

CONSENT FORM FOR THE NATIONAL MEDICALLY-ASSISTED REPRODUCTION REGISTER

of the **FRENCH BIOMEDICINE AGENCY** **(AGENCE DE LA BIOMEDECINE)**

Agency under the aegis of the French Ministry for Health

Dear Sir, Madam,

You have decided to use Medically-Assisted Reproduction (MAR) to have a child.

In France, each year around 66,000 couples benefit from these techniques, and a total of 23,500 children are born. The French Biomedical Agency is the French National State-recognised agency under the aegis of the French Ministry of Health and was commissioned by law to evaluate the consequences of Medically-Assisted Reproduction for the health of people using this technique as well as children born by these channels. Consequently, in order to fully understand the factors behind success or failure of in vitro fertilisation techniques and to identify any consequences of current practices on people's health, statistics are being established and specific studies conducted. These will enable improvement of results of in vitro fertilisation techniques in future.

In order to conduct these studies and oversight operations, the French Biomedical Agency, with the authorisation of the CNIL (French National Data Protection Authority), has implemented a **national register collating all data regarding attempts at MAR**. The aim of this is to record all attempts at Medically-Assisted Reproduction and also to collate data concerning any medical history and previous surgery, the progress of attempt(s) at MAR, the outcome and result of pregnancies and the health conditions of children at birth. This information will be identical to that usually collected for your medical records. Please do not hesitate to request further details from your Gynaecologist.

To keep accurate medical records for an individual, with any medical centre or other establishment and to avoid any crossover, it is necessary to collect the following personal data:

- Your surname (at birth), given name(s) and married surname (preferred surname)
- Your date of birth
- Your country and postcode of residence

- The patient history and biological record numbers in clinical and biological medical establishments where MAR is undertaken. Insofar as data collected pertains to your health, or that of your children born following MAR, your name may appear in the national register if you grant your explicit consent accordingly. Failing this, data collected will be *made anonymous* and the surname(s) and given name(s) of people will not be collected. This information will be stored for a term of 70 years.

In the event of collating nominative data, pursuant to the data protection and freedom of information act, during the entire term of processing, you are entitled to access, amend, and object to use of your personal data. You are also entitled to request deletion of your data, to withdraw your consent to collection of your personal data and to make a claim with the control authority (CNIL). These rights can be exercised at any time by sending a request to the centre where you underwent MAR and/or to the data protection officer (DPO) at the French Biomedical Agency (Legal Directorate at the French Biomedical Agency / 1 avenue du Stade de France, 93212 SAINT DENIS LA PLAINE Cedex or by emailing cil@biomedecine.fr) attaching a copy of a valid identity document bearing your signature. Failing any response within a period of one month, you can refer your claim to the CNIL authority.

The French Biomedical Agency has implemented all necessary personal data protection and privacy measures. Notably, electronic security measures have been taken and only people who are responsible for file management, quality control and data security, duly authorised by the Director General of the Agency are entitled to access personal data, and only when absolutely necessary.

In other words, statistical use of data is undertaken over anonymous data and nominative data is never sent to any other organisations in any manner whatsoever.

Only those people undertaking quality control over data and professionals who are undertaking MAR will have access to personal data.

It is possible in future that you may be contacted to take part in specific additional studies. You will, as required, then be required to either agree or refuse taking part.

We thank you in advance for your valuable contribution to our research and evaluation work concerning medical techniques as well as the improvement of practices and results of these activities.

FOR EACH INDIVIDUAL ATTEMPT AT MAR, WE ACCEPT THAT OUR PERSONAL DATA BE SENT TO THE

FRENCH BIOMEDICINE AGENCY: * YES * NO

(please tick as appropriate)

WE UNDERTAKE TO NOTIFY ANY CHANGE OF OPINION.

Date: / /

Surname/Given name(s) and signature of both parties in the couple:

Mr......

Mrs.

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