

## **COVID-19 "CORONAVIRUS" ACKNOWLEDGEMENT, AGREEMENT AND ASSUMPTION OF RISKS**

NOTE: THIS WRITTEN CONSENT IS AN IMPORTANT DOCUMENT AND THE COPY PROVIDED TO YOU SHOULD BE RETAINED WITH OTHER VITAL RECORDS FOR FUTURE REFERENCE.

(Print Patient's full name)	Date of Birth	Date
(Print Partner's full name)	Date of Birth	Date

CCRM Fertility ("CCRM") is actively monitoring the novel coronavirus ("COVID-19") outbreak and continues to prioritize the safety and well-being of our patients. This document serves to inform you of what your physicians currently understand about this new form of coronavirus so that you can make an informed decision about current or future treatment cycles. Please note that information and recommendations regarding COVID-19 is constantly evolving and there may be risks currently unknown.

Coronaviruses are a large family of viruses common in humans and several animal species. It is currently understood that COVID-19 is spread from an infected person to others through a variety of means, including airborne droplets from coughing and sneezing; close personal contact (e.g. touching and shaking hands); and touching one's nose, mouth or eyes before washing one's hands. It is currently unknown if COVID-19 can be spread through semen, vaginal secretions, or sexual intercourse. Many healthy individuals will experience the most common symptoms of COVID-19, which include, but is not limited to, fever, sore throat, cough, shortness of breath, or loss of sense of taste and/or smell. Many of the people who contract the virus will have symptoms similar to the flu, will not require hospitalization, and will recover with routine supportive medical care. Some people may be at higher risk for serious illness from COVID-19 because of their age or because they have chronic or other serious long-term health problems (e.g., heart disease, diabetes and lung disease). These individuals may experience more severe complications, including pneumonia in both lungs, multi-organ failure, and in some cases death. However, serious illness can still occur in individuals who do not have high risk factors.

It is currently understood that the impact of COVID-19 on reproduction and pregnancy is limited. There are reports of women who have tested positive for COVID-19 and have delivered babies without the virus, while there are reports of women whose babies have tested positive for the virus. It is unknown if a pregnant woman can transmit COVID-19 to her fetus or neonate by other routes of vertical transmission (before, during, or after delivery). Additionally, there is limited information from published scientific reports about the susceptibility of pregnant women to COVID-19 and the severity of infection. Available data may be reassuring, but is limited to small case series. In general, pregnant women experience immunologic and physiologic changes that make them more susceptible to viral respiratory infections, as is observed with other coronavirus infections and viral respiratory infections, such as influenza, during pregnancy. Because of this, pregnant women who contract COVID-19 may be at greater risk for severe illness, and even death, compared with the general population. Pregnant women who have severe chronic medical conditions may be at higher risk of preterm delivery and other pregnancy complications, which requires closer fetal monitoring (per the recommendations of the Society for Maternal-Fetal Medicine). Miscarriage and stillbirth are more common with influenza infections in pregnancy, and therefore could be a risk of COVID-19. Although unknown at this time, birth defects could also result from COVID-19

infection during pregnancy. Delaying pregnancy until the risk of COVID-19 infection is low is currently the most prudent way to minimize the above risks.

At this time, there is limited data available regarding the risks associated with COVID-19 infection in the first and second trimesters of pregnancy. There is also conflicting data regarding the risks of congenital malformations in the setting of maternal fever. Currently, there is inconclusive data on the risk of miscarriage or congenital anomalies following COVID-19 infection given the limited number of cases reported and the quality of the published data available. Data from the recent SARS epidemic suggests there is no increased risk of fetal loss or congenital anomalies associated with infection early in pregnancy, but the data is not conclusive and similar outcomes may not be the same for COVID-19 infections.

CCRM recommends that individuals with a confirmed or presumed COVID-19 infection, or potential exposure to any individual with COVID-19, avoid pregnancy until the symptoms resolve. To reduce the risk of infection, CCRM advises that all patients who are attempting pregnancy engage in routine preventive actions such as frequent handwashing, avoiding close contact with people who have respiratory symptoms (e.g., cough and fever), and avoiding travel to high risk areas as defined by the CDC. Shelter in place requirements, which may vary from state to state, should be adhered to along with any other relevant guidance issued by federal, state or local authorities.

As more information on COVID-19 becomes available, CCRM will attempt to update its patients. Your physician may suggest options available to you, such as freezing oocytes (eggs) or embryos and/or delaying or postponing an embryo transfer. There have been no recommendations or studies to indicate that women should prevent pregnancies, but the science is still evolving and our current understanding of COVID-19 on pregnancies is limited. Current guidance from the American Society for Reproductive Medicine ("ASRM") has recommended deferring cycle initiation, and your physician will discuss with you the benefits and risks of initiating a cycle and whether it may be appropriate to postpone an embryo transfer.

CCRM has an obligation to limit potential COVID-19 exposure to other patients and your medical team. By initiating treatment, I/we understand and acknowledge that my/our treatment cycle will be canceled if I, my partner, or any individual I/we have close contact with has been diagnosed with COVID-19, is suspected of having COVID-19, or exhibits symptoms consistent with COVID-19. I/we also understand that it may be necessary to cancel my/our treatment cycle based on CCRM's interpretation of and need to comply with certain orders, mandates, travel restrictions or other guidance issued by federal, state, or local authorities and professional medical organizations. I/we understand that CCRM may require COVID-19 testing before initiation of or during any portion of my/our treatment cycle, which I/we understand cannot be waived. I/we understand and acknowledge that if my/our cycle is cancelled for any of the above reasons, all cycle and medication fees for therapy completed up to the point of cancellation will not be waived or refunded by CCRM.

I/we have had the opportunity to speak with my/our CCRM physician and any other advisors I/we wish to consult regarding the benefits and risks of starting therapy. I/we have had the opportunity to ask questions of my/our physician and they have been answered to my/our satisfaction. I/we understand that cycle initiation can only occur with the prior approval of CCRM and that the transfer of any embryos may need to be deferred. I/we understand this is a voluntary process and that there are other options available, including, but not limited to, delaying my/our cycle until more is known about COVID-19 and the potential long term affects.

I/we understand and acknowledge the risks described herein and hereby assume those risks. I/we have read this document and understand the information set forth. I/we believe I/we have sufficient information to give my/our consent to proceed with my/our treatment cycle and/or the attempt of pregnancy. By signing this document, I/we feel I/we are fully informed to make the decision to proceed with a treatment cycle given the unknown risks relating to COVID-19.

Patient Signature:	Date:
Partner Signature:	Date:
Clinic representative Signature:	Date:

References:

CDC: <a href="https://www.cdc.gov/coronavirus/2019-ncov/specific-groups/pregnancy-faq.html">https://www.cdc.gov/coronavirus/2019-ncov/specific-groups/pregnancy-faq.html</a>

Society for Maternal Fetal Medicine- https://www.smfm.org/covid19

American Society for Reproductive Medicine (ASRM): <u>https://www.asrm.org/news-and-publications/news-and-research/press-releases-and-bulletins/asrm-issues-new-guidance-on-fertility-care-during-covid-19-pandemiccalls-for-suspension-of-most-treatments/</u>

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