ZIKA IN PREGNANCY REGISTRY

UNIVERSITÉ DE GENÈVE
FACULTÉ DES SCIENCES

CHUV Département de gynécologie obstétrique et génétique médicale

Dear Madam,

The maternity and the school of pharmaceutical sciences of the Lausanne University Hospital are collaborating to promote research on the Zika virus. This virus has recently been associated with adverse fetal outcomes, in particular cerebral malformations. The objective of this collaboration is to create an international registry (i.e a list of patients and certain related medical information) of pregnant women that have been in contact with Zika virus during their pregnancy. You may be integrated in this registry and therefore would like to know whether you would accept to participate in our effort.

The goal of this registry is to evaluate the number of concerned pregnant women and to monitor their pregnancy. We hope to obtain precious information to evaluate the impact of the infection during pregnancy for mothers, fetuses and newborns. This project is open to every consenting pregnant woman who has reached the age of majority and has been exposed to Zika virus during pregnancy.

This project is conducted under regulations established by the Swiss Law and follow international recommendations. In particular, this project has been authorized by the Ethical Comity of the Canton Vaud, in which the Lausanne University Hospital is based.

What does your participation implicate?

By accepting to participate, you allow your physician to add you to the list of patients included in this registry. In addition, he will provide information regarding your current pregnancy at enrollment, as well as regarding your delivery and your baby after your delivery. All information provided will be anonymous, meaning that no information included in the registry will allow your identifications or your baby's. As examples, no names, nor addresses and dates of birth will be collected.

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 similar, 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 in case of participation.

Of notice, if you accept to participate, you will not to be able to change your decision later on. Indeed, as information will be anonymous, it will be technically impossible to retrieve your own personal data and exclude them.

Confidentiality of data

Collected data will be immediately anonymized. No information that allows you personal identification, such as name, address, or date of birth will be collected. The anonymization process is the highest protection measure that exists to insure protection of your confidentiality. The written consent form authorizing the anonymous use of your personal data will not be transmitted to anyone and will be kept in your medical file.

ZIKA IN PREGNANCY REGISTRY

UNIVERSITÉ DE GENÈVE
FACULTÉ DES SCIENCES

CHUV Département de gynécologie obstétrique et génétique médicale

Use of the register by other research groups

This registry may be put at the disposition of other research groups that need some of these data to answer a research question under specific conditions. To obtain access to the database, specific research projects will be evaluated by the managers of the register and will require further approbation by the competent ethical comity. In particular, research projects will have to be conducted in accordance with the principles enounced in the Helsinki declaration, as well as fundamental principles of good epidemiological practice.

Founding sources

The setting up of the database is funded entirely by the University Hospital of Lausanne and the University of Geneva, Switzerland.

In case of doubts or further questions, you may contact at any time the managers of the database:

Dr David Baud, MD PhD
Materno-fetal medicine specialist
+41 21 314 39 53
David.Baud@chuv.ch

Dr Alice Panchaud, PhD
TIS counselor
Alice.Panchaud@chuv.ch

ZIKA IN PREGNANCY REGISTRY

UNIVERSITÉ DE GENÈVE
FACULTÉ DES SCIENCES

CHUV Département de gynécologie obstétrique et génétique médicale

Written consent declaration to participate in a study

- Please read carefully 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)	2016 - 00801
Registry title :	Registry for women exposed to Zika virus during pregnancy
Institution	
Place :	
Collaborator to Zika virus registry on site (name and first name in block letters):	
Participant (name and first name in block letters): Date of birth:	

- I hereby declare having been properly informed by the physician/investegator of the above mentioned study I declare having been informed by the physician/head study undersigned, orally and in writing, the objectives and the progress of the study on the Zika virus during pregnancy.
- I have received satisfactory answers to the questions I asked in connection with my participation in the study.
- I retain this information sheet (version2, 6/13/2016) and get a copy of my written consent statement.
- I accept the content of the information sheet that was handed to me on the above-mentioned study.
- I am taking part in this study on a voluntary basis.
- I understood that because of the anonymisation of data, I could not revoke my consent to participate in the study.
- I had enough time to make my decision.
- I know that my personal data may be transmitted for research purposes in the context of this study in anonymized form.

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