

Possession, Use, and Transfer of Select Agents and Toxins (42 CFR Part 73)

(OMB Control No. 0920-0576)

Attachment 15

Centers for Disease Control and Prevention
Office of Public Health Preparedness and Response
Division of Select Agents and Toxins)

Summary of Revisions

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Revision Summary

Request to Transfer Select Agents and Toxins Form 2

Request to Transfer Select Agents and Toxins Form 2 – Page 1

- Added the sentence “Read guidance instructions at <http://www.selectagents.gov/CDForm.html> before completing this form. Answer all items completely and type or print in ink. The form must be signed and submitted to either APHIS or CDC by email attachment, fax, or mail:
- Added accession number block for program use only to top left of page
- Added space for “APHIS/CDC Authorization Number” and “Expiration Date” to the center of page.

Request to Transfer Select Agents and Toxins Form 2 – Section 1

- Section A Recipient Information
 - Added text #10 RO Telephone #
 - Added text#11 RO FAX
 - Added text #12 RO email.
- In Section B, Sender Information
 - Added text #20 Responsible Official / Facility Director Phone
 - Added text#21 Responsible Official / Facility Director Fax
 - Added text 22 Responsible Official / Facility Director email
 - Added #23 – “This transfer request is for a select agent or toxin that was identified in a clinical or diagnostic sample: Yes No If yes, please ensure that an APHIS/CDC Form 4 “Report of the Identification of a Select Agent or Toxin” is submitted to APHIS or CDC within 7 calendar days.”

Request to Transfer Select Agents and Toxins Form 2 -Section 2

- In Section D List of Selects and Toxins Shipped
- # 27 changed the word “vials” to “items.”

- In Section D List of Selects and Toxins Shipped
- # 29 changed the word “vial” to “item.”

- Added Section E – Recipient Notification Information
- Added name of Individual at recipient entity notified
- Added date of Notification
- Added type of notification

- Added “Section F – Shipping Information”
- Added Name of individual shipping package
- Added Number of packages shipped
- Added Shipment date
- Added Package description
- Added name of carrier
- Added airway bill number

Revision Summary

Reporting of Theft Loss or Release of Select Agents and Toxins (Form 3)

Reporting of Theft Loss or Release of Select Agents and Toxins Form 3- Page1

- Added the sentence “Read guidance instructions at <http://www.selectagents.gov/CDForm.html> before completing this form. Answer all items completely and type or print in ink. The form must be signed and submitted to either APHIS or CDC by email attachment, fax, or mail:

- Added accession number block for program use only to the top right of page

- Added space for “APHIS/CDC Authorization Number” and “Expiration Date” at the center of page

Reporting of Theft Loss or Release of Select Agents and Toxins Form 3 Section 1

- Added a check box to # 14A record lab acquired infections. Although this is a release, it further indicates there has been an occupational illness.
- Added a check box to # 14C record transfer incident. This interfaces with the proposal to have an Appendix B to record the information.
- Added a check box to #15 for potential exposures. (See block 15)
- Added a check box to #15 to ask whether medical surveillance has been initiated.

- Added #23Name of Agent
- Added # 24Characterization of Agent,
- Added # 25 Quantity/Amount

Reporting of Theft Loss or Release of Select Agents and Toxins Form 3 Section 2

- Added a page so entities can continue their narrative / summary OR any other section that need further clarification.
- Added “save and continuation” button at the bottom of the page that will produce additional blank pages as needed. This will allow the entire narrative to be fully recorded on the fillable form. (See Appendix A)

Reporting The Identification of Select Agents and Toxins Form 4

Reporting The Identification of Select Agents and Toxins Form 4 Reference Laboratory Information Page 1

- Added the sentence “Read guidance instructions at <http://www.selectagents.gov/CDForm.html> before completing this form. Answer all items completely and type or print in ink. The form must be signed and submitted to either APHIS or CDC by email attachment, fax, or mail:
- Added accession number block for program use only to right of page
- Added APHIS/CDC Reference number

