INFORMED CONSENT

Name and surname:	**National ID No.:**
Patient's legally acceptable representative (name, surname):	
Designation of medical procedure/treatment procedure (or several procedures): **OPTIONAL TUBERCULOSIS (TB) VACCINATION FOR CHILDREN**	

Purpose, nature, expected benefit, consequences and possible risks of the medical procedure:

With effect from 1 November 2010, a decree of the Ministry of Health abolished compulsory general TB vaccination for children throughout the Czech Republic, with the exception of high risk individuals. Therefore, under this decree only children that have a higher probability of developing TB are vaccinated. TB vaccination in a high risk population significantly reduces the possibility of developing TB, including its more severe forms. The TB vaccination efficacy rate falls with the development of TB in the given population.

The severity of the risk of TB infection in children is evaluated in the maternity hospital and subsequently by the paediatrician and possibly also by a lung specialist. Your child was not found to be at risk of developing tuberculosis and therefore you were not invited for the TB vaccination. However, if you so wish your child can be vaccinated for TB. Usually optional vaccination takes place after 6 months of life, however no later than up to the 1-2 year of the child's age. But this is always the first vaccination, so-called primary vaccination.

There should not be any repeat vaccination, so-called re-vaccination, which you probably remember from the past, since it does not have an additional effect on preventing TB infection. For this reason it is not recommended by the Czech Pneumological and Phthisiological Society or other professional societies.

For TB vaccination a live-attenuated vaccine is used which is injected into the skin on the left arm. A small lump or ulcer of up to 10 mm in diameter may appear in the injection site 6 - 8 weeks after vaccination, and a lymph node under the left armpit or on the left side of the neck may become enlarged up to 10 mm in size.

In islolated cases there may be a greater reaction than 10 mm and the festering of the injection site or lymph nodes. In exceptional cases, vaccination is accompanied by more severe reactions possibly leading to bone infection or resulting in a spread of infection by a weakened strain in individuals with severe immune system disorder.

Optional vaccination at the request of the child's parents takes place in the second half of the child's first year of age. It is recommended to arrange an appropriate vaccination date with a paediatrician for children and adolescents with regard to the planned vaccination schedule so there is no clash with other vaccination. The next vaccination can take place only 3 months after the tuberculosis vaccination (= BCG vaccine) or only after the vaccination scar has healed.

It is not possible to clearly predict a reaction to the vaccination in any individual. However, your child will be under constant supervision of a paediatrician and will be checked at the workplace where vaccination took place. Consult these specialists as soon as possible if there is

INFORMED CONSENT

Name and surname:	**National ID No.:**

any adverse reaction to the vaccine ingredients which would deviate from a normal local reaction.

The patient is administered a non-authorised medicinal product as part of a specific treatment programme.

Other alternatives of the treatment procedure, their suitability, benefits and risks:

There is no alternative to TB vaccination.

The medical procedure/treatment procedure will take place as follows:

1. A nurse will disinfect the skin on the forearm of the left arm and apply a test substance (skin test) with an injection into the skin.

A check is carried out after three days and if there no positive reaction to the test substance, the vaccine ingredients are applied (after disinfecting the skin up to the upper outer part of the left arm).

Restrictions and recommendations in lifestyle with regard to the medical condition and possible changes in medical fitness after the stated medical procedure/treatment procedure:

The only restriction is that no other vaccine can be given for 3 months after the application of the vaccine (vaccine ingredients) (or until the injection site has healed).

Further required treatment:

A tuberculosis skin test needs to be carried out before vaccination to rule out the minimum probability of TB infection after the child's accidental contact with TB. Only children with a negative tuberculin reaction are vaccinated.

No further treatment is required.

I declare that the doctor who instructed me personally explained the entire content of this written informed consent and I had the opportunity to ask him/her questions to which he/she gave a proper answer. I declare that I have fully understood the above instructions and information and give express consent to this medical procedure.

In case that the patient is **underage or has limited legal capacity** and is reasonably mentally and freely mature:

I declare that I have been instructed to the extent stated above.

This form is also directly available in the HIS.

INFORMED CONSENT

Name and surname:	**National ID No.:**

If the patient was not provided with such data, he/she shall state the reason why:

In Prague on

....

patient's/legally acceptable representative's signature *doctor's name, surname and signature*

.....

signature of the underage patient/ patient with limited legal capacity

If the patient/legally acceptable representative cannot sign because of his/her medical condition:

Reason why the patient/legally acceptable representative is unable to sign:

Manner in which the patient/legally acceptable representative expressed his/her will:

.....

name, surname and signature of the witness