Dear Madam,

The maternity department of the Lausanne University Hospital is engaging in research on the SARS-CoV-2. The objective of this collaboration is to create a registry (i.e list of patients and their relevant medical information) of pregnant women who are at risk of being infected by SARS-CoV-2 during their pregnancy. This registry includes CHUV patients and will be extended to the Swiss and international level.
You may be integrated into this registry and we would therefore like to determine whether you would accept participation in our effort.
The goal of this registry is to evaluate the number of pregnant women affected by the SARS-CoV-2 during their pregnancy and to monitor their pregnancy outcomes. We hope to obtain crucial information to evaluate the impact of the infection during pregnancy for mothers, fetuses and newborns through their physicians. This project is open to every consenting pregnant woman who has reached the age of majority and are suspected to be infected by SARS-CoV-2 during pregnancy.
This project is being conducted under regulations established by the Swiss Law and follows international recommendations. In particular, this project has been authorized by the Ethical Committee of the Canton Vaud, in which the Lausanne University Hospital is based.

What does your participation involve?
By accepting to participate, you allow your physician to add you to the list of patients included in this registry. In addition, he/she will provide information regarding your current pregnancy at enrollment, as well as your delivery and newborn. Your doctor will assign a code to you that only he/she can associate with you. The decision to participate will have no consequence on your medical follow-up. You will not, for example, have any additional visits or exams. You will also have no obligations related to this project.
The decision to participate in this project is your own and you should not be influenced by anyone or anything. In particular, your medical treatment and associated fees will be unchanged, whether you decide to participate or not. If you decline, you will not have to justify your decision. No remuneration or any kind of compensation is offered for your participation.

Confidentiality of data
All information entered in the registry will be coded such that no personal identifiable information will appear in the database for yourself or your newborn. For example, we will not record any names, addresses or dates of birth. If you agree to participate, your doctor will assign an identification code to you which will allow him/her to identify your data in the registry. The code will remain permanently stored in the institution / hospital. If the registry is utilized for scientific publication, the aggregated data will not be attributable to you as a person. Your name will never appear on the Internet or in a publication. Occasionally, scientific journals require the transmission of individual data (raw data). If individual data must be transmitted, it is always

encoded (deidentified) and therefore does not allow you to be identified as a person. All persons involved in the study in any way are bound by professional confidentiality. All data protection directives will be respected and you have the right to consult and view your data at any time. Additionally, if data is transferred abroad, the level of data protection in the destination country must be at a minimum equivalent to that existing in Switzerland.
During its course, the project may be subject to inspection for compliance. These can be carried out by the ethics committee which undertook its initial control and authorized it, but also can be mandated by the body which initiated it. The project management may have to communicate your personal and medical data for the purposes of these inspections.

Expected benefits
The data we currently have are reassuring regarding the health of pregnant women and their newborns who have been exposed to the SARS-CoV-2. This registry will enable a rapid and secure collection of data, and their analysis will better inform patients and improve their care.

Withdrawal from the study
You can withdraw from the project at any time if you wish, without justifying your decision. This decision will have no consequence on your medical follow-up and that of your child. The medical data collected so far will still be analyzed.

Use of the register by other research groups
Access to the registry is limited to researchers who will demonstrate their scientific need and their ability to protect your rights as described in this form. Any research request must obtain the agreement of the management of the registry as well as of the research ethics committee before starting. Research projects are carried out at CHUV or in collaboration with other public institutions (e.g. other hospitals or universities) and private entities (e.g. pharmaceutical companies) in Switzerland or abroad.
Any research project using the data collected through this registry will be carried out in accordance with a research plan and with the principles set out in the current version of the Helsinki Declaration (DOH), the Taipei Declaration and the fundamental principles of good epidemiological practice.

Insurance
Any damages that you may suffer as a result of this study are the responsibility of CHUV. The conditions and procedures are set by law.

Funding sources

The database development is funded entirely by the University Hospital of Lausanne, Switzerland. There are no additional costs to you or your insurance for your participation.

It is your decision to inform or not inform the father of the child about this study if he has parental authority. This information can also be transmitted to him by a member of the research team designated by your attending physician if you request it.

For further questions, you may contact the managers of the database at any time:

Prof David Baud
Département femme-mère-enfant,
Service d'obstétrique
Avenue Pierre-Decker 2,
1011 Lausanne
+41 21 314 39 53
David.Baud@chuv.ch

Dre Alice Panchaud, PhD
Département des centres interdisciplinaires,
Service de Pharmacie, CHUV,
Route Bugnon 17,
1011 Lausanne+41 79 556 49 73
Alice.Panchaud@chuv.ch

Written declaration of consent to participate in a study

- Please carefully read this form
- Do not hesitate to ask questions if you some parts are not clear of if you would like more information

Registry number (according to the Swiss ethical comity)	2020-00548
Registry title :	Registry for women suspected to be infected by SARS-CoV-2 during pregnancy
Responsible Institution	CHUV
Place :	
Collaborator to SARS-CoV-2 registry on site (name and first name in block letters):	
Participant (name and first name in block letters, date of birth)	

- I declare that I have been informed, by the investigating doctor / by the undersigned ensuring the information, orally and in writing, of the objectives and progress of the project as well as the advantages, possible disadvantages and possible risks.
- I take part in this study on a voluntary basis and I accept the content of the information sheet which was given to me on the aforementioned project. I have had enough time to make my decision.
- I received satisfactory answers to the questions I asked in relation to my participation in the project. I keep the information sheet (version 3, 19/03/2020)and receive a copy of my written consent statement.
- I also give my consent that data related to my newborn may be collected at birth and can be used for research purposes under the same conditions as my own data. I declare that I have been informed that it is my responsibility to inform the father of my child if he has parental authority (or to a person designated by my attending physician if I request it).
- I accept that the specialists of the institution, the project representative, the Ethics Commission responsible for this study, may consult my raw data in order to carry out checks, provided, however, that the confidentiality of these data be strictly insured.
- I will be informed of (fortuitous) discoveries having a direct impact on my health. If I do not wish to obtain this information, I will notify the medical investigator.
- I know that my personal data can be transmitted for research purposes within the framework of this project only and in coded form (also abroad).
- In the event of subsequent treatment outside the place where this project is carried out, I authorize my doctor (s) to provide the individuals responsible for the project / project management with the post-treatment data relevant to the project.

- I can, at any time and without having to justify myself, revoke my consent to participate in the study, without this having an adverse impact on the rest of my usual medical treatment. I know that the medical data that have been collected so far, however, will be analyzed.
- I am informed that the civil liability of the CHUV covers any damages that I may suffer that are attributable to the project.

Place, date	Participant's signature

Certification of physician-investigator: Hereby I certify having explained to the participant the nature, the importance and the scope of the study. I declare that all obligations in connection with this study are satisfied in accordance with the law in force.

Place, date	Name, surname and signature of the physician-investigator