



MOUNT SINAI
SCHOOL OF
MEDICINE

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LR/SAT -Select Agent Transfers

[Refer to: <http://www.cdc.gov/od/ohs/lrsat/42cfr72.htm>]

(a) Requests for Select Agents.

- (1) Prior to the transfer of any agent to or from the Mount Sinai School of Medicine contained in the Select Agent List [[Appendix A](#)], a **CDC Form EA-101*** must be completed for each transfer sought. As specified in **CDC Form EA-101**, the information provided must include:
 - (i) The name of the **requestor** and **requesting facility**;
 - (ii) The name of the **transferor** and **transferring facility**;
 - (iii) The names of the **responsible facility officials** for **both** the transferor and requestor;
 - (iv) The **requesting facility's registration number**;
 - (v) The **transferring facility's registration number**;
 - (vi) The **name of the agent(s)** being shipped;
 - (vii) The **proposed use** of the agent(s); and
 - (viii) The **quantity** (*number of containers and amount per container*) of the agent(s) being shipped.
- (2) **The EA-101 form must be signed by the transferor and requestor, and the responsible facility officials representing both the transferring and requesting facilities. [All four parties must sign- off]**
- (3) A copy of the completed **CDC Form EA-101** must be retained by both transferring and requesting facilities for a period of **five (5) years after** the date of shipment or **for five (5) years after the agents are consumed** or properly disposed, whichever is longer.
- (4) All **CDC forms EA-101** must be produced upon request to appropriate federal and authorized local law enforcement authorities, officials authorized by the Secretary of Health and Human Services (HHS), and officials of the registering entity.

* Available only from the Institutional Biosafety Officer

(b) Verification of registration.

- (1) Prior to transferring any agent covered by this part, the transferror's responsible facility official must verify with the requestor's responsible facility official, and as appropriate, with the registering entity:
 - (i) That the requesting facility retains a **valid, current registration**;
 - (ii) That **the requestor is an employee** of the requesting facility; and
 - (iii) That the proposed use of the agent by the requestor is correctly indicated on **CDC Form EA-101**.
- (2) In the event that **any party is unable to verify** the information required in paragraph (e)(1) of this section, or there is suspicion that the agent may not be used for the requested purpose, **then the party shall immediately notify CDC**. [Every attempt should be made to verify information or resolve a discrepancy before alerting the CDC.]

(c) Transfer.

- (1) Upon completion of the **CDC Form EA-101** and verification of registration, the transferring facility must comply with the packaging and shipping requirements in this part or other applicable regulations when transferring the agent.
[**Go to:** <http://www.mssm.edu/biosafety/policies/pdfs/shipping.pdf>]
- (2) The **requesting facility's responsible official must acknowledge receipt** of the agent telephonically or otherwise electronically **within 36 hours of receipt** and provide a paper copy or facsimile transmission of receipt to the **transferror** within **3 business days** of receipt of the agent.
- (3) Upon telephonic acknowledgment of receipt of the agent, **the transferor shall provide a completed** paper copy or facsimile transmission of **CDC Form EA-101 within 24 hours** to the registering entity (holding that facility's registration; currently the **LR/SAT Office-CDC**), in accordance with §72.6(c)(2) for filing in a centralized repository.

(d) Inspections.

- (1) Registering entities (the CDC) or the Secretary (HSS) may conduct random or for cause inspections of registered facilities to assure compliance with this part. All **CDC forms EA-101** and records deemed relevant by inspecting officials must be produced upon request to authorized personnel conducting these inspections. Inspections may also include review of the mechanisms developed by a facility to track intrafacility transfers as well as the facility's agent disposal procedures.
- (2) In addition, the Secretary (HSS) may conduct inspections of registering entities, and/or any consolidated database established in accordance with §72.6(c)(3), to assure compliance with this part.

(e) Exemptions.

- (1) **Exemptions for certain select agents:** Select agents otherwise covered by this part are exempt from its provisions if:
 - (i) **The agent is part of a clinical specimen intended for diagnostic, reference, or verification purposes.** Isolates of covered agents from clinical specimens shall be disposed of in accordance with §72.6(i) after diagnostic, reference, or verification procedures have been completed;
 - (ii) The agent is a **toxin having an LD50 for vertebrates of more than 100 nanograms per kilogram of body weight** which is used for legitimate medical purposes or biomedical research or is one of the listed toxins which has been inactivated for use as a vaccine or otherwise detoxified for use in biomedical research procedures; or
 - (iii) The agent(s) is an exempted strain specified in [Appendix A](#) and/or **CDC Form EA-101**. Additional exemptions for otherwise covered strains will be considered when CDC reviews and updates the list of select agents [[Appendix A](#)]. Individuals seeking additions to the list of exemptions should submit a request to CDC that specifies the agent or strain to be exempted and explains why such an exemption should be granted. Future changes to the list of exemptions will be published in the Federal Register for review and comment prior to inclusion on [Appendix A](#).
- (2) **Exemption of CLIA certified laboratories:** Clinical laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, (42 U.S.C. § 263a) (CLIA), that utilize these select agents for diagnostic, reference, verification, or proficiency testing purposes are exempt from the provisions of 72.6.
- (3) **Procedures for facilities that are not CLIA laboratories but are transferring or receiving select agents to or from a CLIA laboratory.** Facilities that are not CLIA laboratories but are transferring or receiving select agents to or from a CLIA laboratory must comply with the following provisions. (No additional paperwork on behalf of CLIA laboratories is required by this section.)
 - (i) Prior to transferring a select agent subject to this part to a CLIA laboratory for diagnostic, reference, verification, or proficiency testing purposes, the **transferrer** must:
 - (A) Provide the following information on **CDC Form EA-101**:
 - (1) The name of the requestor and requesting facility;
 - (2) The name of the transferrer and transferring facility;
 - (3) The name of the transferor's responsible facility official;
 - (4) The requesting facility's CLIA certification number (which the transferrer must verify as valid and current with the registering entity);
 - (5) The transferring facility's registration number;

- (6) The name of the agent(s) being shipped;
- (7) The proposed use of the agent(s); and
- (8) The quantity (number of containers and amount per container) of the agent(s) being shipped.

