INFORMED CONSENT

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

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

According to available data, it was found that your child has a greater risk of developing tuberculosis (TB). This disease poses a very serious health risk particularly to younger children. TB vaccination significantly reduces the possibility of developing TB, including its most severe forms, and thus fundamentally protects the health of a child with increased risk of developing TB. There is full indication of vaccination for your child according to legal regulations as soon as possible after birth. The advantage of early TB vaccination is the earliest possible induction of immunity against this disease and none or minimum delay in having other vaccinations. Other vaccinations can be given only after the reaction to the TB vaccination has healed.

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 usually appears in the injection site 6 – 8 weeks after TB 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 isolated cases vaccination is accompanied by more severe reactions such as possible development of a bone infection or spread of the live weakened vaccine in the child's body in a child with severe immune system disorder. Not even a detailed examination soon after birth can predict a reaction to the vaccination. Your child will be under the constant supervision of a paediatrician and will be checked at the workplace where the vaccination took place (Tuberculosis Vaccination Unit of the Department of Paediatrics and Adolescent Medicine, General University Hospital in Prague, tel. 224 967 063).

Consult these specialists as soon as possible if there is 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:

A nurse will disinfect the skin on the forearm of the left arm and apply the vaccine ingredients to the upper outer part of the left arm. The reaction to the vaccination is checked in three

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months.

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:

None

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.

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:

This form is also directly available in the HIS.

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

This form is also directly available in the HIS.