

Important Information for Human Cell, Tissue, and Cellular and Tissue-based Product (HCT/P) Establishments Regarding Monkeypox Virus and HCT/P Donation

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FDA is working closely with the CDC and other federal and international agencies to monitor reports of monkeypox and populations at greatest risk of infection. We are issuing this communication to provide information regarding monkeypox virus and donation of human cells and tissues.

Worldwide, there have been no reports of transmission of monkeypox virus through use of human cells, tissues, or cellular or tissue-based products (HCT/Ps); therefore, the risk of infection transmitted by implantation, transplantation, infusion, or transfer of HCT/Ps remains theoretical. Monkeypox virus nucleic acid has been detected in tissues and secretions of infected humans, such as in skin, semen, and placenta; however, the levels of infectious virus in human cells and tissues have not been well characterized.

Considerations

Routine screening measures, for the purposes of making a donor eligibility determination, are already in place for evaluating risk factors and conditions as well as clinical evidence and physical evidence of infection in HCT/P donors. For example, donor screening includes performing a donor medical history interview (21 CFR 1271.3(n)) and review of relevant medical records (21 CFR 1271.3(s)) to look for risk factors and conditions that may lead to a determination that the donor is ineligible. These safeguards may identify individuals who are screened for potential donation who are diagnosed with monkeypox virus or who are currently at greatest risk for infection with monkeypox virus. To date, most cases of monkeypox have been diagnosed among men who have sex with other men, although the virus can spread to anyone through close, personal, often skin-to-skin contact, such as direct contact with monkeypox rash or scabs. In addition, for cadaveric (non-heart-beating) donors, HCT/P establishments should determine whether an autopsy was not performed due to a perceived risk of transmission of communicable disease or, if an autopsy was performed, whether any special precautions were taken that would suggest there was a special concern over the risk of transmission of a communicable disease from the donor.

Due to the robustness of existing donor screening recommendations, FDA does not recommend using laboratory diagnostic tests to screen HCT/P donors for monkeypox virus.

The HCT/P establishment's responsible person (21 CFR 1271.3(t)) must determine and document the eligibility of a cell or tissue donor (21 CFR 1271.50). Based on information available at this time, establishments may wish to consider, whether, in the 21 days prior to HCT/P recovery, the donor:

- was diagnosed with or was suspected of having a monkeypox infection;
- had close contact with a person or an animal diagnosed with or suspected of having monkeypox infection regardless of the donor's vaccination status; or
- developed a rash or other symptoms suggestive of monkeypox infection.

A licensed live replicating virus vaccine indicated for active immunization against smallpox (ACAM2000) may be used against monkeypox under FDA's Expanded Access Investigational New Drug (IND) mechanism, and recommendations remain applicable in the 2007 [Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products \(/regulatory-information/search-fda-guidance-documents/eligibility-determination-donors-human-cells-tissues-and-cellular-and-tissue-based-products\)](#), related to evaluating an HCT/P donor for receipt of

smallpox vaccination in the preceding 8 weeks and screening donors for clinically recognizable vaccinia virus infection from contact with someone who received the live replicating virus smallpox vaccine. The licensed non-replicating virus vaccine indicated for prevention of monkeypox (JYNNEOS) does not carry this same concern.

FDA will continue to monitor cases of monkeypox in the U.S. and worldwide and available information about potential risks of monkeypox virus transmission by HCT/Ps. We will communicate, as appropriate, as additional information becomes available.

Additional Resources:

- [About Monkeypox | Monkeypox | Poxvirus | CDC \(https://www.cdc.gov/poxvirus/monkeypox/about.html\)](https://www.cdc.gov/poxvirus/monkeypox/about.html)
- [Monitoring and Risk Assessment for Persons Exposed in the Community | Monkeypox | Poxvirus | CDC \(https://www.cdc.gov/poxvirus/monkeypox/clinicians/monitoring.html\)](https://www.cdc.gov/poxvirus/monkeypox/clinicians/monitoring.html)
- [FDA Monkeypox Response | FDA \(/emergency-preparedness-and-response/mcm-issues/fda-monkeypox-response\)](#)