(B) Verify receipt of the agent with the CLIA laboratory and note such receipt on **CDC Form EA-101**;

(C) Transmit a copy of the form, signed by the **transferrer** and the **responsible facility official representing the transferring facility**, to the registering entity holding the transferring facility's registration; and

(D) Retain a copy of **CDC Form EA-101** in accordance with 72.6(d)(3) and §72.6(d)(4).

- (ii) Prior to receiving a select agent listed in [Appendix A](#) from a CLIA laboratory, the *requestor* must be registered in accordance with 72.6(a) and comply with the following requirements:

(A) Provide the following information on the **CDC Form EA-101**:

- (1) The name of the requestor and requesting facility;
- (2) The name of the transferrer and transferring facility;
- (3) The name of the requestor's responsible facility official;
- (4) The transferring facility's CLIA certification number;
- (5) The requesting facility's registration number;
- (6) The name of the agent(s) being shipped;
- (7) The proposed use of the agent(s); and
- (8) The quantity (number of containers and amount per container) of the agent(s) being shipped.

(B) Upon receiving the agent, note such receipt on **CDC Form EA-101**;

(C) Transmit a copy of **CDC Form EA-101**, signed by the requestor and the responsible facility official representing the requesting facility, to the registering entity holding the requesting facility's registration;

(D) Retain a copy of the **CDC Form EA-101** in accordance with 72.6(d)(3) and 72.6(d)(4);

(E) Comply with the disposal requirements of §72.6(i) and all other sections of this part when subsequently transferring the agent.

(f) Agent disposal.

- (1) Upon termination of the use of the agent, all cultures and stocks of it will be
 - (i) Securely stored in accordance with prudent laboratory practices,
 - (ii) Transferred to another registered facility in accordance with this part, or

- (iii) Destroyed on-site by autoclaving, incineration, or another recognized sterilization or neutralization process.
- (2) When an agent, previously transferred to a facility in accordance with this part, is consumed or destroyed, the **responsible facility official must formally notify the registering entity**. Formal notification must be noted on **CDC Form EA-101** and a copy kept on record by the responsible facility official for a period of **five (5) years** and is subject to paragraph (g) of this section.

(g) Definitions. As used in this section:

Facility means any individual or government agency, university, corporation, company, partnership, society, association, firm, or other legal entity located at a single geographic site that may transfer or receive through any means a select agent subject to this part.

Registering entity means an organization or state agency authorized by the Secretary (HSS) to register facilities as capable of handling select agents at Biosafety Level 2, 3, or 4, depending on the agent, in accordance with the CDC/NIH publication "[Biosafety in Microbiological and Biomedical Laboratories](#)." [**Presently, the CDC is the Authorized Registering Entity**]

Requestor means any person who receives or seeks to receive through any means a select agent subject to this part from any other person.

Responsible facility official (RFO) means an official authorized to transfer and receive select agents covered by this part on behalf of the transferor's and/or requestor's facility. This person should be either a safety officer, a senior management official of the facility, or both. The responsible facility official should not be an individual who actually transfers or receives an agent at the facility. [**For the Mount Sinai School of Medicine, the RFO is the Institutional Biosafety Officer.**]

Secretary (HSS) means the Secretary of the Department of Health and Human Services or her or his designee.

Select agent means a microorganism (virus, bacterium, fungus, rickettsia) or toxin listed in [Appendix A](#) of this part. **The term also includes:**

- (1) Genetically modified microorganisms or genetic elements from organisms on [Appendix A](#) , shown to produce or encode for a factor associated with a disease, and
- (2) Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins on [Appendix A](#) , or their toxic subunits.

Single geographic site means a building or complex of buildings at a single mailing address.

Transfer means:

- (1) The conveyance or movement from a point of origination to a point of destination either
 - (i) From one state or territory to another or
 - (ii) Entirely within one contiguous state or territory.
- (2) **Intrafacility transfers** within a registered facility located at a single geographic site **are not covered** by the provisions of Section 72.6 (d), (e), and (f) provided that:
 - (i) the intended use of the agent remains consistent with that specified in the most current transfer form and
 - (ii) for each intrafacility transfer, the facility maintains records that include the name and location of the recipient; the amount of agent transferred, and the date transferred. At Mt. Sinai School of Medicine, these activities are reported to the Institutional Biosafety Officer. Such records must be maintained for **a period of five (5) years** after the date of transfer or for **five (5) years** after the agents are consumed or properly disposed, whichever is longer.

Transferor means any person who transfers or seeks to transfer through any means a select agent subject to this part to any other person.

§72.7 Penalties.

Individuals in violation of this part are subject to a fine of no more than \$250,000 or one year in jail, or both. Violations by organizations are subject to a fine of no more than \$500,000 per event. **A false, fictitious, or fraudulent statement or representation** on the Government forms required in the part for registration of facilities or for transfers of select agents **is subject to a fine or imprisonment for not more than five years, or both for an individual; and a fine for an organization.**

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