



USDA

**APPLICATION FOR
REGISTRATION FOR POSSESSION, USE, AND
TRANSFER OF SELECT AGENTS AND TOXINS
(APHIS/CDC FORM 1)**

FORM APPROVED
OMB NO. 0579-0213
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MOST COMMONLY ASKED APHIS/CDC FORM 1 QUESTIONS

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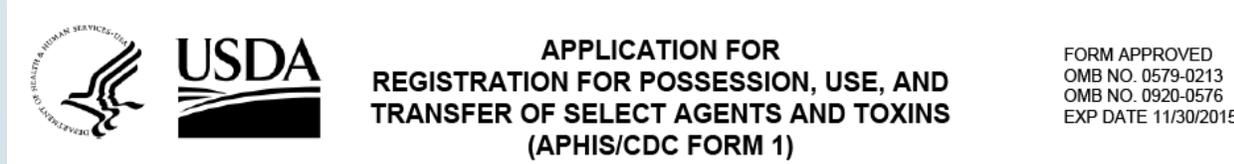


Demonstration of Form 1 Instructions, and Amendment Section

- **Table of Contents links**
- **Links to external information**
- **Amendment table**
- **Navigation within the document**

- **Reminder: Refer to the posted online Form 1 Instructions due to continuous updates**

FORM 1



Question

- **Can I release information about my entity's select agent program, such as the APHIS/CDC Form 1, to an outside source?**

Response

- **Yes, the RO may release any information that he/she deems appropriate regarding the entity's select agent program.**
- **FSAP recommends not releasing the entire Form 1 to an outside source, since the Form 1 contains sensitive information regarding personnel, location of select agents, etc.**

FORM 1, SECTION 1A

Section 1A - Entity Information			
OWNER / CONTROLLER INFORMATION (If Applicable)			Delete
Last Name:	<input type="text"/>	First Name:	<input type="text"/>
DOJ Number:	<input type="text"/>	Date of Birth:	<input type="text"/> Tier 1 Access: <input type="checkbox"/>

Question

- I am the RO at a private university. Who is the appropriate person to designate as the owner or controller?

Response

- ***For a private institution of higher education, an individual will be deemed to own or control the entity if the individual is in a managerial or executive capacity with regard to the entity's select agents or toxins or with regard to the individuals with access to the select agents or toxins possessed, used, or transferred by the entity. These conditions may apply to more than one individual. See 42 CFR 73.7 (c)(3)(i).***

FORM 1, SECTIONS 4 AND 7 TIER 1 STATUS

Tier 1 Access	Last Name	First Name	DOJ Unique Identifier Number	Date of Birth (mm/dd/yyyy)	Role	Supervising Principal Investigator
<input type="checkbox"/>					Select a Role	

PI Last Name	PI First Name	PI DOJ Number	PI Date of Birth	PI Tier 1 Access
				<input type="checkbox"/>

Question

- **How do I indicate Tier 1 status of a PI who directs the work of a non-Tier 1 agent, but who is a laboratorian for another PI working with a Tier 1 agent?**

Response

- **FSAP assesses an individual's access to Tier 1 select agents and toxin on an entity-wide basis. Therefore, all Form 1 Sections must agree when indicating an individual's Tier 1 status, regardless if an individual performs jobs with varied access to Tier 1 agents and toxin.**

FORM 1, SECTION 4A

Tier 1 Access	Last Name	First Name	DOJ Unique Identifier Number	Date of Birth (mm/dd/yyyy)	Role	Supervising Principal Investigator
<input type="checkbox"/>					Select a Role	ALL PIs

Question

- **If our entity's Section 4A indicates "all PIs" on our currently approved registration, are we required to submit a Section 4A when adding a new PI?**

Response

- **A Section 4A is not required if there are no changes to the supervising PI as indicated on the Section 4A.**

FORM 1, SECTION 4A

Tier 1 Access	Last Name	First Name	DOJ Unique Identifier Number	Date of Birth (mm/dd/yyyy)	Role	Supervising Principal Investigator
<input checked="" type="checkbox"/>	Jones	Mary		01/01/1970	Laboratorian	John Smith

