



CHIREC - Centre for Medically Assisted Reproduction – HBW/DELTA

Patients' Passport and Consent Form - COVID	<i>Rédacteur : Romain Imbert</i>
FE-MEDI-055-GB-version02	<i>Vérificateur : Deborah Desmet</i>
<i>Date d'application : 01/07/2020</i>	<i>Approbateur : Romain Imbert</i>

Agreement for Medically Assisted Reproduction treatment during COVID-19-pandemic

This informed consent form was given to the prospective parents on /...../.....
by Dr

Doctor's stamp and signature:	
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This agreement is hereby entered into by, on the one hand, **the CHIREC Medically Assisted Reproduction (MAR) Centre**, represented by Dr Romain Imbert, MD, Manager of the HBM (Human Body Material) biobank, and located at:

CHIREC - Braine L'Alleud-Waterloo :	CHIREC – Delta :
Address: Rue Wayez, 35 1420 Braine-l'Alleud	Address: Boulevard du Triomphe, 201 1160 Brussels
Phone: + 32 2 434 95 55 on working days	Phone: + 32 2 434 81 73 on working days
Fax: + 32 2 434 95 56	Fax: + 32 2 434 81 98
E-mail: pma.hbw@chirec.be	E-mail: pma.delta@chirec.be

And on the other hand, **the prospective parents:**

SURNAME – First name:	SURNAME – First name:
Date of birth:	Date of birth :
Address	Address:
Label Mrs	Label of the partner (<i>if necessary</i>)

e-mail address(es): _____@_____
_____@_____



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1. INTRODUCTION

The current pandemic Covid-19 has changed the way we treat patients.

The purpose of this document is to inform you about the risks associated with the SARS-CoV-2 virus, the cause of Covid-19 disease, and to explain the measures taken by the Belgian Centres for Medically Assisted Reproduction so that you can decide whether or not to continue your parental project under the current pandemic conditions. This document is based on the current state of our knowledge of the virus.

A. General information

In December 2019, the COVID-19 epidemic began in the Chinese city of Wuhan with people who had pneumonia of unknown cause.

Since then, the outbreak has spread around the world to the point of becoming a pandemic.

The virus is transmitted mainly from person to person through droplets. Infectious droplets are released into the air by talking, coughing and sneezing. Surfaces are contaminated by droplets falling on them or by being touched by contaminated hands. A person can be infected when the virus enters their nose or mouth, either directly through the air or by putting their virus-contaminated hands to their nose or mouth. Hands are contaminated by touching contaminated objects and surfaces (for example, door handles).

The average incubation period (period between contact with the virus and the onset of symptoms) is about 4 to 6 days but can take up to 14 days or more.

The **contagious period** begins a few days before the onset of COVID-19 symptoms, but its end varies depending on the individual and the duration of their symptoms. In MAR, it is therefore considered safe to wait 40 days after the onset of symptoms before initiating any kind of treatment.

The **most common symptoms** of Covid-19 are fever, cough and dyspnoea (shortness of breath). In 80% of cases, infections are mild, 15% are severe, 5% are critical or even fatal. Some people have few or no symptoms. Other symptoms have been described such as fatigue, headache, myalgia (muscle pain), throat pain, runny nose, anosmia (the absence or total loss of smell), dysgeusia (a disorder of normal taste perception most often consisting of a decrease or even loss of taste), dermatological disorders, gastrointestinal disorders and conjunctivitis (inflammation of the eye).

Certain underlying diseases predispose to the development of severe forms of COVID-19: obesity, high blood pressure, cardiovascular disease, diabetes, chronic obstructive pulmonary disease (COPD), malignancies and immune system disorders.

There is at the moment **no treatment or vaccine** against this virus. The medical management of serious infections consists of treating the symptoms (e.g. oxygen or artificial respiration).

B. COVID-19 Infection and pregnancy

Based on the studies available today, pregnant women are no more likely to contract coronavirus than the general population. What we do know is that pregnancy can change the way the body deals with serious viral infections. Midwives and obstetricians have known this for many years and are used to dealing with it. To date, there is no evidence that pregnant women who contract coronavirus are more likely to experience serious complications than any other healthy person.

C. Effect of COVID-19 infection on the foetus and pregnancy

As this is a new virus, we are only beginning to discover it.



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There is no evidence of an increased risk of miscarriage at this time when the mother is infected. Rather, it is the high and prolonged fever associated with infection that increases the risk of miscarriage, premature delivery, foetal malformations, foetal death in utero, or neonatal death.

When the mother has a severe form requiring intensive care management, it may be necessary to deliver her baby prematurely. Based on the available studies, it is currently impossible to have complete data on the risk of transmission of the virus between the pregnant woman and her foetus or the subsequent development of the foetus.

