

CONSENT FOR ASSISTED REPRODUCTION TREATMENT DURING THE SARS - CoV - 2 PANDEMIC (COVID 19)

I. Information on the possible risks of Assisted Reproduction Techniques in relation to the disease COVID - 19, caused by the SARS - CoV - 2 coronavirus.

Infertility is a disease and, as the COVID - 19 Pandemic stabilizes and the risk of infection is reduced, it is possible to perform assisted reproduction treatments, for any clinical indication. However, this must be done by taking a series of security measures to minimize the risks related to the spread of the SARS - CoV - 2 virus.

According to what was reported by the World Health Organization (WHO), pregnant women do not seem to have a higher risk of serious evolution of COVID-19 compared to non-pregnant women of the same age and the clinical manifestations are not different in this population group.

Similarly, it has not been shown that there is vertical transmission of the virus, that is, from mother to fetus, so that no scientific society or government of any country has advised against natural pregnancy.

However, knowledge about the effects of COVID - 19 on pregnant women is still limited. Most of the information available is from women infected in the third trimester of pregnancy, with few reported cases of infection in the first trimester. Although infection in most patients is usually without symptoms or with mild symptoms, experience with other coronaviruses, such as SARS - CoV or MERS - CoV, in pregnant women, suggests that exceptionally, a result of death in case the disease evolved into severe respiratory failure, although this risk is considered to be very remote and does not have to be related with the fact of being pregnant.

Therefore, at the present time, before starting any reproduction treatment, it is essential to make an assessment with the doctor of the risk-benefit balance of becoming pregnant, taking into account the scarcity of data on the effect of COVID-19 on the course of gestation, mainly in the first trimester, being that the possibility that there could be a complication for the fetus in the event of a severe evolution of the disease in the pregnant woman and the added possibility of perinatal infection that could have adverse effects on the newborn.

II. Information on the management and evaluation of a possible infection with the SARS - Cov - 2 virus, before or during the performance of an assisted reproduction treatment.

In the current pandemic situation due to COVID - 19, it is essential to exercise extreme caution in evaluating each clinical case, maintaining the security measures established by the health authorities and implementing the recommendations published by the ESHRE, ASRM, AMMR, REDLARA, SEF and ASEBIR for safety and risk reduction against SARS- Cov - 2 coronavirus infection in assisted reproduction units.

According to these recommendations, if the patients presented symptoms or evident suspicion of SARS-CoV-2 infection before starting treatment, it would be indicated to postpone it, **as well as to avoid attending the assisted reproduction center until 4 weeks after disappearing. the symptoms and recommend that you consult the medical center of your primary care. If the suspicion was more nonspecific, validated screening tests (RT-PCR, ELISA) could be applied and the resumption of treatment could be assessed once active infection is ruled out.**

In the same way, if symptoms suggestive of infection, changes in the near environment with respect to COVID-19 or the result of carrying out specific tests were positive throughout the treatment, the risk-benefit of cancel ovarian stimulation, endometrial preparation, follicular puncture, or artificial insemination.

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In the event that these changes were detected before the embryo transfer was performed, the embryo transfer would be postponed. It is therefore very important that patients communicate to the center any changes they perceive in their health status during the assisted reproduction treatment.

III. Information on biosecurity measures taken in the assisted human reproduction laboratory to prevent possible cross-contamination of gametes or embryos by SARS-CoV-2 during their cultivation or storage.

Based on current scientific knowledge, it appears unlikely that sperm, oocytes, and embryos will become infected with the SARS-CoV-2 coronavirus. Although the evidence remains limited, it is estimated that the risk of viral contamination of gametes (oocytes and sperm) and embryos in the IVF laboratory, either from samples of infected patients or by the laboratory personnel themselves, is also minimal. .

It is considered that the good practice of the usual protocols within the human reproduction laboratory is sufficient to prevent contagion between embryologists, patients and the contamination of reproductive samples for biological agents such as SARS - CoV - 2.

Due to biosafety knowledge, current precautions and procedures are also considered sufficient to avoid contamination between samples cryo-stored in tissue and cell banks. There is no evidence of the presence of viruses that cause other communicable infectious diseases in cryopreserved oocytes and embryos from affected patients, neither in the culture media nor in the liquid nitrogen with which they were in contact.

IV. Information on possible alternatives to treatment in case it is not recommended to carry it out in its entirety or in any of its phases.

In certain circumstances, the doctor may recommend the cancellation or postponement of the assisted reproduction treatment or any of its phases. This may occur when a specific test indicates the existence of a SARS - CoV - 2 virus infection or due to the suspicion of an increased risk of COVID - 19, for having appeared in the three weeks prior to treatment or throughout the course of treatment. Himself, symptoms such as cough, sore throat, fever, fatigue, muscle pain, diarrhea or other suspicious symptoms of the disease. Also if you have had contact with someone who presented these symptoms or who has had or could have COVID-19.

In this situation, the convenience of carrying out specific tests and / or canceling or postponing treatment or any of its phases will be assessed in each case, and may be resumed or restarted once the risk of contagion has been ruled out.

V. Information on the measures that must be followed after applying the treatment to prevent infection during pregnancy.

With the scientific evidence available as of April 8, 2020, pregnant women were defined as a vulnerable group for COVID-19. The efforts of a Reproductive Medicine center should also be aimed at providing patients with the hygienic and preventive measures after applying the treatments.

Specifically, during pregnancy, the following recommendations should be followed:

- Frequent hand washing.
- When coughing or sneezing, cover your nose and mouth with your elbow flexed.
- Avoid touching the eyes, nose and mouth, since the hands facilitate the transmission.
- Use disposable tissues to remove respiratory secretions and throw them away after use.
- Avoid crowds and public transport.
- Limit face-to-face social relationships.
- Limit travel only to what is strictly necessary.

These measures will be adapted to the state of the infection in the City at the time of applying the treatment.

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All of the above

I DECLARE / WE DECLARE:

That I have received understandable and sufficient information and have had the opportunity to ask all questions of the medical team regarding:

- Possible risks derived from contagion by the SARS-CoV-2 virus during pregnancy.
- Measures that can be taken to assess a possible SARS-CoV-2 infection in a patient who is going to undergo, or is undergoing, assisted reproduction treatment.
- Measures taken to prevent the possibility of cross contamination of gametes or embryos by SARS-CoV-2 in assisted human reproduction laboratories.
- Possible alternatives to treatment in case it is not recommended to carry it out in its entirety or any of its phases.
- Care to take after treatment to prevent SARS-CoV-2 infection during pregnancy

We (name of the patient and her partner) _____, **WE AUTHORIZE**, to carry out the indicated assisted reproduction treatment: _____ for which the specific consents will be completed and signed separately.

I understand / we understand that in the event that, during the application of said treatment, there were any clinical and / or analytical changes that would lead to suspicion of a SARS-CoV-2 infection, this should be notified to the doctor and the Clinic (LIV FERTILITY CENTER) and it may become advisable to cancel or postpone the treatment or any of its phases.

The content of this document reflects the current state of knowledge, and therefore, is subject to modification if new scientific findings or advances.

In accordance with the provisions of the law on protection of personal data and guarantee of digital rights, you are informed that you can freely exercise your rights of access, rectification, cancellation, opposition, portability, limitation of treatment and forgetfulness, by writing to the center, either by attending in person, either by post or email.

Patient's name and signature _____

Name and signature of the couple _____

Physician's name and signature _____

Name and signature of the witness _____

Name and signature of the witness _____

Place and Date _____.

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