Tier 1 Access	Last Name	First Name	DOJ Unique Identifier Number	Date of Birth (mm/dd/yyyy)	Role	Supervising Principal Investigator
<input type="checkbox"/>	John	Smith	C-JS-123456	01/01/1970	Laboratorian	John Smith

Question

- **How do I indicate the PI on Section 4?**

Response

- **PIs are only indicated as supervising principal investigators on Section 4A. PI-specific information (DOB, DOJ, Tier 1 status, etc.) is recorded in Section 7A.**

FORM 1, SECTION 7

Section 7A - Principal Investigator (PI) Information and Select Agent and Toxin Locations

A complete Section 7 must be submitted for each PI. If separate PIs would result in an identical Section 7 being completed, multiple PIs can be listed in the header.

Section 7C - Description of Work

1. Provide the objectives of work for each select agent and/or toxin listed in Section 7A **by agent/toxin and containment level(s)**, including a description of the methodologies or laboratory procedures that will be used. Include any work involving animals, arthropods or plants. Attachments A-G must be completed if appropriate for the work described. If no work is being performed with select agent and/or toxin, indicate "storage only".

Question

- **Can a PI's Section 7 be completed according to the biosafety level (e.g., separate Section 7s for BSL3 versus BSL4 work)?**

Response

- No, FSAP accepts a single, comprehensive Section 7 for a PI.
- A PI's work objectives (Section 7C, Question 1) are described based on the agents and biosafety level, thereby distinguishing work conducted at BSL3 versus BSL4
- Multiple PI groups with different work objectives will result in multiple Section 7s.

FORM 1, SECTIONS 3 AND 7

Question

- How do I register if there is no current work with or storage of with the select agent?

Response

- Complete the form for the anticipated work and/or storage
 - Section 3: indicate the agent that you wish to register but do not indicate possessed
 - Section 7: PI Work Objectives
 - Section 7A: indicate storage and/or the biosafety level for the anticipated work
 - Section 7B: indicate “TBA”
 - Section 7C: describe the anticipated work objectives or storage

FORM 1, SECTION 7C

Section 7C - Description of Work

Question

- Does FSAP accept a partial Section 7C?

Response

- No, partial Section 7Cs are not allowed. Please remember to include all attachments as applicable.

FORM 1, SECTION 7C

Section 7C - Description of Work

Question

- Is a Section 7C required when requesting to add new space?

Response

- No, a Section 7A is required when adding new space.
- A Section 7C and appropriate attachments are required if the PI's work objectives are being affected.
- Please indicate in your cover letter if there are no changes to the work objectives in Section 7C.

FORM 1, SECTION 7C, QUESTION 5

Section 7C - Description of Work
5. Name(s) of Individual(s) responsible for inventory of select agent(s) and/or toxin(s):
<input type="text"/>

Question

- Am I required to submit an updated Section 7C when removing an individual who is responsible for inventory?

Response

- No, you are not required to provide a Section 7C when removing an individual who is responsible for inventory. Please provide this information the next time you are required to submit a subsequent Section 7C.

Please note that the amendment reference table in the Form 1 Instructions does not align with the updated written text.

FORM 1, SECTION 7C, QUESTION 5

Section 7C - Description of Work
Inventory record is reconciled:
<input type="checkbox"/> Annually
<input type="checkbox"/> Other (specify frequency)

Question

- If all registered PIs store their inventory in the same freezer, is a 100% inventory audit required if a PI leaves the institution?

Response

- An inventory audit is specific to the departing PI's inventory collection.
- FSAP recommends that a 100% inventory audit is conducted of the entire freezer or shared storage locations that the departing PI had access to.

FORM 1: AMENDMENT SUBMITTAL – HELPFUL HINTS

- To add an individual to **Section 4**:
 - Submit a partial Section 4 with only the name of the individual(s) being added
- **Section 7** is organized by the PI or PI Group
 - Submit only the affected PI or PI Group when changes occur to the PI work objectives
 - One Section 7 per PI or PI Group
- Contact your file manager with any question regarding your registration
- Please remember to use the posted online Form 1 instructions as the document is updated on a regular basis

FORM 1: UPDATES COMING

- Digital Signatures are an option to sign the APHIS/CDC Form 1.
- Language has been clarified in Section 7C, Question 9a for when to complete Attachment A.
 - Use to describe work with registered toxins.