



Informed Consent/Understanding the Risks of Zika and Pregnancy- Electing to Continue Fertility Treatments

The Centers for Disease Control and Prevention (CDC) has alerted couples attempting pregnancy to be aware of the risks that the Zika virus can pose to a potential pregnancy. CCRM is urging patients to limit travel to areas where there is ongoing active transmission of the Zika virus in order to limit the risk of a potential Zika virus infection while in treatment at CCRM and during an entire potential pregnancy. By signing this consent you are acknowledging that you understand the risks, warnings and recommended preventative measures while seeking treatment at CCRM and during a pregnancy.

SYMPTOMS OF THE ZIKA VIRUS DISEASE AND RISK TO PREGNANCY

The Zika virus disease (Zika) is a disease caused by Zika virus that is spread to people primarily through the bite of an infected *Aedes* species of mosquito. Only about one in five people infected with Zika actually have symptoms. The most common symptoms of Zika are fever, rash, joint pain, and conjunctivitis (red eyes). The illness is usually mild with symptoms lasting from several days to a week. Severe disease requiring hospitalization is uncommon. Sexual transmission of Zika from a male to a female has been reported. No instances of Zika virus transmission during fertility treatment have been documented, but transmission of the Zika virus can be present in semen, and sexual transmission has occurred.

Zika infection during pregnancy can cause serious birth defects such as microcephaly (underdeveloped brain and skull) and has been associated with other birth defects (such as intracranial calcifications, other brain abnormalities, abnormal cerebral artery flow) as well as other pregnancy complications such as pregnancy loss and intrauterine growth restriction. Following a Zika infection, some individuals have developed Guillain Barre syndrome.

- Guillain Barre symptoms include weakness of the arms and legs that is usually the same on both sides of the body. In some cases, the muscles of the face that control eye movement or swallowing may also become weak. In the most serious cases, this muscle weakness can affect breathing and can lead to death.
- Microcephaly is a medical condition in which the circumference of the head is smaller than normal because the brain has not developed properly or has stopped growing. Microcephaly can be present at birth or it may develop in the first few years of life. It is most often caused by genetic abnormalities that interfere with the growth of the cerebral cortex during the early months of fetal development. Babies may also be born with microcephaly if, during pregnancy, their mother abused drugs or alcohol; became infected with a cytomegalovirus, rubella (German measles), varicella (chicken pox) virus, or possibly Zika virus; was exposed to certain toxic chemicals; or had untreated phenylketonuria (PKU, a harmful buildup of the amino acid phenylalanine in the blood). Microcephaly is associated with Down’s syndrome, chromosomal syndromes, and neurometabolic syndromes.

PREVENTION

- The current Zika virus outbreak was identified in Brazil in May 2015, and knowledge about Zika virus infection, its potential adverse effects on pregnancy, and transmission is rapidly evolving. As of March 23, 2016, there were 39 countries and U.S. territories reporting active Zika virus transmission (6). Updates on areas with active Zika virus transmission are available online at <http://wwwnc.cdc.gov/travel/notices>. Avoid travel to Central and South America as well as the Caribbean, Puerto Rico and the U.S. Virgin Islands. These countries/regions where Zika has been identified and should be avoided for women/couples attempting pregnancy or/are pregnant. Because Zika continues to spread, geographic areas of concern are difficult to determine and likely to change over time.
- CCRM has informed me that current testing for Zika is limited and in many cases inconclusive.
- Mosquito bite prevention:
 - Use of insect repellent
 - Wear clothing which covers arms and legs

- Assure window screens and mosquito nets are used.
- Avoid leaving windows open
- Avoid travel to affected areas of concern – review the CDC website for affected areas prior to travel.

SEXUAL TRANSMISSION OF AN AFFECTED PERSON PASSING INFECTION TO OTHERS

- During the first week of infection, Zika virus can be found in the blood and passed from an infected person to another mosquito through mosquito bites. An infected mosquito can then spread the virus to other people.
- Zika virus can be spread during sex by a man infected with Zika to his sex partners.
 - It is thought that the virus is present in the semen of men who have had Zika for three months or longer.
 - We do know that the virus can stay in semen longer than in blood.
- To help prevent spreading Zika, use condoms the correct way during intercourse. This includes vaginal, anal, and oral (mouth-to-penis) intercourse. Avoiding intercourse is the best way to be sure that someone does not get sexually transmitted Zika.
- Pregnant women should talk to a doctor or healthcare provider if they or their male partners recently traveled to an area with Zika, even if they don't feel sick.

