demeanor, or actions (e.g., increasingly withdrawn; significant and prolonged deterioration in appearance; unjustified anger or aggression; unexplained absences; signs of alcohol/drug abuse; criminal activity; and unexplained absences)?</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>3. To the best of your knowledge and belief, has the employee stated or implied threats to colleagues, institutions, the security of Tier 1 BSAT, the wellbeing of laboratory animals, or the general public, whether written or verbal?</td>
<td>☐</td>
<td>☐</td>
<td></td>
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<tr>
<td>4. To the best of your knowledge and belief, has the employee been willfully non-compliant with the select agent regulations?</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>5. To the best of your knowledge and belief, is there any information that causes an individual to have concerns about the employee's ability to perform a job safely and securely?</td>
<td>☐</td>
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<tr>
<td>6. To the best of your knowledge and belief, are there any circumstances regarding the employee that appear suspicious such as laboratory work that does not correspond to official project goals or work, requests for security or laboratory information without justification, acts of vandalism or property damage, attempts to gain unauthorized access for friends or colleagues?</td>
<td>☐</td>
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<tr>
<td>7. To the best of your knowledge and belief, has the employee unlawfully carried weapons (or carried weapons in violation of ASU policies)?</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>8. To the best of your knowledge and belief, has the employee provided false information on applications or other formal institutional documents?</td>
<td>☐</td>
<td>☐</td>
<td></td>
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<tr>
<td>9. To the best of your knowledge and belief, has the employee performed unauthorized off-hours work in the facility?</td>
<td>☐</td>
<td>☐</td>
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</tbody>
</table>
| 10. To the best of your knowledge and belief, has the employee been involved in circumstances that may affect their SRA status? Items that affect SRA status include:  
• The individual is under indictment for (or convicted of) a crime punishable by imprisonment for a term exceeding 1 year.  
• The individual is a fugitive from justice.  
• The individual is an unlawful user of any controlled substance (as defined by the Controlled Substance Act).  
• The individual is an alien illegally or unlawfully in the United States.  
• The individual has been adjudicated as a mental defective or has been committed to any mental institution.  
• The individual has been discharged from the Armed Services of the United States under dishonorable conditions.  
• The individual is a member of, acts for or on behalf of, or operates subject to the direction of, a terrorist organization as defined by the Immigration and Nationality Act.  
• The individual has committed a crime considered an act of terrorism transcending national boundaries [specified in 18 USC 2332b(g)(5)].  
• The individual has knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 USC 2331) or with any other organization that engages in intentional crimes of violence.  
• The individual is an agent of a foreign power (as defined in 50 USC 1801). | ☐   | ☐  |                                                                                                                                                                                                                                                                                                                                                                                                  |

<table>
<thead>
<tr>
<th>Name of Reviewer:</th>
<th>Date</th>
<th>Reviewer's Signature:</th>
</tr>
</thead>
</table>

My answer to each question is truthful and accurate to the best of my knowledge and belief.
Appendix C: Certificate of Occupational Health Clearance for Tier 1 BSAT

ASU ID #: ____________________  Department: ____________________

Last Name: ____________________  First Name: ____________________

Supervisor: ____________________

Status:

☐ Cleared to work in the Tier 1 BSAT program

☐ Conditional clearance to work in the Tier 1 BSAT program

☐ NOT cleared to work in the Tier 1 BSAT program: ☐ Indefinitely ☐ Temporarily

If “Conditionally Cleared” or “Temporarily Not Cleared” please provide relevant information as it pertains to employee’s job duties in the Tier 1 BSAT program:

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

Occupational Health Provider ____________________  Date ________________

cc:  ASU Responsible Official
     Employee’s Supervisor

Appendix D: Temporary Voluntary Opt-Out Form for Tier 1 BSAT