

FDA Staff Manual Guides, Volume III - General Administration

Safety and Occupational Health Programs

Travel to Active Zika Areas

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[Attachment A – FDA Zika Virus Counseling Form](#)

1. Purpose.

Zika virus has been associated with increased risk of severe birth defects. As per Occupational Safety and Health Administration (OSHA) guidance and the Centers for Disease Control and Prevention (CDC) guidelines on travel to Zika affected areas, FDA will allow flexibility in travel arrangements for workers concerned about Zika virus exposures. Accordingly, the purpose of this policy is to clearly articulate that FDA does not require travel to active Zika areas for employees who are concerned about the risks of exposure to Zika.

2. Background.

Zika virus is a mosquito-borne illness. Prior to 2015, Zika virus outbreaks only occurred in areas of Africa, Southeast Asia, and the Pacific Islands. However, outbreaks have recently occurred in many countries in Central America, South America, the Caribbean, and Pacific Islands. Anyone travelling to areas where Zika virus is circulating is at risk of becoming infected. The virus is transmitted to humans primarily through the bite of an infected *Aedes* species mosquito. However, perinatal, in utero, sexual, and transfusion methods of transmission have also been reported. Eighty percent of people infected with Zika are asymptomatic. When symptoms are present, they are usually mild and include fever, rash, joint pain, and conjunctivitis (red eyes with irritation).

Symptoms may last from several days to a week. Severe symptoms requiring hospitalization are uncommon; however, Zika virus infection during pregnancy can cause a serious birth defect called microcephaly, in which the baby's head is smaller than normal and its brain less developed. In addition, a possible link between Zika virus and Guillain-Barré syndrome has been reported in some individuals.

The link between Zika infection and microcephaly prompted CDC to issue guidelines recommending that women who are pregnant postpone travel to areas with ongoing local transmission of Zika virus. CDC guidelines also recommend anyone planning to become pregnant or whose spouse is pregnant or planning to become pregnant should consult with their health care provider prior to travel. If an individual chooses to travel to areas where Zika virus is active, CDC recommends strict precautions to [avoid being bitten by mosquitoes](#), including wearing protective clothing such as long sleeves and long pants, using [Environmental Protection Agency registered insect repellents](#), and working and/or sleeping in rooms with window screens, bed netting, or air conditioning. FDA's Zika policy is intended to be consistent with [CDC guidelines](#).

3. Policy.

Any FDA employee, including USPHS Officers, planning FDA related travel to an area with active local transmission of Zika virus, as designated by CDC travel alerts and advisories, requires consultation with FDA Occupational Health Services (in person or by telephone) or their health care provider within one year prior to travel. This will afford employees an opportunity to assess their current personal situation with a clinician in order to make the most appropriate decision for them and their families. Employees will sign the FDA Zika Virus Counseling Form (See Attachment 1) indicating they accept or decline work-related travel based on the risks associated with potential exposure to Zika virus. FDA employees choosing to decline work-related travel, due to concerns to Zika virus exposure which have been validated by a healthcare provider, will not have negative employment status consequences.

4. Responsibilities and Procedures.

Prior to travel, FDA employees are required to check the [CDC website](#) for travel alerts and advisories.

1. For work-related travel to active Zika areas FDA employees are required to consult with FDA Occupational Health Services or their health care provider regarding the risks of Zika transmission.
2. The FDA Zika Virus Counseling Form must be signed by the employee and the health care provider who performed the counseling within

twelve months prior to the travel. (See attached: FDA Zika Virus Counseling Form)

3. Employees will return the signed copy of the FDA Zika Virus Counseling Form to their supervisor for acknowledgement and final signature.
4. The form will be uploaded with travel documents in Concur if travel risks are accepted by the employee.

5. References.

1. CDC Website: http://www.cdc.gov/mmwr/volumes/65/wr/mm6512e3.htm?s_cid=mm6512e3_w.htm
2. CDC Website: <http://wwwnc.cdc.gov/travel/page/zika-travel-information>
3. CDC Website: <http://www.cdc.gov/zika/index.html>
4. OSHA Website: <https://www.osha.gov/zika/index.html>
5. EPA Website: <https://www.epa.gov/insect-repellents/find-insect-repellent-right-you>

6. Definitions.

Concur: Federal Government online travel system

Microcephaly: a congenital condition associated with incomplete brain development and an abnormally small head

Outbreak: the occurrence of cases of disease in excess of what would normally be expected in a defined community, geographical area or season

SOPP: Standard Operating Policy and Procedures

7. Effective Date.

The effective date of this guide is July 20, 2016.

8. Document History - SMG 2130.9, "Travel to Active Zika Areas"

Status (I, R, C)	Date Approved	Location of Change History	Contact	Approving Official
Initial	07/01/2016	N/A	OO/OSSCM	Carl Pavetto, Director, OO/OSSCM
Revision	07/20/2016	N/A	OO/OSSCM	Carl Pavetto, Director, OO/OSSCM
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Change	12/22/2022	Sect. 3 and 4.2; Attachment A	OO/OFEMS/ ESOHC	Sacha H. Gutierrez, Chief Medical Officer, Occupational Health Services

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ATTACHMENT A

NOTE: This form will be used to document informed decision making in acceptance or declination of Zika exposure risks during work-related travel or work in FDA laboratories

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Zika Virus Counseling Record

Name	Date
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I have received counseling about:

- how I may be exposed to Zika virus during travel or in the laboratory;
- the risks of infection with Zika virus, including the potential for birth defects in the fetus; and
- how to protect myself from exposure to Zika virus during travel or in the laboratory, including covering exposed skin, using EPA-registered insect repellents, and using standard precautions, certain types of personal protective equipment, and specific lab practices/procedures.

In addition:

- I have discussed my Zika virus-related health concerns with the OHS clinician or my health care provider, and my questions were answered to my satisfaction.

As a result of the information I have received, I am able to make an informed decision as to ~~whether or not~~ I will accept the risk of being exposed to Zika virus.

I decide to (Select one):

- accept the risks of Zika virus transmission associated with travel or other FDA duties, or
- decline FDA duties and travel that may increase risk of Zika transmission.

Employee Acknowledgement, and Concurrence of Clinician/Provider and Supervisor

Employee Signature	Date
OHS Clinician or Healthcare Provider Signature	Date
Physician Comment	Expiration Date
Supervisor Signature	Date