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North America Legal and Regulatory Affairs

Watchdog Update

REGULATORY WATCHDOG

Health Canada

Nothing to report

FDA

Advice to Blood Collection Establishments on Non-Travel Related Cases of Zika Virus in Florida

Updated 8/4/2016 to remove Broward County

In consideration of the possibility of an emerging local outbreak of Zika virus, and as a prudent measure to help assure the safety of blood and blood products, FDA is requesting that all blood establishments in Miami-Dade County cease collecting blood immediately until the blood establishments implement testing of each individual unit of blood collected in the county with an available investigational donor screening test for Zika virus RNA or until the blood establishments implement the use of an approved or investigational pathogen inactivation technology. For blood collection establishments outside of this region, FDA suggests that donors who have traveled to Miami-Dade County during the previous 4 weeks be deferred.

The Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP) have issued draft guidance titled, "Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs".

This draft guidance was prepared jointly by FDA and OHRP and is intended to assist IRB administrators, IRB chairpersons, and other institutional officials responsible for preparing and maintaining written procedures for the IRB. This joint draft guidance is now available on FDA's website at http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm512761.pdf, and OHRP's website at http://www.hhs.gov/ohrp/newsroom/rfc/index.html.

The draft guidance provides an IRB Written Procedures Checklist that incorporates the HHS and FDA regulatory requirements for IRB written procedures and additional topics that FDA and OHRP recommend including in IRB written procedures.

Comments are due by October 3, 2016.

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New Guidance Documents

- Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components. For immediate implementation. **Posted 8/26/2016**

- Use of Nucleic Acid Tests to Reduce the Risk of Transmission of Hepatitis B Virus from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products. **Posted 8/15/2016**
- Determining Donor Eligibility for Autologous Donors of Blood and Blood Components Intended Solely for Autologous Use – Compliance Policy. **Posted 8/1/2016**