Reporting The Identification of Select Agents and Toxins Form Form 4 Section A

- Added Reference Laboratory Report and Sample Provider Sections to improve process flow
- Removed Reference Laboratory Information decrease number of similar questions
- Added check box to # 4 Clinical or Diagnostic Laboratory [non-registered entity (NRE)] (NRE # (provided by APHIS or CDC):

Reporting The Identification of Select Agents and Toxins Form 4 Section B

- Added case/patient ID # to #4
- Added # of samples to # 3
- Added cases patient origin by zip code #6
- Added comments section 311

Reporting The Identification of Select Agents and Toxins Form Form 4B Sample Provider Information

- Added the sentence “Read guidance instructions at <http://www.selectagents.gov/CDForm.html> before completing this form. Answer all items completely and type or print in ink. The form must be signed and submitted to either APHIS or CDC by email attachment, fax, or mail:
- Added APHIS/CDC REFERENCE ID#.

- Added the sentence “Read guidance instructions at <http://www.selectagents.gov/CDForm.html> before completing this form. Answer all items completely and type or print in ink. The form must be signed and submitted to either APHIS or CDC by email attachment, fax, or mail:
- Added accession number block for program use only.
- Removed check boxes for destruction methods Original source of sample: Human Animal (species) to decrease similar questions
- Removed Plant (species)
- Removed Other (specify) to decrease similar questions
- Remove summary of the methodology used to identify select agent or toxin to decrease similar questions

Reporting The Identification of Select Agents and Toxins Form Form 4B Proficiency Report

- Added the sentence “Read guidance instructions at <http://www.selectagents.gov/CDForm.html> before completing this form. Answer all items completely and type or print in ink. The form must be signed and submitted to either APHIS or CDC by email attachment, fax, or mail:
- Added accession number block for program use only.

Reporting The Identification of Select Agents and Toxins Form Form 4B Section B

- Added table collecting the following: Select Agent or Toxin Identified, Date obtained from sponsor and Date identified to improve surveillance.
- Added TLR Question: Were any of the samples containing a select agent or toxin, listed in the table above, and handled outside of primary containment which may have led to an unintentional release and/or exposure to the select agent or toxin? No Yes (If Yes, you are required under 7 CFR Part 331.19, 9 CFR Part 121.19, and 42 CFR Part 73.19 to complete and submit an APHIS/CDC Form 3) to improve surveillance.
- Removed total quantity identifies to decrease similar questions
- Removed location of testing to decrease similar questions
- Removed BSL of laboratory or PPQ designation to decrease similar questions
- Removed name of lab test that proficiency was designed to access to decrease similar questions

Reporting The Identification of Select Agents and Toxins Form 4C Federal Law Enforcement Seizure Report

- Added the sentence “Read guidance instructions at <http://www.selectagents.gov/CDForm.html> before completing this form. Answer all items completely and type or print in ink. The form must be signed and submitted to either APHIS or CDC by email attachment, fax, or mail:
- Added accession number block for program use only.

Reporting The Identification of Select Agents and Toxins Form Form 4C Section A

- Added #1 Name of federal law enforcement agency.

Reporting The Identification of Select Agents and Toxins Form Form 4C Federal Law Enforcement Seizure Report

- Added # 6 Comments/Notes section.
- Added TLR Question: Were any of the samples containing a select agent or toxin, listed in the table above, and handled outside of primary containment which may have led to an unintentional release and/or exposure to the select agent or toxin? No Yes (If Yes, you are required under 7 CFR Part 331.19, 9 CFR Part 121.19, and 42 CFR Part 73.19 to complete and submit an APHIS/CDC Form 3) to improve surveillance
- Removed Badge # from old form # 52
- Removed strain of designation being seized from old form # 54
- Removed Entity registration number from old form #58
- Removed Entity address, city, state, zip code from old form # 59
- Removed Responsible Officials name, telephone number, FAX, email from old form #63