There is currently **no evidence that the virus is teratogenic** (causing malformations in the embryo) but studies are still needed to assess the proportion of pregnant women affected by the virus and the exact impact of the virus on the newborn.

D. Effect of the virus on gametes and fertility

To date, there is no information on the presence of the virus in oocytes and embryos. With regard to spermatozoa, the presence of viruses in men with a more or less severe form of COVID-19 is reported. However, current knowledge does not allow us to say whether or not the virus can be transmitted sexually.

The data concerning reproductive medicine are still unclear, but sufficient for the academic societies, both Belgian (BSRM: <https://bsrm.be/covid-19-and-art/>) and European (ESHRE), to recommend the resumption of treatments in fertility medicine.

ESHRE, through a series of guidelines, points out that infertility is a disease and that all MAR treatments can be restarted for all clinical indications but in accordance with national regulations.

Any indication for treatment is left to the discretion of the medical team of the MAR centre and will not be disputed under any circumstances.

2. SCREENING AND TRIAGE PROCEDURES

Vigilance and strict measures must be taken for safe practice in order to minimise the risk of transmission to patients or staff.

This concerns both the patient under treatment and her partner.

You will therefore be asked to fill in a questionnaire on the first day of your treatment and on the day before your fertility treatment (insemination or embryo transfer). It can also be filled in one more time during the pregnancy test.

Additional tests such as virus-specific blood tests, **a nose and throat smear** or even a **lung scan** may be required at various stages of your care and at least once in the days prior to oocytes retrieval.

Depending on the results of the questionnaires and the various examinations, your treatment can be stopped or modified at any stage.

3. CONDITION FOR ACCESS TO YOUR TREATMENT

Throughout your treatment, we ask you to respect social distancing, wearing of masks, regular hand disinfection and barrier gestures during your visits to the hospital but also at work and in your private life.

You should also be aware of possible symptoms, such as a rise in temperature, coughing or sore throat. You should let us know as soon as possible so that we can refer you for a smear test for the virus.

If you come into contact with someone who is positive or strongly suspected of having Covid-19, please inform us.



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4. ADAPTATION OF MAR SERVICES

Our entire way of caring for patients has been adapted to minimize contact between patients and staff.

A specific cleaning and disinfection protocol will also be applied. It will no longer be possible to come accompanied if it is not necessary. Punctuality at your appointments becomes more important than ever; in case of delay, we ask you to call us before entering the department.

We ask you to be attentive to these new procedures and to comply with them even though we are well aware that this will make things less pleasant. In case of non-compliance with these procedures and/or risky behaviour, **the medical team will be entitled to cancel the follow-up of the current cycle/treatment.**

5. TREATMENT OF MEDICAL ASSISTANCE FOR PROCREATION

Your treatment may change from what you have experienced previously. Preference will be given to treatments that minimise the number of check-ups and additional examinations.

Intrauterine insemination or in vitro fertilization treatment may be discontinued if you (patient and/or her partner) develop symptoms of suspected infection or a proven infection with COVID-19 prior to induction, embryo transfer or insemination.



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6. CONSENT FORM

I/we, the prospective parent(s), declare that I/we

- Have received the information related to the COVID-19 pandemic.
- Have been informed of the possibility of postponing my (our) parental project given the current health crisis.
- Have been informed of the advantages, but also of the disadvantages and risks inherent to *in vitro* fertilization (IVF), insemination or embryo transfer treatment considering the current pandemic.
- Accept that not all of the risks and complications related to COVID-19 that could occur during treatment or the resulting pregnancy are necessarily known and attributable to the MAR centre and the medical doctors working there.
- Have been informed that, to date, it is not possible to guarantee that the gametes (male sperm and female oocytes) and/or embryos used are or are not carriers of the virus responsible for COVID-19.
- Answer honestly about possible exposure to the virus when filling in the various questionnaires.
- Am/Are aware that it is impossible for the medical team to guarantee that the virus responsible for COVID-19 will not have a long/medium or short term impact on the unborn child or its subsequent development.
- Am/Are aware that I/we have to postpone my (our) parental project for 28 days after a possible exposure to the COVID-19 virus.
- Am/Are aware that I/we have to postpone my (our) project for 28 days after the symptoms disappear and the end of treatment in case of confirmed infection.
- Comply with the hospital's internal instructions (barrier measures, wearing of masks, social distancing, triage...).
- Avoid unnecessary exposure and respect social distancing and barrier gestures before and during treatment, including at work and in private life.
- Have asked the Centre for Medically Assisted Reproduction (MAR), on my/our own initiative and in the absence of coercion, to carry out this fertility treatment in the knowledge of the information related to the COVID-19 pandemic.
- Am/Are aware of the risk that the treatment can be stopped at any stage of the cycle depending on the health crisis or a possible detection of the virus in me or my partner.
- Respect barrier gestures (maintain a distance of 1.5 metres between people, wear a mask in the hospital, wash hands regularly, sneeze into the elbow, use disposable tissues...).