VACCINATION/TREATMENT AND TESTING

- There is currently no vaccine or medication for cure at this time and testing patients for the virus is limited. I/we understand that this information and future recommendations may change as more is known about this virus and the affects that it could have on me/us and my/our potential pregnancy.
- Patients and partners should immediately report any signs and/or symptoms consistent their physician.
- I/we understand that Zika testing is limited but will consult my physician should I have symptoms and need for testing.

CCRM POLICY FOR FREEZING EGGS/EMBRYOS OR SPERM

- Zika virus is not likely to be destroyed in the cryopreservation process. Due to the nature of freezing techniques and need to limit risk for inadvertent exposure, patients considered at risk will be required to freeze their embryos, eggs, or sperm for long term storage at Reprotech Limited.
- CCRM requires all couples who have traveled to countries/regions that the CDC has deemed at risk areas for Zika, postpone their treatment cycle for eight weeks to decrease the risk of a Zika exposure.
- If either partner had symptoms of Zika, the treatment cycle will be postponed for six months if the infection occurred in the male partner and eight weeks if the infection occurred in the female partner.
- If living in an area "at risk", Reprotech Limited storage is required. For persons living in "at risk" Zika areas; if the female has Zika symptoms the cycle will be delayed eight weeks from last day of symptoms. If the male partner has symptoms of Zika, the cycle will be delayed for six months from the last day of symptoms. Additional acknowledgement of risk documents will be required.

ACKNOWLEDGEMENT

I/we understand that this is a voluntary process and there are options to my/our care including, but not limited to, postponing my/our cycle until more is known about Zika and the potential long term affects, postponing treatment for six months per current FDA guidance after residence in an area affected with Zika and avoiding intercourse without barrier contraception.

I/we understand that the ZIKA virus is not likely destroyed in the freezing/ cryopreservation process.

I/we understand that the Federal Food and Drug Administration has set guidelines for donor tissue use in reproductive practices to decrease the risk of a transmission of the Zika virus. Individuals are ineligible to donate sperm/eggs if they have had a medical diagnosis of Zika virus infection in the past six months; residence in or

travel to an area with active Zika virus transmission within the past six months; or within the past six months had sex with a male partner who, during the six months before this sexual contact, received a diagnosis of or experienced an illness consistent with Zika virus disease, or had traveled to an area of active Zika virus transmission.

I/we understand that having the proper evaluation, testing, as well as our physician's recommendations for treatment prior to and during pregnancy may lower the risk for the treatment cycle and for the potential resulting pregnancy.

I/we understand that should my partner or I travel to areas with active Zika transmission--as identified by the CDC-- during our treatment cycle, we will be required to delay our cycle for up to eight weeks, or if the male partner has symptoms the cycle will be delayed for up to six months.

I/we understand that CCRM cannot guarantee a normal health baby and recommends patients seek early pregnancy screening and serial fetal ultrasound examinations during pregnancy and work closely with our obstetrician and pediatrician if a pregnancy is achieved.

I/we understand the CDC is rapidly creating policy and recommendations in regards to Zika, which may result in risks not described in this document.

I/we understand that our physician can alert us to the risks, but it is our obligation to follow the recommendations described within this document.

I/We have read the Zika risks as described within this document, understand that we may request a consultation with our physician so we may fully and sufficiently understand the potential Zika risks to our offspring. An appointment with a physician may be scheduled. My/our signature(s) below indicates that I/we understand the risks stated.

Print Patient Name	Signature	DOB	Date
Government ID – Patient	ID Number		
Print Partner Name	Signature	DOB	Date
Government ID – Partner	ID Number		
Practice Representative	Date		

I/We confirm that I have read and fully understand the information contained in this consent and agreement and have been given an unrestricted opportunity to ask questions and receive answers to my/our satisfaction and understanding. I further understand that if I have any remaining or additional questions or concerns, I should contact a CCRM physician or nurse. I understand that participation is purely voluntary and that my refusal to participate or withdraw from the program at any time will not involve any penalty or loss of benefit to which I am otherwise entitled. I am of sound mind and understand that, if signing this document electronically subject to my agreement and understanding, that my electronic signature has the same force and effect in acknowledging my understanding and consent as set forth above, as if I had signed this consent and agreement in person before a notary public.