GENERAL UNIVERSITY HOSPITAL IN PRAGUE
U Nemocnice 499/2, 128 08 Praha 2 | ID: 00064165, tel.: 224 961 111

INFORMED CONSENT

Name and surname:	**National ID No.:**
Patient's legally acceptable representative (name, surname):	
Designation of the medical procedure/treatment procedure (or several procedures): **DIAGNOSTIC SKIN BIOPSY**	
Purpose, nature, preparation, expected benefit, consequences and possible risks of the medical/treatment procedure: A skin biopsy is taken for the purpose of diagnosis. This particularly involves enzymatic analysis, or molecular – genetic testing from cultured skin cells (fibroblasts) and electron microscopic analysis. The attending doctor decides about performing this specialised examination. A blood test that is less demanding for the patient cannot replace these examinations. It is also possible to keep the tissue culture of fibroblasts with the patient's consent for several years and use for necessary analysis in future. The risks of the procedures are associated with complications in the surgical wound (infection, bleeding, wound separation). Another risk is the deterioriation of the removed material such as bacterial overgrowth. We avoid complications by standardising the procedure and following procedures preventing contamination of the sterile environment of the microorganisms.	
Other alternatives of the treatment procedure, their suitability, benefits and risks: A skin biopsy is also possible with the consent of the examined patient and in ensuring adequate conditions for the biopsy during a different surgical procedure. However, if the skin biopsy is taken separately, there is the certainty that it will take place under the required conditions and from the required site, so there will be a high likelihood that the tissue culture of the fibroblasts can be grown allowing the optimum capture of the relevant structures.	
The medical procedure/treatment procedure will take place as follows: The biopsy is taken from the inner side of the arm. After numbing the skin a local anaesthetic is applied, under sterile conditions and after careful disinfection of the site a small sample of skin of about 8 x 3 mm in diameter is removed (in case of a classical incision) or 7 mm in diameter if a so-called punch biopsy tool is used. The superficial wound will be sealed either by a skin stitch (stitches) or strips and covered with a sterile dressing.	
Restrictions and recommendations in lifestyle with regard to the medical condition and possible changes in medical fitness after the stated medical procedure/treatment procedure: No water should come into contact with the sterile wound. It is not recommended to place greater physical strain on the area of the arm from which the sample was taken.	

This form is also directly available in the HIS.

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Further required treatment:

The wound should be redressed 48 hours after the procedure in a medical facility. It should be checked at a drop-in outpatients surgical or dermatology clinic if there are signs of inflammation (local reddening, swelling, pain). It is best to keep the sterile dressing on the wound until it heals. If the wound is stitched with nonabsorbable stitches, these need to be removed after 7 days also at the drop-in outpatients surgical or dermatology clinic.

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.