Date:/...../.....	Date:/...../.....
Signature of the patient:	Signature of the partner :
Doctor's stamp and signature :	

This agreement is drawn up in three copies, one for the prospective parent(s) and the others for the centre.



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Questionnaire

I, the undersigned, Ms., declare that I have answered the questionnaires over the phone on...../...../..... and on/...../..... and declare not having described at least one of the major symptoms nor at least 2 minor symptoms described here above during the call.

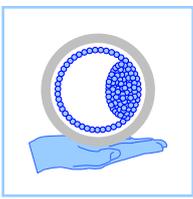
In addition, if I undergo an oocyte retrieval, I agree to notify the staff of the MAR center of any sign listed in the table below I would developed between the egg retrieval and the fresh embryo transfer.

I, the undersigned, Mr., declare that I have answered the questionnaires over the phone on...../...../..... and on/...../..... and declare not having described at least one of the major symptoms nor at least 2 minor symptoms described here above during the call.

In addition, if my partner undergoes an oocyte retrieval, I agree to notify the staff of the MAR center of any sign listed in the table below I would developed between the egg retrieval and the fresh embryo transfer.

I declare, at the end of the last 14 days, that I have shown:

	Madam		Partner	
Major Symptoms				
Cough	<input type="radio"/> YES	<input type="radio"/> NO	<input type="radio"/> YES	<input type="radio"/> NO
Dyspnoea	<input type="radio"/> YES	<input type="radio"/> NO	<input type="radio"/> YES	<input type="radio"/> NO
Chest pain	<input type="radio"/> YES	<input type="radio"/> NO	<input type="radio"/> YES	<input type="radio"/> NO
Anosmia (loss of sense of smell)	<input type="radio"/> YES	<input type="radio"/> NO	<input type="radio"/> YES	<input type="radio"/> NO
Ageusia (loss of taste)	<input type="radio"/> YES	<input type="radio"/> NO	<input type="radio"/> YES	<input type="radio"/> NO
Aggravation of chronic respiratory symptoms	<input type="radio"/> YES	<input type="radio"/> NO	<input type="radio"/> YES	<input type="radio"/> NO
Minor Symptoms			<input type="radio"/>	<input type="radio"/>
Fever	<input type="radio"/> YES	<input type="radio"/> NO	<input type="radio"/> YES	<input type="radio"/> NO
Rhinitis	<input type="radio"/> YES	<input type="radio"/> NO	<input type="radio"/> YES	<input type="radio"/> NO
Sore throat	<input type="radio"/> YES	<input type="radio"/> NO	<input type="radio"/> YES	<input type="radio"/> NO
Myalgia (muscle pain)	<input type="radio"/> YES	<input type="radio"/> NO	<input type="radio"/> YES	<input type="radio"/> NO
Anorexia	<input type="radio"/> YES	<input type="radio"/> NO	<input type="radio"/> YES	<input type="radio"/> NO
Confusion	<input type="radio"/> YES	<input type="radio"/> NO	<input type="radio"/> YES	<input type="radio"/> NO
Headache	<input type="radio"/> YES	<input type="radio"/> NO	<input type="radio"/> YES	<input type="radio"/> NO
Diarrhoea	<input type="radio"/> YES	<input type="radio"/> NO	<input type="radio"/> YES	<input type="radio"/> NO
Fatigue	<input type="radio"/> YES	<input type="radio"/> NO	<input type="radio"/> YES	<input type="radio"/> NO
Sudden fall without apparent cause	<input type="radio"/> YES	<input type="radio"/> NO	<input type="radio"/> YES	<input type="radio"/> NO



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Furthermore, I declare:

	YES	NO	NA		YES	NO	NA
<i>MADAM</i>				<i>PARTNER</i>			
Being a carrier of COVID-19				Being a carrier of COVID-19			
The last 28 days, I still had symptoms after I developed COVID-19:				The last 28 days, I still had symptoms after I developed COVID-19			
Have been exposed to a person carrying COVID-19 for 28 days				Have been exposed to a person carrying COVID-19 for 28 days			

Date:...../...../.....	Date:...../...../.....
Signature of the patient:	Signature of the partner :
Doctor's signature and stamp :	

Deferral of donors candidates as a precautionary measure for at least 28 days after possible exposure to a confirmed case.

Deferral of donors candidates of confirmed cases until at least 28 days after symptoms have resolved and treatment has been completed.