

Interim Guidance Regarding Compliance with Select Agent Regulations for Laboratories Handling Patient Specimens that are Known or Suspected to Contain Ebola Virus

Ebola virus is regulated as a “select agent” in accordance with the HHS Select Agent regulations (42 CFR Part 73). Given below, in question and answer format, is guidance on how to apply the select agent regulations to activities associated with the diagnosis and care of individuals suspected of having an infection with Ebola virus. All questions concerning this guidance, and other aspects of the Ebola response should be submitted to:

Centers for Disease Control and Prevention
1600 Clifton Rd
Atlanta, GA 30333
800-CDC-INFO
(800-232-4636)
TTY: (888) 232-6348
Contact CDC-INFO

Ebola Virus

Is Ebola virus a select agent?

Yes, Ebola virus is listed as a select agent. Biological agents that the Department of Health and Human Services (HHS) has determined to have the potential to pose a severe threat to public health and safety, such as Ebola virus, are regulated under the HHS Select Agent regulations (42 CFR Part 73).

A current list of select agents and toxins can also be found at:

<http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html>.

Ebola virus is also listed as a Tier 1 agent. (A subset of select agents and toxins have been designated as Tier 1 because these biological agents and toxins present the greatest risk of deliberate misuse with significant potential for mass casualties or devastating effect to the economy, critical infrastructure, or public confidence, and pose a severe threat to public health and safety).

Entities that possess, use, or transfer Tier 1 select agents and toxins must adhere to the additional requirements detailed within the Select Agent Regulations:

<http://www.selectagents.gov/Regulations.html>.

Is genetic material from the Ebola virus regulated as a select agent?

No. Nucleic acids that cannot produce infectious forms of a select agent (such as from the Ebola virus) are not regulated as a select agent.

Patient and Specimen Management Issues

Is waste generated during delivery of care to Ebola virus-infected patients subject to select agent regulations (42 CFR Part 73)?

As long as facilities treating Ebola virus-infected patients follow the CDC's "[Infection Prevention and Control Recommendations for Hospitalized Patients with Known or Suspected Ebola Hemorrhagic Fever in U.S. Hospitals](http://www.cdc.gov/vhf/ebola/hcp/infection-prevention-and-control-recommendations.html)(<http://www.cdc.gov/vhf/ebola/hcp/infection-prevention-and-control-recommendations.html>)" or equivalent actions, waste generated during delivery of care to Ebola virus-infected patients would not be subject to select agent regulations (see the exclusion provision 42 CFR § 73.3(d)(1)). However, this exclusion would not apply to any facility that intentionally collected or otherwise extracted the Ebola virus from waste generated during the delivery of patient care.

Are specimens collected from a patient suspected to have Ebola infection covered by the select agent regulations?

No, specimens would not be subject to the Federal select agent regulation until identified as containing Ebola virus by viral isolation.

How do select agent regulations apply to specimens that have tested positive by molecular methods?

The select agent regulations would not apply until the specimen that has tested presumptively positive using molecular methods has been proven to contain live-infectious Ebola virus by virus isolation.

Any specimens that are confirmed by virus isolation to contain live-infectious Ebola virus must be reported to DSAT immediately by telephone (404-718-2000), Email (lrsat@cdc.gov), or FAX (404-718-2096) and be followed up with [APHIS/CDC Form 4](#) within seven days of the initial report.

Are specimens from a patient confirmed by viral isolation to contain Ebola virus covered by the select agent regulations?

Yes. If live-infectious Ebola virus is confirmed, any diagnostic or clinical specimens (e.g., blood, urine, tissue, and other body fluids) that are kept would be covered by the regulations and would have to be destroyed, decontaminated, or transferred to a registered select agent facility within seven days of notification that live-infectious Ebola virus was detected. Specimens that were collected but not kept, e.g. blood collected for routine patient care and then decontaminated or destroyed after testing, are not subject to the regulations.

After the patient has been determined to no longer be infected with Ebola virus, specimens taken after that point are not subject to the select agent regulations.

Is the APHIS/CDC Form 2 required to transfer specimens from a patient confirmed by viral isolation to contain Ebola virus?

Yes, [APHIS/CDC Form 2](#) would be required to request prior authorization for the transfer of the identified select agent.

Would the APHIS/CDC Form 4 need to be completed for reporting specimens that are confirmed by viral isolation to contain the Ebola virus?

Yes. For reporting the isolation of the Ebola virus from the clinical sample, only one [APHIS/CDC Form 4](#) should be completed for each patient.

We have performed a nucleic acid extraction on a sample from a confirmed Ebola patient. Is the extracted nucleic acid covered by the select agent regulations?

No. The nucleic acid of the Ebola virus is not infectious therefore it is not a select agent.

What safety precautions should I use to perform routine medical testing for patients suspected or known to contain the Ebola virus?

Please refer to “[Interim Guidance for Specimen Collection, Transport, Testing, and Submission for Persons Under Investigation for Ebola Virus Disease](http://www.cdc.gov/vhf/ebola/hcp/interim-guidance-specimen-collection-submission-patients-suspected-infection-ebola.html)(<http://www.cdc.gov/vhf/ebola/hcp/interim-guidance-specimen-collection-submission-patients-suspected-infection-ebola.html>)” for guidance regarding safety precautions.

What should be done if there is a potential exposure to blood, body fluids and other infectious materials to a patient suspected or known to contain the Ebola virus?

Please refer to “[Infection Prevention and Control Recommendations for Hospitalized Patients with Known or Suspected Ebola Hemorrhagic Fever in U.S. Hospitals](http://www.cdc.gov/vhf/ebola/hcp/infection-prevention-and-control-recommendations.html)(<http://www.cdc.gov/vhf/ebola/hcp/infection-prevention-and-control-recommendations.html>)” for guidance regarding occupational exposures.

If the patient confirmed to have contracted Ebola has died as a result of virus, would the patient’s body be considered a select agent?

No. The patient’s body would not be considered a select agent. Select agents in their naturally occurring environment are not subject to the regulations; this includes a human that was naturally infected with a select agent.